

# The Impact of eHealth on the Quality & Safety of Healthcare



## A Systemic Overview & Synthesis of the Literature

Report for the NHS Connecting for Health Evaluation Programme  
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## ABBREVIATIONS

<b>ADE</b>	Adverse drug events
<b>ADR</b>	Adverse drug reaction
<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>AI</b>	Artificial intelligence
<b>BCSH</b>	British Committee for Standards in Haematology
<b>BS7799</b>	British Standard for Information Security Management
<b>BWH</b>	Brigham and Women's Hospital
<b>C&amp;B</b>	Choose and Book
<b>CAD</b>	Computer-aided detection or diagnosis
<b>CASP</b>	Critical Appraisal Skills Programme
<b>CBMR</b>	Computer-based medical record
<b>CBPRS</b>	Computer-based patient record system
<b>CCR</b>	Continuity of care record
<b>CDSS</b>	Computerised decision support system
<b>CFHEP</b>	See NHS CFHEP
<b>CHI</b>	Community Health Index number
<b>CHIN</b>	Community Health Information Network
<b>CHTS</b>	Computer history taking systems
<b>CIS</b>	Clinical information system
<b>CMR</b>	Computerised medical record
<b>COTS</b>	Commercial off-the-shelf
<b>CPR</b>	Computerised patient record
<b>CPOE</b>	Computerised provider order entry
<b>CRDB</b>	Care Record Development Board
<b>CSA</b>	Clinical Spine Application
<b>CSC</b>	Computer Sciences Corporation
<b>DCR</b>	Detailed Care Record
<b>DH</b>	Department of Health
<b>DIRC</b>	Dependable Interdisciplinary Research Collaboration
<b>dm+d</b>	Dictionary of Medicines and Devices
<b>DMR</b>	Digital medical record
<b>ECRI</b>	Emergency Care Research Institute
<b>EHR</b>	Electronic health record
<b>eMAR</b>	Electronic medication administration record
<b>EMIS</b>	Egton Medical Information Systems
<b>EMR</b>	Electronic medical record
<b>EPR</b>	Electronic patient record

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<b>EPS</b>	Electronic prescription service
<b>ERP</b>	Enterprise resource planning
<b>ETD</b>	Education Training and Development
<b>ETP</b>	Electronic Transmission of Prescriptions
<b>FAA</b>	Federal Aviation Authority
<b>FDA</b>	Food and Drug Administration
<b>GEP-HI</b>	Guidelines for Best Evaluation Practices in Health Informatics
<b>GMS</b>	General Medical Services
<b>GP</b>	General Practitioner
<b>GPSoC</b>	GP Systems of Choice
<b>HCI</b>	Human-computer interaction
<b>HF</b>	Human factors
<b>HFE</b>	Human factors engineering
<b>HIE</b>	Health information exchange
<b>HIEI</b>	Health information exchange and interoperability
<b>HIMSS</b>	Healthcare Information and Management Systems Society
<b>HIS</b>	Hospital information system
<b>HL7</b>	Health Level Seven
<b>HRO</b>	High Reliability Organizations
<b>HTA</b>	Health Technology Assessment
<b>ICR</b>	Integrated care record
<b>IEHR</b>	Interoperable electronic health record
<b>IM&amp;T</b>	Information management and technology
<b>InPS</b>	In Practice System
<b>INR</b>	International Normalised Ratio
<b>IQAP</b>	Information Quality Assurance Programme
<b>IP</b>	Internet protocol
<b>ISB</b>	Information Standards Board
<b>ISO</b>	International Organization for Standardization
<b>ISIP</b>	Integrated Service Improvement Programme
<b>IT</b>	Information technology
<b>JACHO</b>	Joint Commission on Accreditation of Healthcare Organizations
<b>KLAS</b>	Keystone Library Automation System
<b>LAN</b>	Local Area Network
<b>LHR</b>	Longitudinal health record
<b>LIS</b>	Laboratory information system
<b>LOINC</b>	Logical observation identifiers names and codes
<b>LPfIT</b>	London Programme for Information Technology
<b>LSPs</b>	Local Service Providers

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<b>MeSH</b>	Medical Subject Headings
<b>MRC</b>	Medical Research Council
<b>MRHA</b>	Medicines and Healthcare Products Regulatory Agency
<b>N3</b>	National Network for the NHS
<b>N3SP</b>	N3 Service Provider
<b>NASP</b>	National Application Service Provider
<b>NHS</b>	National Health Service
<b>NHS BSP</b>	NHS Breast Screening Programme
<b>NHS CFH</b>	NHS Connecting for Health
<b>NHS CFHEP</b>	NHS Connecting for Health Evaluation Programme
<b>NHS CRS</b>	NHS Care Record System
<b>NICE</b>	National Institute for Health and Clinical Excellence
<b>NIHR</b>	National Institute of Health Research
<b>NISP</b>	National Infrastructure Service Provider
<b>NKS</b>	National Knowledge Service
<b>NLOP</b>	National Programme for IT Local Ownership Programme
<b>NMEPfit</b>	North, Midland and East Programme for Information Technology
<b>NPfit</b>	National Programme for Information Technology
<b>NPSA</b>	National Patient Safety Agency
<b>NPT</b>	Near patient test
<b>NSF</b>	National Service Framework
<b>OAT</b>	Oral anticoagulation therapy
<b>OBS</b>	Output based specification
<b>OCCO</b>	Office of the Chief Clinical Officer
<b>OITIM</b>	Organisation Information Technology/System Innovation Model
<b>OSCHR</b>	Office for Strategic Coordination of Health Research
<b>OSI</b>	Open system interconnection
<b>PACS</b>	Picture Archiving and Communications System
<b>P&amp;P</b>	Pen and paper
<b>PAS</b>	Patient administration systems
<b>PBR</b>	Payment by Results
<b>PC</b>	Personal computer
<b>PCR</b>	Patient care record
<b>PCT</b>	Primary care trust
<b>PDA</b>	Personal digital assistant
<b>PDF</b>	Portable Document Format
<b>PDS</b>	Personal Demographic Service
<b>PHQ</b>	Patient Health Questionnaire
<b>PHR</b>	Personal health record



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<b>PMR</b>	Patient (carried) medical records
<b>PMRI</b>	Patient medical record information
<b>PRO</b>	Patient reported outcomes
<b>PMS</b>	Personal medical services
<b>PRIMIS</b>	Primary Care Information Services
<b>PSIS</b>	Personal Spine Information Service
<b>QMAS</b>	Quality Management and Analysis Subsystem
<b>QOF</b>	Quality and Outcomes Framework
<b>QoS</b>	Quality of Service
<b>RCT</b>	Randomised controlled trial
<b>RDBT</b>	NHS CFH Requirements, Design, Build and Test
<b>RHIOs</b>	Regional Health Information Organizations
<b>RID</b>	Regional Implementation Director
<b>RTC</b>	Roadmap for Transformational Change
<b>SBCCE</b>	Santa Barbara County Care Exchange
<b>SCI</b>	Scottish Care Information
<b>SCR</b>	Summary Care Record
<b>SDS</b>	Spine Directory Service
<b>SE</b>	Software engineering
<b>SHAs</b>	Strategic Health Authorities
<b>SI</b>	Service implementation
<b>SIGN</b>	Scottish Intercollegiate Guidelines Network
<b>SMS</b>	Short message service
<b>SNOMEDCT</b>	Systematized Nomenclature of Medicine Terminology-Clinical Terms
<b>SPfIT</b>	Southern Programme for Information Technology
<b>SR</b>	Systematic review
<b>STARE-HI</b>	Statement on Reporting of Evaluation Studies in Health Informatics
<b>SUS</b>	Secondary Uses Service
<b>TMS</b>	Transaction Messaging Service
<b>TRaMS</b>	Training Messaging Service
<b>TTD</b>	Table-Top Challenge
<b>UK</b>	United Kingdom
<b>UKCRN</b>	United Kingdom Comprehensive Research Network
<b>US</b>	United States
<b>VATAM</b>	Validation of Telematics Applications in Medicine
<b>VME</b>	Vancomycin resistant <i>Enterococcus faecium</i>
<b>VPN</b>	Virtual private network
<b>WAN</b>	Wide area network
<b>WHO HEN</b>	World Health Organization's Health Evidence Network

## EXECUTIVE SUMMARY

### INTRODUCTION

- Increasing life expectancy, improved survival in people with acute and long-term conditions and a greater array of available treatment options are combining to place an increasing burden on healthcare organisations internationally.
- This picture is particularly true of the economically developed world where high salaries for healthcare professionals and ever increasing public expectations contribute to the challenges facing governments trying to contain spending on healthcare provision and planning.
- There is now a substantial body of research, both domestic and international, identifying considerable shortfalls in the current provision of healthcare.
- Key issues emerging from this literature are substantial variations in the quality of healthcare and the considerable risks of iatrogenic harm.
- These failings contribute in a major way to the high rates of potentially avoidable morbidity and mortality, and healthcare expenditure.
- There have been substantial developments in information technology (IT), hardware and software capabilities over recent decades and there is now considerable potential to apply these technological developments in relation to aspects of healthcare provision (the application of IT in this way will henceforth be subsumed by the term eHealth).
- Of particular international interest is the deployment of eHealth applications, with a view to improving both the quality and safety of healthcare delivery.
- Whilst these eHealth applications have considerable potential to aid professionals in delivering healthcare, it is not widely appreciated that use of these new technologies may also introduce significant new risks to patients.
- Also of concern is that even when high quality interventions are developed, they frequently fail to live up to their potential when deployed in the “real world”; a major factor contributing to this paradox is professional resistance to their introduction and use due in part to relative lack of sophistication and an a risk adverse culture of practice.
- Given that the National Health Service (NHS) is now committed to

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the largest eHealth-based modernisation programme in the world, it is appropriate and timely to critically review the international eHealth literature with a view to identifying lessons that can usefully be learnt with respect to the development, design, deployment and evaluation of eHealth applications.

## **AIMS AND OBJECTIVES**

- We were commissioned by the Patient Safety Research Programme (which now no longer exists and whose remit has in part been subsumed by the recently created NHS Connecting for Health Evaluation Programme (CFHEP)) to produce a systematic overview of the literature examining the effectiveness of IT (eHealth) applications to improve the quality and safety of healthcare.
- Given the change in the commissioning body, recent publications in the field, the need for relevant developmental work and the volume of material identified, we agreed with the funders and the project's External Steering Group to focus our work on evidence relating primarily to:
  - the storage and retrieval of medical information
  - tools to support healthcare professionals in making clinical decisions
  - ways of promoting the effective development, deployment and use of eHealth applications in routine healthcare settings.
- Our planned future work will seek coherently to expand on this report by encompassing other facets of eHealth not covered in this volume, these include patient identification devices, consumer informatics, telecare and eLearning.

## **METHODS AND FORMATIVE WORK**

### **METHODS**

- We conducted a systematic search and critique of the empirical literature on eHealth applications and their impact on the quality and safety of healthcare delivery and synthesised this with relevant theoretical, technical, developmental and policy relevant literature with a view to producing an authoritative and accessible overview of the field.
- Whilst we drew on established Cochrane review principles to systematically search for, critique and synthesise the literature, this approach needed to be adapted in several respects in order to produce a meaningful umbrella review of the literature (see below).
- Searching the literature was complicated by the lack of internationally (or

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indeed in some cases nationally) agreed terminology relating to eHealth applications, the lack of agreed definitions of quality and safety, and consequently poor indexing of these constructs in databases of published literature.

- In order to undertake a thorough review of the literature, we therefore needed to undertake initial developmental work to formulate a comprehensive search strategy.
- Using the set of comprehensive Medical Subject Headings (MeSH) and free text search terms developed, we systematically searched major medical databases over a 10-year period (1997–2007) to identify systematic reviews, technical reports and health technology assessments, and randomised controlled trials investigating the effectiveness of eHealth applications. The specific databases searched were:
  - ❑ MEDLINE
  - ❑ EMBASE
  - ❑ The Cochrane Database of Systematic Reviews
  - ❑ Database of Abstracts of Reviews of Effects
  - ❑ The Cochrane Central Register of Controlled Trials
  - ❑ The Cochrane Methodology Register
  - ❑ Health Technology Assessment Database and NHS Economic Evaluation.
- We, in addition, searched key national and international databases to identify unpublished work and research in progress.
- The systematic reviews have then been subjected to critical review using the Critical Appraisal Skills Programme (CASP) approach, adapted for use with eHealth applications.
- These reports of high quality evidence form the essential core of our proposed *NHS Connecting for Health Database of Systematic Reviews and Randomised Controlled Trials in eHealth*.
- To provide a broader appreciation of the context of this work and furthermore to aid conceptual development and interpretation of findings, we supplemented this systematic search for empirical evidence with a more emergent approach to identify relevant background and theoretical literature in relation to the essential concepts underpinning this overview—namely: eHealth; quality; safety; and the National Programme for Information Technology (NPfIT). This involved drawing on our personal databases of relevant papers, identifying seminal papers and reports as well as searching the grey literature.

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- The overall body of literature identified was too diverse to make any meaningful quantitative synthesis of the literature desirable, nor was it possible. Rather, we chose to qualitatively synthesise the literature drawing on the relevant preliminary conceptual work to guide this narrative synthesis.
  - Our overall assessment of the volume and strength of evidence in relation to key findings are summarised in this Executive summary using a modified version of the World Health Organization's Health Evidence Network (WHO HEN) system for public health evidence, which grades evidence into three main categories:
    - ❑ strong (consistent, good quality, plentiful or generalisable)
    - ❑ moderate (consistent and good quality)
    - ❑ limited to none (inconsistent or poor quality).

## NHS CONNECTING FOR HEALTH AND THE NATIONAL PROGRAMME FOR INFORMATION TECHNOLOGY

- The NPfIT is the most comprehensive, ambitious and expensive eHealth based overhaul of healthcare delivery ever undertaken.
- This Programme has its origins in the 1998 Department of Health strategy *Information for Health*, which committed the NHS to lifelong electronic health records for everyone with round-the-clock, on-line access to patient records and information about best clinical practice for all NHS clinicians. The current Programme, launched in 2002, is a 10-year initiative aimed initially to create the infrastructure, tools and environment through which it is possible to deliver:
  - ❑ a longitudinal electronic patient record (from “cradle to grave”) accessible to multiple users throughout the NHS; this (ie NHS Care Records Service or NHS CRS) together with the dedicated NHS broadband (National Network for the NHS or N3) and the national database on which these records will be held (the *Spine*); represents the backbone to the Programme
  - ❑ a service through which prescriptions can be transferred electronically from the general practitioner and other prescribers to pharmacists (Electronic Prescriptions Service) and integration with NHS CRS (Electronic Transmission of Prescriptions or ETP)
  - ❑ an electronic appointment booking service enabling general practitioners to electronically book hospital appointments (Choose and Book).

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- The Programme has, however, subsequently been expanded to include amongst other things:
    - ❑ a Picture Archiving and Communication System (PACS)
    - ❑ GP2GP, which is a system that enables transfer of patient records between GP practices
    - ❑ Quality Management Analysis System (QMAS), which automates assessment of GP practice performance against criteria included in the new GP contract
    - ❑ ePrescribing
  - Whilst these represent the headline deliverables of the Programme, our scoping of the field has identified a number of other related eHealth projects or applications which, although officially falling within the remit of the National Knowledge Service (such as ePrescribing and computerised decision support systems), are also within the remit of NHS CFH and are therefore also closely inter-connected with the delivery of the Programme.
  - Originally managed directly by the Department of Health, oversight of NPfIT transferred in 2005 to a newly created arm's length body, namely NHS CFH.
  - Foremost amongst the roles of NHS CFH is responsibility for nationally procuring systems and services that will be needed to ensure delivery of NPfIT.
  - Given the extremely high level of public expenditure, the Programme has and continues to attract considerable public, professional, legal, financial, political and international scrutiny.
  - It is thus probably no exaggeration to say that in addition to it being the most comprehensive, ambitious and expensive eHealth reform programme in the world, it is also the most influential in that its success or failure is likely to have major domestic and international ripples for many years to come.

## **EXPLORING, DESCRIBING AND INTEGRATING THE FIELDS OF QUALITY, SAFETY AND EHEALTH**

- eHealth is a relatively new and rapidly evolving field and so many of the concepts, terms and applications are still in a state of flux.
- There is furthermore no agreed definition of eHealth, with some researchers using this to relate primarily to the area of consumer informatics, whereas others use it more generically to refer to any of the ways in which IT can be employed to improve delivery of healthcare. For

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the purposes of this review, we considered it important to use an inclusive definition and chose to use Eysenbach's definition as the basis for our work, as adapted by Pagliari:

‘eHealth is an emerging field of medical informatics, referring to the organisation and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology.’

- Whilst the number of eHealth applications is potentially endless, these can nonetheless be divided into three broad domains relating to key activities they support:
  - ❑ storing, managing and sharing data
  - ❑ informing and supporting clinical decision-making
  - ❑ delivering expert professional and or consumer care remotely.
- The effective commissioning, development, deployment and routine use of eHealth applications is a cross-cutting area that impacts on each of these three domains.

## **QUALITY**

- There are no internationally agreed definitions of healthcare quality.
- Most frameworks of quality currently in use do, however, incorporate the following key dimensions of care:
  - ❑ effectiveness of treatments
  - ❑ appropriateness of means of delivery
  - ❑ acceptability
  - ❑ efficiency
  - ❑ equity.

## **SAFETY**

- Whilst there are no internationally agreed definitions of patient safety, adaptations of the National Patient Safety Agency's definition of Patient Safety Incidents are increasingly being used. This, in its original form, states that:

‘A patient safety incident is any unintended or unexpected incident which could have harmed or did lead to harm for one or more patients being cared for by the NHS.’



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- There are a number of patient safety taxonomies currently in existence, however, our scoping of this literature found that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) *Patient Safety Event Taxonomy* is the most comprehensive and clinically relevant in that it incorporates five key primary areas:
    - impact of medical error
    - type of processes that failed
    - domain, ie the setting in which an incident occurred
    - cause or factors leading to the safety incident
    - prevention and mitigation factors to reduce risk of recurrence and or improve outcomes in the case of a further incident.

#### **INTEGRATING EHEALTH, QUALITY AND SAFETY**

- Integrating the fields of eHealth, quality and safety clearly demonstrates the numerous ways in which technology has the potential to improve the efficiency of many facets of healthcare delivery through, for example, helping clinicians to readily access comprehensive information on their patients, aiding monitoring of their conditions and the treatments being issued, reducing inappropriate variability in healthcare delivery, and proactively identifying and alerting clinicians to threats to patient safety.
- This integrating of these domains however also highlighted the many ways in which introduction of new eHealth applications could inadvertently increase risks.

#### **MAIN FINDINGS**

- Our searches retrieved a total of 46,349 potentially relevant publications from which we selected a total of 414 relevant publications for inclusion, this comprising of 67 systematic reviews and 284 randomised controlled and controlled clinical trials.
- The volume of primary and secondary literature is large, rapidly expanding, poorly collated and of very variable quality; as a result the literature surrounding eHealth poses unique challenges to synthesis and interpretation.
- In synthesising the available evidence, we used the following generic approach in relation to different eHealth applications and their related considerations:
  - clarifying definitions, description and scope for deployment



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- ❑ drawing on our conceptual maps to reflect on the potential benefits and risks of each application
  - ❑ identifying the empirically demonstrated benefits and risks, using exemplar subject areas and or detailed case studies on issues that are of direct or potential future relevance to NHS CFH
  - ❑ based on a synthesis of the above, highlighting the policy, clinical and research implications for the individual areas of interest with a view to realising the potential that eHealth has to offer.
  - Our findings' chapters are grouped together in relation to the three main foci of this report, namely the domains of:
    - ❑ managing, storing and transmitting data
    - ❑ supporting clinical decision making
    - ❑ the cross-cutting issue of the socio-techno-cultural dimensions of developing and implementing eHealth applications.

## **DATA STORAGE, MANAGEMENT AND RETRIEVAL**

### *Health information exchange and interoperability*

- Effective and efficient sharing of clinical information is essential to the future development of modern healthcare systems, which are increasingly characterised by the involvement of many specialist healthcare providers, often working from different sites, contributing to the care of individual patients.
- The ideal in this respect is for professionals and patients themselves to have the ability to simultaneously access and seamlessly transfer, contribute to and integrate clinical data from disparate sources.
- The potential gains in relation to improving the quality, safety and overall efficiency of healthcare delivery are potentially enormous, as demonstrated by a recent US-based economic analysis.
- Most UK healthcare settings are however currently characterised by relatively low levels of health information exchange and interoperability (HIEI) capability, this being particularly true of the hospital sector, where paper-based records are still the main means of recording and communicating clinical information.
- NPfIT has already and will greatly increase the potential for HIEI, for example, through N3 and through deployment of the NHS Care Record Service, which will result in the creation of summary and detailed electronic health records that have the potential to be shared, to varying degrees, across healthcare settings and between providers.

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- Although NHS CFH's insistence that new eHealth applications must be Health Level Seven compliant—this referring to a voluntary but nonetheless widely used standard for interoperability—thereby assuring a degree of ability to exchange information between systems, is undoubtedly welcome, none of the headline NPfIT applications will however achieve the optimum levels of HIE, with the result that patient safety may needlessly be compromised.
  - The current empirical evidence-base in support of such HIEI considerations is however at present weak in relation to this improving organisational efficiency, practitioner performance or indeed any clinical patient outcomes.
  - Improving HIE to the optimal level so as to allow seamless transfer and access to data in all settings, whilst probably resulting in cost-savings in the longer run, will inevitably require considerable upfront investment in hardware and software capabilities.
  - An important paradox to further developments in this area is that whilst increasing levels of HIE are clearly desirable for many reasons, greater availability of data also inevitably increases the risk of threats to data security and breaches of patient confidentiality.
  - Key outstanding issues that face healthcare systems in realising the potential for seamless exchange of information include the need to develop and deploy standard coding structures across all care settings (eg using Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)), facilitate integration of the increasing amounts of patient-generated data (eg through HealthSpace, home sensors or telemetry devices), and improve secure audited access to electronic records to minimise the risks of breaching confidentiality.

#### *Electronic health records*

- The electronic health record (EHR) represents the backbone of all major international eHealth developments currently taking place internationally, including NPfIT.
- The ultimate goal is to have available comprehensive longitudinal health information for all members of the population, with the potential for accessing and contributing to these records by multiple users working across a range of healthcare settings; no country has however yet to achieve this comprehensively and if successful the NHS CRS will be one of the first in the world to come close to this aspiration.

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- Electronic health records range from simple storage devices to those with varying degrees of added functionality, including the ability to electronically prescribe (ePrescribing) and access to computerised decision support systems (CDSSs), which are active knowledge systems, which use individual patient data to generate case-specific advice.
  - The main potential advantages of EHRs relate to improved legibility and comprehensiveness of recording information, access by multiple users that is not geographically-bound (if interoperable), the ability to incorporate professional support tools, and time and cost-savings.
  - There are, however, important potential risks associated with the EHR, these in the main relating to data security considerations; there is in addition, the concern that clinically important information may be overlooked, particularly in contexts where there is parallel recording of data using both electronic and paper records.
  - The empirically demonstrated benefits relating to introduction of EHRs are currently limited to improved legibility, time savings for some professionals (nurses), and the facilitation of higher order functions such as audit, secondary analysis of routine data and performance management.
  - Time taken for doctors to enter and retrieve data has in contrast been found to increase; studies have furthermore found that the time disadvantage for clinicians to record and retrieve information did not attenuate with increased familiarity and experience with using EHRs.
  - Given the lack of evidence of empirically demonstrated benefits associated with EHRs, it is important that NHS CFH undertakes a comprehensive evaluation of the effects of the introduction of the NHS CRS. Before-and-after design comparisons on measures of safety, markers of quality, accessibility of information and impact on workflow are needed and these would be enhanced by incorporating a contemporaneous control arm into prospective studies.
  - There is moderate evidence that these can help improve patient outcomes, particularly in relation to provision of preventative care.
  - Standardised and widely accepted measures of data quality in EHRs are lacking and their development should be a priority.
  - An important potential national future development for EHRs is the ability to readily incorporate multi-media files such as heart sounds, retinal screens and audio or video recordings of consultations.

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### *Computer history taking systems*

- Most computer history taking systems (CHTSs) are designed for use by healthcare professionals, although some elicit information directly from the patient, as in the case of pre-consultation interviews.
- Computer history taking systems can be used in a variety of clinical settings and have, when eliciting data directly from patients, proven particularly useful in identifying potentially sensitive information such as alcohol consumption, sexual health and psychiatric illnesses, eg suicidal thoughts.
- Computer-based questionnaires are particularly useful for gathering important background data prior to the consultation, which can then allow more time for focusing on key aspects of the health problems in the actual consultation. These systems can also save money by reducing administrative costs.
- Speech software and speech completed response computer history taking systems allow adaptability for those with particular needs such as non-English speaking patients, patients with hearing impediments and those who are illiterate.
- There is moderate evidence that data collected electronically tend to be more accurate and contain fewer errors than data captured manually with traditional pen and paper techniques; such data are also more legible.
- The current generation of computers is however not adept at detecting non-verbal behaviour; these systems should therefore be seen as not a substitute but rather an adjunct to the clinical history.
- There have as yet been no comparative studies that have formally assessed the effectiveness and cost-effectiveness of different CHTSs.
- It is important for NHS CFH to carefully consider the considerable potential efficiency gains to be made from incorporating CHTS functionality—particularly if this involves direct entry of data by patients—into future iterations of the NHS CRS. HealthSpace could facilitate this as could a number of other modalities such as touch-screen or voice-recognition equipped computers available in waiting rooms. This will, however, need to be introduced within a clear evaluative context.

## **SUPPORTING PROFESSIONAL DECISION MAKING**

### *Computerised decision support systems*

- There are strong theoretical reasons for believing that improved access to relevant clinical information for healthcare professionals, at the point of

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care, can translate into improvements in healthcare quality, patient safety and organisational efficiency.

- Defined as software applications that use individual patient data, CDSSs utilise a repository of clinical information (knowledge-base) and an inference mechanism (logic) to generate patient specific output. These applications are highly variable in sophistication, output and the extent to which they can integrate with other clinical information systems.
- Computerised decision support systems have the potential to improve clinical decision making by providing practitioners with real time patient specific and evidence-based support and by providing individually tailored feedback.
- Although numerous evaluations of CDSSs have taken place, very little consistent and generalisable evidence exists on their ability to improve practitioner performance and patient outcomes; evidence is often limited to particular conditions (eg diabetes and hypertension) or an aspect of clinical care (eg preventative care).
- The use of computerised reminders for provision of preventative care has been empirically demonstrated to be of benefit. However, trials have not assessed patient outcomes as for most preventative care interventions, the time needed to demonstrate an effect on patient outcomes is prohibitive.
- Through a detailed case study investigating the potential of CDSSs to support diagnostic screening we demonstrate how these tools may fail to realise their potential, particularly in relation to complex tasks such as diagnostics.
- CDSSs are largely unregulated in the US and UK due to exclusion from the Federal Drug Administration and Medicine and Healthcare Products Regulatory Agency respectively.
- Without formal quality and safety assurances in relation to CDSS applications, the potential risks to patient safety need to be seriously considered as they may in certain situations inadvertently introduce new errors.
- As CDSSs work best when interfacing with or integrated within existing clinical information systems, and the evidence of benefit is clearest and risk of harm is least for provision of preventative healthcare, NHS CFH should consider introducing a range of computerised health promotion tools into primary care and with the roll-out of the EHR into secondary care.
- The hope of finding one overarching message regarding the effectiveness and safety of CDSSs is naïve and should be abandoned. Rather, research

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should focus on understanding the contexts in which these decision support tools are most likely to prove effective and this should be a priority consideration for NHS CFH as it introduces new eHealth applications with built-in decision support functionality.

### *ePrescribing*

- There is considerable variation in the quality of prescribing. Medicines management errors are common, costly and an important source of iatrogenic harm.
- ePrescribing is defined as the use of computing devices to enter, modify, review and output or communicate prescriptions. ePrescribing systems are highly variable in functionality, configurability and the extent to which they integrate with other systems.
- ePrescribing has the potential to greatly improve the quality and safety of prescribing, through facilitating cost-conscious evidence-based prescribing and in particular reducing errors associated with knowledge gaps and routine tasks such as repeat prescribing.
- There is moderate evidence that practitioner performance is improved through better access to these guidelines. Patient outcomes are however less well studied and when assessed, most studies have not been able to demonstrate a clinical benefit.
- The detailed case study of supported oral anticoagulant dosing revealed some evidence for improved practitioner prescribing performance as demonstrated by improved control; this has however not been shown to translate into decreased adverse drug events.
- Evidence of benefit from ePrescribing systems has in the main been demonstrated from evaluations of home-grown systems in a few centres of excellence. Most systems in use are however commercially procured and these systems typically lack the sophistication, clinical relevance and sense of ownership associated with the tailored home-grown systems.
- Poorly designed ePrescribing systems and a failure to appreciate the socio-techno-cultural issues associated with their introduction can introduce unexpected new risks to patient safety.
- In the UK, the Medicines and Healthcare Products Regulatory Agency does not consider ePrescribing systems to be a medical device and does not therefore require these systems to be quality assured. This is an important policy failing that needs to be addressed.
- Further research into the design features, knowledge-bases and underlying



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algorithms, clinical relevance of output, interoperability of ePrescribing systems and socio-technical factors that enhance use is needed in order to replicate the benefits of ePrescribing that have been demonstrated in US centres of excellence.

## **SOCIO-TECHNICAL DIMENSIONS OF DESIGNING, DEVELOPING, AND DEPLOYING eHEALTH APPLICATIONS**

### *Human factors*

- The nature of human factors (ergonomics) is to understand people and their interactions, as well as the relationships between these interactions, and to improve those interactions in real life settings.
- For human performance and safety considerations to effectively influence the design and project specifications, they need to accommodate the following essential factors for all users: staffing constraints; system operator and maintainer (user) skills; training time available and cost limitations for formal, informal and on-the-job skill development; and acceptable levels of human and system performance when operated and maintained by members of the target population.
- Healthcare has been slow to incorporate human factors considerations into assessments of eHealth applications, despite the mounting complexity of care delivery systems and evidence of resulting risk to patients.
- A well designed user interface is, for example, as important as functionality and reliability in ePrescribing applications. Confusion and frustration with an application interface are enough to impede users' acceptance of an application, with an adverse subsequent knock-on effect on implementation.
- There are important gaps in the literature regarding how best to conduct usability testing with the end-users of eHealth applications such as ePrescribing.
- NHS CFH needs to ensure that the results of human factors assessments are provided by developers and that the findings of these tests are incorporated into decisions to grant approvals before new eHealth products are introduced into the NHS.
- The EHR, ePrescribing and CDSS systems are examples of complex applications for which it is clearly essential that end-users have been involved in all stages of design, development and deployment.
- Critical feedback from end-users of new eHealth applications should not only be facilitated, but must also be actively encouraged so as to ensure

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that new applications are fit for purpose and minimise risks to patient safety.

- Embedding human factors principles and thinking is not free; NHS CFH needs to ensure that adequate time, resources and prioritisation are given to this so as to maximise the chances of success of its various eHealth initiatives.

#### *Effective implementation and adoption of eHealth applications*

- Most technological innovations fail to realise their potential and this unfortunately has also been true with respect to the history of eHealth applications.
- Major factors contributing to these failures—which may in some cases be spectacular—include the lack of appreciation and attention paid to the human factors issues during product development and socio-technical factors that subsequently enable innovations to diffuse and embed themselves into healthcare organisations and then be successfully adopted.
- There is a burgeoning change management literature, dating back to the influential *Diffusions of Innovation* theory and stretching to the more recent *Diffusion of Innovations in Health Service Organisations* work. Much of this is however descriptive and so the predictive ability of these models of change management is as yet unknown.
- Using an adaptation of the above and other theories to render them more relevant to the planned dissemination of eHealth applications we used our *Infusion of eHealth Innovations in Health Services Organisations Model* to undertake a detailed case study assessing NHS CFH's current approach to promoting the NHS CRS in secondary care.
- We found this Model helpful, particularly in highlighting the need to pay attention to human factors when developing and designing IT solutions and this failure to engage with end-users at this crucial formative stage represents a major weakness of the NHS CRS implementation of plan, as does the continuing lack of clarity over the details of what this will comprise of, the opportunity to trial and gain confidence in using it, ongoing concerns about confidentiality and the lack of a clear timeline for implementation.
- That said, NHS CFH are instituting a comprehensive multi-faceted approach to implementing the NHS CRS which, given the disruptive potential of this innovation with respect to normal working patterns, is very appropriate.



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- It is however very important that particular attention is now also paid to ensuring that there are ample training opportunities for staff before its actual introduction and real time support during the actual implementation phase. The success (or failure) of the central plank of the multi-billion pound investment in NPfIT will ultimately depend only in part on technological competence; far more important will be the attention awarded to understanding and managing the socio-technical dimensions and it appears that at present inadequate time, attention and resources have been focused on this latter issue.

## CONCLUSIONS AND FUTURE RESEARCH PRIORITIES

- We have in undertaking this work made four main methodological contributions to this nascent field, namely:
  - development of a very comprehensive search strategy for identifying high quality primary and secondary literature investigating the impact of eHealth on the quality and safety of healthcare
  - development of integrated conceptual maps of eHealth, quality and safety, which have, as demonstrated in this project, the ability to draw attention to the major potential benefits associated with use of different eHealth applications
  - development of a tool for critically appraising systematic of eHealth applications based on internationally agreed approaches
  - development of a framework with which to consider the planned implementation of eHealth innovations into complex health service organisations.
- This project has also laid the foundations for the future creation of a potentially important international resource—*NHS Connecting for Health Database of Systematic Reviews and Randomised Controlled Trials in eHealth*—that should we believe be of considerable usefulness to all those with an interest in IT and its impact on healthcare delivery.
- The formative work for this project and the review of technical reports and a variety of review documents clearly demonstrate that eHealth applications have the potential to dramatically improve the quality of healthcare delivery; even more importantly, perhaps, there is considerable potential to improve the safety profile of medicine through elimination of both latent and active errors and through promoting real time systems checks.
- The major finding from reviewing the empirical evidence—which is of variable quality—however, is that there is very limited rigorous evidence

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demonstrating that these technologies actually improve either the quality or safety of healthcare.

- The reasons for this are multi-faceted, these including:
  - ❑ a lack of primary research, this to an extent reflecting the assumption that the benefits associated with these applications is obvious
  - ❑ using proxy outcome measures as opposed to those that are actually clinically important
  - ❑ poorly theorised interventions and studies
  - ❑ overestimating likely effect sizes
  - ❑ methodological limitations, particularly the failure to appropriately use cluster designs in studies that are at risk of contamination, poor outcome definition and measurement, and approaching these interventions as the equivalent of simple interventions, which they are typically clearly not.
  - ❑ naïve assumptions that these technologies will be equally effective in all contexts
  - ❑ inappropriately short timeframes to study likely health gains
  - ❑ the failure to involve end-users at a sufficiently early stage in the design and deployment process that they can actually influence factors that are likely to increase acceptability of the interventions to clinicians
  - ❑ a failure to pay adequate attention to the socio-technical factors that are likely to be important in relation to the diffusion, implementation and use of these applications.
- Despite these substantial gaps in the evidence-base—which can be filled—we are, on the basis of the theoretical work and empirical evidence reviewed, cautiously optimistic that a number of the eHealth applications being introduced into the NHS through the NHS CFH's NPfIT are likely to result in significant medium- to long-term benefits to organisation efficiency and patient care.
- We would in particular also encourage NHS CFH to prioritise the implementation of ePrescribing, ideally with CDSS functionality in an integrated way within the NHS CRS within secondary and tertiary care settings and also to improve ePrescribing functionality in primary care.
- Realising the benefits is however likely to be crucially dependant on actively and formally facilitating end-user input throughout the commissioning, design, development and implementation process as this will maximise the chances that aspects of these technologies that are actually clinically useful are developed (for example, ETP as opposed to

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Choose and Book) and promote a sense of ownership and buy-in into the technology.

- Appreciating the structural, organisational and, to a lesser extent, professional challenges that need to be overcome in the deployment should however never be overlooked, particularly when complex transformative technologies such as the NHS CRS are introduced. The need for training in use of new technologies and on-the-job support also needs much greater appreciation.
- End-user consultation and feedback should be viewed as an on-going process and should therefore continue after deployment to ensure that problems are identified early, as are possible solutions which can be incorporated into system upgrades.
- Given the real paucity of evidence, we very strongly encourage NHS CFH to centralise their evaluation programme so that this permeates all aspects of the Programme's development and implementation. Given the historic failure of many previous IT initiatives, such investment is we believe likely to prove a most valuable investment.
- We have throughout this report identified a number of areas in relation to specific technologies where further research is warranted. There are however a number of broader research considerations that need to be prioritised which we emphasise here, namely:
  - the need for further conceptual development and then international consensus building on use of standardised terminologies to facilitate future primary and secondary work
  - the development of a methodological toolkit to facilitate evaluation of eHealth applications throughout all aspects of the development and deployment life cycle of these technologies.
  - the need to encourage researchers to combine rigorous quantitative and simultaneously conducted qualitative assessments when evaluating the effectiveness of new eHealth applications to allow a detailed appreciation of relevant contextual factors that might help better understand the reasons for the success or failure of the intervention to emerge and also, where found to be successful, to allow an assessment of the likely generalisability of the intervention to be made.
- Given the vast gulf between the potential advantages associated with eHealth applications and the actual empirically demonstrable benefits, our major research recommendation is however to ensure that evaluative considerations are centralised within NHS CFH: given the scale of the

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investment taking place, it is vital that every opportunity is taken to ensure that this public money produces the desired outcomes. In view of the likely timeframe for these improvements to be demonstrated, it is important that this commitment to evaluation continues beyond the end of the 10-year lifetime of the Programme.

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# SECTION 1

## BACKGROUND

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# CHAPTER 1

## Introduction

### SUMMARY

- Increasing life expectancy, improved survival of people with acute and long-term conditions and a greater array of available treatment options are placing an increasing burden on healthcare organisations internationally.
- There is now a substantial body of research, both domestic and international, identifying considerable short-falls in the current provision of healthcare.
- Key issues emerging from this literature are substantial variations in the quality of healthcare and the considerable risks of iatrogenic harm.
- These failings make a significant contribution to the high rates of potentially avoidable morbidity and mortality, and healthcare expenditure.
- There have been substantial developments in information technology hardware and software capabilities over recent decades and there is now considerable potential to apply these technological developments in relation to aspects of healthcare provision
- Of particular international interest is the deployment of eHealth applications—that is the use of information technology in healthcare contexts—with a view to improving the quality, safety and efficiency of healthcare.
- Whilst these eHealth technologies have considerable potential to aid professionals in delivering healthcare, the use of these new technologies may also introduce significant new unanticipated risks to patients.
- Also of concern is that even when high quality interventions are developed, they frequently fail to live up to their potential when deployed in the “real world”; a major factor contributing to this paradox is professional resistance to the introduction and use of poorly designed applications.
- Given that the NHS is now committed to the largest eHealth-based modernisation programme in the world, it is appropriate and timely to critically review the international eHealth literature with a view to identifying lessons that can usefully be learnt with respect to the future development, design, deployment and evaluation of eHealth applications.

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## 1.1 BACKGROUND TO THIS STUDY AND POLICY CONTEXT

The Institute of Medicine has defined quality as the ‘. . .degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.’<sup>1</sup> The quality of services provided by the National Health Service (NHS) in England varies widely, and there is often a large gap between the optimal standard of services—when judged based on professionally agreed criteria—and the actual quality of practice.<sup>2;3</sup>

This quality gap can have serious health consequences and major implications for the intimately inter-related notion of patient safety.<sup>4</sup> These deficiencies can manifest, for example, as misdiagnosis,<sup>5</sup> medication errors,<sup>6,7</sup> increased rates of complications in patients with long-term diseases,<sup>8</sup> hospital admissions for adverse drug reactions,<sup>9;10</sup> and outbreaks of preventable infectious diseases such as measles.<sup>11</sup>

This gap between optimal and actual levels of healthcare also has large financial costs for the healthcare system, national governments, and society, as well as affecting patients’ quality of life and, in far too many cases, life expectancy.<sup>10;12;13</sup> Problems with the quality of care can have a considerable impact on healthcare costs; for example, through increased hospital admission rates for unscheduled care and or longer lengths of hospital stay.<sup>10</sup> Problems with the safety of healthcare can similarly have major cost implications; for example, adverse drug reactions are in the UK estimated to result in approximately 250,000 hospital admissions per year<sup>9;10</sup> at a total cost of about £500 million (€700 million; \$1,008 million).<sup>9;10</sup>

Mounting evidence of the disease burden associated with variations in standards of care, especially with regard to medical errors, has informed a number of recent national policy and strategic reports on patient safety.<sup>14–19</sup> These documents have highlighted the pressing need for healthcare policy to focus more clearly on developing systems—and strategies for their implementation—that facilitate the delivery of safe and effective high quality healthcare.<sup>20–23</sup> This response being catalysed by the identification of a series of failings, both with respect to policy and approaches to strategically implement these healthcare reforms.<sup>24</sup>

Added to the mix are a variety of other factors, these including: the fact that economically developed (and developing) countries are facing increases in the proportions and number of older people in their populations; increasing public expectations with respect to rapid access to high quality patient-centred health services; and an expectation from governments, professionals and the public

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alike that people should be able to live with the minimum possible impact from disease and disability on their quality of life and day-to-day activities.<sup>15</sup>

Capitalising on the information technology (IT) revolution is increasingly seen as pivotal to redesigning healthcare systems so that they are able to deliver safe, effective and convenient healthcare. Such objectives lie at the heart of the NHS's Information Strategy and have led to the creation of structures such as the National Patient Safety Agency (NPSA),<sup>25</sup> the National Reporting and Learning System (NRLS),<sup>26</sup> National Knowledge Service, and NHS Connecting for Health (NHS CFH) and its National Programme for Information Technology (NPfIT) (see Chapter 3 for a detailed discussion of NHS CFH and NPfIT).

## 1.2 AGENDA FOR SYSTEM REDESIGN: QUALITY AND SAFETY IN HEALTHCARE

The Department of Health (DH) estimates that 10 per cent of patients admitted to NHS hospitals are unintentionally harmed, this high rate being similar to that in other developed countries. If lessons had been learnt from previous incidents around 50 per cent of these patient safety incidents could have been avoided.<sup>17</sup> In its report *An Organisation with a Memory*, an expert committee, chaired by the Chief Medical Officer, identified four conditions that the NHS must meet to learn effectively from failures and offer the best possible protection to patients in the future.<sup>14</sup> These relate to the development of:

- a more open culture, in which clinical errors or failures of service delivery can be reported and discussed by NHS staff
- unified mechanisms for reporting and analysing patient safety incidents in healthcare delivery
- mechanisms to ensure that, where lessons are identified, the necessary changes to improve the delivery of healthcare are put into practice.
- a much wider appreciation of the value of system-based approaches in preventing, analysing and learning from errors.

These requirements call for complex and comprehensive solutions as no single “silver bullet” will be sufficient. As an example of the role of IT in these endeavours, evidence-based technological solutions may provide significant support for the development of standardised incident reporting and analysis mechanisms, as well as providing a platform for automated interventions to ensure that lessons learned from past mistakes are incorporated into daily practice.<sup>26</sup> Such interventions also demonstrate the system-based approach called for in the Chief Medical Officer's report.



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### 1.3 IMPORTANCE OF TECHNOLOGY IN DESIGNING SAFE HEALTHCARE SYSTEMS

Enthusiasm about the potential that IT offers for improving health services has resulted in unprecedented investments into IT by the NHS (and other healthcare systems internationally). Technology-based health services and clinical systems come in many different forms, have myriad aims, and can be implemented in numerous ways. Information technologies (sometimes also referred to as information and communication technology (ICT)), health informatics or eHealth applications, this latter being our preferred term in this report) may be used to record, collate and share information on patients (eg electronic health records (EHRs)). eHealth applications may also be used to support evidence-based practice both in general terms (eg guideline-linked reminders)<sup>27</sup> or more specifically through advice on the management of individual patients (eg advice on avoiding drug-drug interactions).<sup>28;29</sup> eHealth applications can also serve to facilitate care from a distance<sup>30</sup> (eg telecare), patient self-care (eg through consumer informatics applications), epidemiological research (eg using databases that collate data derived from electronic health records)<sup>31</sup> and healthcare management activities such as quality improvement initiatives.<sup>32;33</sup>

eHealth solutions range from computer history taking systems,<sup>34–42</sup> computerised decision support systems (CDSSs),<sup>43</sup> computerised provider order entry (CPOE) and ePrescribing,<sup>44–52</sup> computerised medication administration records,<sup>53</sup> automated pharmacy systems and bar-coding to “smart” intravenous devices, point-of-care personal digital assistants and robot-assisted surgery.<sup>54–60</sup> Because of the often complex nature of these systems, there are important considerations relating to appropriately evaluating their impact and we reflect on these issues in more detail in Chapter 2 and 16. The theoretical advantages of these eHealth applications are considered in Chapter 4 and the empirical evidence in relation to a number of key exemplary eHealth applications is summarised in Chapters 6–13.

The desire to realise the potential of technology to improve the quality and safety of healthcare often leads to the introduction of new IT solutions, on a large or even national scale, with typically only a limited evidence-base in support of the systems’ overall effectiveness and safety. Of particular relevance here is that the hardware-software development mismatch often creates unrealistic expectations about the potential impact of eHealth systems. Processing power doubles approximately every 18 months and storage capacity and network bandwidth also increase rapidly within relatively short time periods. In contrast, productivity in software development has been increasing at only about five per

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cent per year. The Chaos studies performed by the Standish Group have, for example, shown that the majority of software projects (across all industries) are delivered late and over budget.<sup>61</sup> Specifically, software applications often become a bottleneck for healthcare organisations trying rapidly to improve their processes, this despite substantial investments in IT.<sup>62</sup> To meet the expectations of the market, systems developers have thus far been more concerned with meeting design briefs and satisfaction than with assessing the efficacy and effectiveness of systems in terms of producing actual health gains. Consequently, many eHealth innovations remain either unstudied or understudied. Indeed, when evaluated, the evidence-base on the question of their effectiveness is often inconsistent, frequently reflecting, as we will see, a lack of attention to issues pertaining to context, which is so crucial to success.<sup>63–68</sup> Researchers have paid even less attention to patient safety (ie the potential for harmful effects), as demonstrated by recent work in England and Wales, and more recently in Scotland, evaluating the safety profile of general practice (GP) computing software in providing decision support for prescribing.<sup>69;70</sup> Other areas of relevance in the context of both clinical effectiveness and safety are user acceptance, workflow integration, compatibility with legacy applications, and system maturity.<sup>71</sup>

Emerging eHealth systems have the potential to reduce errors and enhance patient safety by, amongst other things, improving the legibility of clinical communications, enabling shared access to health records, reducing reliance on human memory and prompting evidence-based prescribing.<sup>33;72–75</sup> For example, automated monitoring and routine feedback have been shown to reduce the rate at which hospitalised adults with renal insufficiency received excessive doses of medication.<sup>76</sup>

However, such systems also have the potential to introduce risks and compromise quality as demonstrated in Chapter 4, where we map the key health risks associated with eHealth solutions. For example, a study examining the types of errors facilitated by a leading CPOE (sometimes also referred to as ePrescribing) system found that it regularly increased the risk of a variety of errors, with users describing up to 22 different types of failures.<sup>77</sup> Similarly, a recently published study revealed high rates of adverse drug events in a highly computerised hospital.<sup>78</sup> Although improved case finding (in part resulting from IT use) may partially explain these high rates, the overall rate of adverse drug events (related to problems in drug selection, dosage, and monitoring) per 1,000 patient-days was 5 to 19 times higher than that reported in previous studies. These examples illustrate the point that, as new IT solutions are conceived and

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implemented, there is also a need to develop mechanisms to proactively study the potential for these systems to inadvertently cause harm.<sup>79–84</sup>

As with many innovative ventures, not all ideas ultimately prove beneficial. It is salutary to note that, even when safe, some 50 to 70 per cent of eHealth projects fail.<sup>85</sup> These failures do not in the majority of cases represent technological problems, but rather human and organisational factors. Problems may arise due to developers misjudging the functioning of health systems or not envisaging the full range of consequences. Even when the ideas prove effective in controlled research settings, they often challenge prevailing thinking and behaviour in a way that renders them difficult to implement.<sup>86;87</sup> There is ample evidence to show that the past failures of technological innovations with respect to improving health outcomes (or to drive improvements in other industries)<sup>88–91</sup> have not necessarily been due to their clinical ineffectiveness, but rather to social, technological and cultural issues relating to their implementation and adoption. In particular, the human elements affecting the success of technological implementation and adoption should not be underestimated, whether these relate to organisational issues, eg managing complexity<sup>92</sup>—complex systems involve many gaps between people, stages, and processes;<sup>93</sup> and or availability, accessibility and user attitudes towards, or usability of the technology.<sup>70;87;94–100</sup> Furthermore, integration of IT systems into clinical settings fundamentally changes not only how clinicians view their daily work practices, but also the very process of medical reasoning itself, introducing new elements into care pathways, often with unpredictable effects.<sup>101;102</sup>

Any significant adverse events due to a failure of new eHealth solutions have the potential to lead to disastrous effects in the way in which these programmes are perceived by professionals and the public alike. It is therefore vital to ensure that implementation considerations are given at least equal importance as questions of IT effectiveness and safety. Successfully integrating new IT solutions into the healthcare workflow is crucially dependant on engagement of clinicians and patients right from the start of the development and ongoing evaluation of these new applications. In addition to providing important insights into user requirements, such engagement leads to a sense of ownership and buy-in that is critical to the success of the often radical programmes to transform health services that are currently underway in different parts of the world.<sup>87;103</sup> These socio-techno-cultural considerations are reviewed in Chapters 12–14.

In summary, key challenges currently facing NHS CFH's ambitious NPfIT and the NHS quality and patient safety agendas include ensuring that new eHealth solutions developed for and introduced into the NHS represent a genuine

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clinical advantage, that their deployment is, wherever possible, supported by a secure evidence-base, and that evaluative mechanisms are in place to assess their effects with regard to both quality and safety of health service delivery. As a recent Institute of Medicine report highlighted, patient safety must be indistinguishable from the delivery of quality care<sup>23</sup> and must score top on our agendas.<sup>104</sup>

## **1.4 AIMS OF THIS REVIEW**

This report, which builds on our recent eHealth scoping study,<sup>33</sup> completed and on-going systematic reviews,<sup>105–108</sup> and both quantitative and qualitative studies on eHealth approaches to enhancing quality and minimising threats to patient safety, aims to provide a systematic overview of the impact of eHealth on the safety and quality of healthcare. In so doing, we seek to identify, critically appraise and then synthesise evidence to develop a theoretically informed framework for understanding the potential and empirically demonstrated benefits and risks associated with eHealth and to describe and understand approaches that can be used to guide the successful implementation and adoption of effective interventions. We also aim to identify areas of eHealth in need of further study, highlighting possible approaches that might successfully be employed to ensure a well rounded, context-bound appreciation of the overall impact of IT interventions in healthcare.

## **1.5 STRUCTURE OF THIS REPORT**

After this introductory chapter, Section 2 begins with a detailed description of our methods (Chapter 2) and this is followed by the findings of our attempts at understanding the history, development and policy foci of NHS CFH and NPfIT (Chapter 3) and describing and mapping the fields of eHealth, quality and safety (Chapter 4).

In Section 3 we present our main findings, beginning with the essential underpinning issues of health information exchange capability and interoperability (Chapter 5), and then moving on to reviews of key eHealth applications, namely EHRs (Chapter 6), computer history taking systems (Chapter 7), ePrescribing (Chapter 10) and CDSSs (Chapter 8). We then turn to the cross-cutting issues of how to design safe, effective and usable systems (Chapter 12) and how then to ensure their effective implementation and adoption into routine models of care (Chapter 13). In each of these chapters we begin by considering key definitional issues and the relevant theoretical literature with a view to having a firm foundation from which to interpret the empirical evidence; the chapters

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conclude with a reflection of key policy, practice and research implications arising from this work. We then reflect on this evidence in considerably more detail in the context of applying it to three exemplary case studies looking at important clinical and policy questions in the remaining chapters in this section (Chapters 9, 11 and 14).

Our overriding conclusions and policy recommendations from this review are presented in Chapter 15. Section 4 concludes with our reflections on the quality of the evidence reviewed and overarching suggestions for future research which should, if pursued, help to improve both the quality and quantity of empirical evidence for eHealth applications and their successful deployment.

The final section contains a number of appendices relating to the methods employed (Appendices 1–3) and detailed findings (Appendices 4–6). This section also includes a glossary of key terms.

## 1.6 CONCLUSIONS

As a result of the work carried out for this report, we have, we believe, made a number of key conceptual and methodological advances in relation to techniques for identifying, appraising, synthesising and interpreting the evidence. Furthermore, our work has laid the foundation for the creation of a comprehensive, critically appraised, and carefully interpreted database of systematic reviews and randomised controlled trials in eHealth, which should, once fully developed, be of international interest to all those with an interest in eHealth and its impact on healthcare delivery. We hope that the theoretical and empirical evidence presented in this report, when viewed in the context of ongoing policy developments, provides a reliable and accessible overview of a vast corpus of hitherto disparate knowledge and through so doing helps to inform on-going deliberations on how to ensure that eHealth realises its enormous potential to impact positively on both the quality and safety of healthcare delivery.

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## SECTION 2

# METHODS AND FORMATIVE WORK

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## CHAPTER 2

### Methods

#### SUMMARY

- We conducted a systematic search and critique of the empirical literature on eHealth applications and their impact on the quality and safety of healthcare delivery; this body of work was then synthesised with relevant theoretical, technical, developmental and policy relevant literature with a view to producing an authoritative and accessible overview of the field.
- Whilst we drew on established Cochrane review principles to systematically search for, critique and synthesise the literature, this approach needed to be adapted in several respects in order to produce a meaningful “umbrella” review of the literature.
- Searching the literature was complicated by the lack of internationally (or indeed in some cases nationally) agreed terminology relating to eHealth applications, the lack of agreed definitions of quality and safety, and consequently poor indexing of these constructs in databases of published work.
- In order to undertake a comprehensive review of the literature we therefore needed to undertake initial developmental work to formulate highly sensitive search strategies.
- Using this comprehensive set of search terms, we systematically searched: MEDLINE, EMBASE, The Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, The Cochrane Central Register of Controlled Trials, The Cochrane Methodology Register, Health Technology Assessment Database, NHS Economic Evaluation Database over a 10-year period (beginning with 1997 to May 2007) to identify systematic reviews, technical reports and health technology assessments, and randomised controlled trials investigating the impact of eHealth applications on the quality and safety of healthcare. We also searched the National Research Register and registers of clinical trials to identify relevant on-going or unpublished work.
- These reports of high quality evidence will be collated in our planned *NHS Connecting for Health Database of eHealth Studies*.

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- To provide a broader appreciation of the context to this work and furthermore to aid development and interpretation of findings, we built our interpretation of evidence around relevant theoretical literature. We used a more emergent approach to identify relevant background literature in relation to the core concepts underpinning this overview—namely eHealth, quality, safety and the National Programme for Information Technology. This involved drawing on our personal databases of relevant papers, identifying seminal papers and reports, and searching the grey literature.
  - We integrated the findings from this broader theoretical and empirical evidence-base in relation to each of the domains of enquiry.
  - The overall body of literature identified was too diverse to make any meaningful quantitative synthesis of the literature desirable, nor was it possible. Rather, we chose to qualitatively synthesise the literature drawing on the relevant preliminary conceptual work to guide this narrative synthesis.
  - Our assessment of individual reviews is summarised in Appendix 5 using modified Critical Appraisal Skills Programme criteria and the overall assessment of the volume and strength of evidence in relation to key findings is summarised in the Executive Summary using a modified version of the World Health Organization’s Health Evidence Network system for public health evidence, which grades evidence into three main categories:
    - ❑ strong (consistent, good quality, plentiful or generalisable)
    - ❑ moderate (consistent and good quality)
    - ❑ limited to none (inconsistent or poor quality).

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## 2.1 OUTLINE OF METHODS

Research in the field of eHealth is exponentially expanding in breadth and increasing in volume thus rendering it impossible for any individual to read, critically appraise and synthesise the state of current knowledge, let alone remain up-to-date in this dynamic area. Systematic reviews have become essential sources of information for policy-makers and practitioners who need to remain abreast of important new developments in their fields of interest. These also serve another important function, namely helping to identify areas where there are important gaps in the literature and where further primary studies are hence required.

Our aim in conducting this systematic overview of the literature was to survey the relevant theoretical, technical and empirical literature to produce a comprehensive summary of the evidence for eHealth applications to improve the quality and safety of healthcare delivery, and identify key issues in relation to the design, development, implementation and adoption of eHealth applications into routine healthcare settings. More specifically, in keeping with our brief we were primarily interested in two broad areas of eHealth applications, these relating to technologies concerned with improving the storage and management of patient data and tools that support professional decision-making (see Chapter 4).

Given the extensive body of eHealth literature, we considered various approaches to searching, appraising, interpreting and synthesising the evidence. Considering the aim of this report and in order to make our findings accessible to policy-makers, managers and end-users,<sup>1</sup> We throughout attempted to generate new insights and pragmatic recommendations suitable for effective policy-making in healthcare.

Based on our recent experiences of conducting systematic reviews in the subject area, we considered it important to take a broad approach to identifying potentially relevant work in this systematic overview.<sup>2</sup> This approach has the advantage of allowing the strength (generalisability and consistency) of research findings to be assessed across a wide range of different settings, study populations, and behaviours, thereby reducing the risks of drawing erroneous conclusions. Established rigorous systematic review methods were used to identify and critically appraise studies and then abstract and synthesise findings. We explicitly sought to factor into our assessment important contextual factors.

### 2.1.1 LITERATURE REVIEWS OF OTHER SOURCES OF EVIDENCE

Standard systematic review methods (eg Cochrane), which focus on identifying comparable studies addressing specific research topics and combining their

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results to establish general effect sizes, were too narrow for the purposes of meeting the objective of research brief.<sup>3–5</sup> While evidence collated from such reviews appropriately carried greater weight in relation to assessing questions of effectiveness, our interpretation of evidence was also informed by other research architectures or designs, primarily randomised controlled trials (RCTs) and other experimental designs at relatively low risk of bias,<sup>6</sup> but also case series, instructive case reports, and conceptual papers to inform safety considerations.

Systematic reviews of RCTs are, on account of their ability to control for known and unknown confounders, the “gold standard” evidence source in relation to studying the effectiveness of interventions. Whilst RCTs and systematic summaries of these are ideally suited for studying drug treatments, they are typically far less appropriate for studying safety issues, a major problem being the prohibitively large RCTs that are typically needed to study adverse events. A meaningful study of safety considerations must therefore embrace a broader literature than that needed to establish efficacy or effectiveness.<sup>6</sup> Randomised controlled trials are furthermore unable to shed detailed insights on whether systems will be used or indeed how they will be used—factors which greatly influence the effectiveness (as opposed to efficacy) of interventions when implemented in routine practice. As the commissioning brief advised a focus on both quality and safety issues of IT deployment in healthcare services, we therefore needed to develop a novel combination of approaches to knowledge acquisition and evidence appraisal to ensure that we produced a valid summary of the literature.

We began evidence synthesis by drawing primarily on high quality evidence from systematic reviews. Where these did not provide adequate answers to the questions of interest, we employed a “snowball” approach to identifying additional potentially relevant literature, starting our additional searches for and examination of evidence from RCTs and, as necessary and feasible, then also considering other study designs (for example, controlled before-after designs, time-motion, descriptive and qualitative studies), as well as relevant theoretical and technical papers.<sup>7</sup> Since the field is rapidly developing, a key aim of these additional searches was to ensure that any important primary evidence that has emerged since the included reviews were conducted was not overlooked.

Many of the included studies went beyond the usual measures of system performance or doctors’ behaviour by focusing on “fit” of the system with other aspects of professional and organisational life.<sup>5</sup> We carefully considered issues relating to the measurement of error.<sup>8</sup> Patient safety research initiatives can



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be considered in three different stages: (1) identification of risks and hazards; (2) design, implementation, and evaluation of patient safety practices; and (3) vigilance to ensure that a patient safety environment and culture is maintained. Clearly, different research methods and approaches are needed at each of the different stages of the continuum. No single method can be universally applied to identify risks and hazards in patient safety. Rather, multiple approaches using combinations of these methods increased identification of risks and hazards in terms of potential injury or harm to patients.<sup>9</sup>

## 2.2 PLANNING PHASE

In terms of developing an overall search strategy, we considered several options, such as employing individual strategies for each of the different eHealth areas of interest (discussed below). However, instead we decided to develop a single all encompassing search strategy in order to improve overall efficiency by avoiding overlapping multiple retrieval of publications in these closely related areas.

We began by building on the findings of our eHealth scoping report to the NHS Service Delivery & Organisation<sup>10</sup> and our existing multi-disciplinary programme of work on the impact of eHealth on the quality and safety of health services. Our search strategy for bibliographic databases was developed in accordance with the recommendations for search strategies in the *Cochrane Handbook for Systematic Reviews of Interventions*<sup>11</sup> and encompassed broad, comprehensive Medical Subject Headings (MeSH) and free text terms in order to achieve high sensitivity in our search for possibly eligible studies.

Initially, we also planned to employ computerised knowledge mapping methods and analysis of non-standard data sources using free text terms. However, due to the volume of literature from established databases, this step was, in agreement with our External Steering Group, not performed due to project time constraints (the Delphi method for identifying research priorities was also omitted for the same reason).

### 2.2.1 RATIONALE FOR AN OVERVIEW OF REVIEWS

The success of the evidence-based medicine movement has resulted in a proliferation of systematic reviews of the literature, this in turn necessitating the need for overviews of systematic reviews to allow policy-makers, clinicians and increasingly patients to obtain an accurate overview of the literature in a broad field of medicine. These overviews, also sometimes known as “umbrella” reviews seek to collate and synthesise evidence from multiple systematic reviews on the effectiveness of different approaches to addressing a specific or set of

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related problems or, in contrast, the effectiveness of related interventions for a range of conditions, into one accessible document.

Assessing and comparing the effectiveness of different approaches to dealing with a particular problem is clearly of considerable potential importance to healthcare professionals and patients. Of note is that the same or similar interventions may sometimes be used to treat different conditions and whilst an overview of this evidence is likely to be of only limited interest to clinicians or consumers, such an overview can, however, be of considerable interest to policy-makers, basic scientists and technical developers as well as academics working in related areas.

Such overviews of the high quality evidence are now routinely being undertaken by a range of commercial (eg Clinical Evidence), professional (eg the British Thoracic Society and Scottish Intercollegiate Guideline Network Asthma Guideline), and regulatory bodies (eg the National Institute for Health and Clinical Excellence (NICE)).<sup>12</sup> We sought to draw upon and build on the approaches that have been developed by such organisations.

### **2.2.2 DETAILING THE SCOPE AND FOCI OF THE REVIEW AND MAPPING THE AVAILABLE EVIDENCE**

Getting the question(s) “right” is critical to the success of any systematic review process.<sup>13</sup> In the present case, whilst the review question was clearly formulated by the commissioner of our work, this was very broad. The mapping exercise described below was employed to guide and refine the focus of the review and assess the volume of potentially relevant literature.

In the context of reviews of the effectiveness of interventions, there is general agreement that a well formulated question involves the following key components: (1) participants who are the focus of the interventions (in our case both clinicians as users of eHealth applications and patients as those for whom these applications are being used by clinicians); (2) the interventions; and (3) the outcomes.<sup>13</sup> As our review was also concerned with the factors that influence the design, implementation and use of technological interventions, our question included components related to (4) the context in which the intervention was developed and implemented (see Chapter 1).

Shortly after the commissioning of this report, a systematic review was published investigating the impact of IT on the quality, efficiency and costs of healthcare. This was commissioned by the US Agency for Healthcare Research and Quality (AHRQ) and undertaken by Southern California Evidence-based Practice Center, Santa Monica, CA and the RAND Corporation.<sup>14</sup>

Their searches covered the time period (January 1995 to January 2004) and involved systematically searching MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Abstracts of Reviews of Effects, and the Periodical Abstracts Database. These searches yielded a total of 257 eligible studies, which were then synthesised qualitatively (see Box 2.1 for key findings).

**Box 2.1: Key findings from the Agency for Healthcare Research and Quality 's report**

- IT has been shown to improve quality by increasing adherence to guidelines, enhancing disease surveillance, and decreasing medication errors.
- Much of the evidence on quality improvement relates to primary and secondary preventive care.
- The major demonstrated efficiency benefit has been decreased utilisation of healthcare.
- Evidence of the impact of these technologies on the professional time is inconclusive.
- There are only limited data on the cost-effectiveness of eHealth interventions.
- Most of the high quality evidence on eHealth applications comes from four benchmark research institutions.
- Little evidence is available on the effectiveness of multi-functional commercially developed systems.
- There is scant evidence available on interoperability and consumer health informatics.
- A major shortcoming of the evidence is its limited generalisability.

*Adapted from reference No. 14.*

This AHRQ review necessitated a need to reconsider the scope of our proposed review as there was little point in simply duplicating this work. This issue was raised with our External Steering Group (comprising of representatives of the funders and independent expert advisors) and based on the advice received, we re-focused our efforts to expand and update this review, but also to frame the findings within a relevant theoretical framework to aid interpretation and assessment of the generalisability of findings. As the AHRQ report did not cover the dimension of patient safety or implementation issues, we retained our focus on these issues.

The field of eHealth spans a vast and complex range of applications, technologies and issues for implementation. An important component of our formative work has been the development and refinement of conceptual frameworks, as an aid to managing and meaningfully interpreting the relevant literature. A key objective of this exercise has been to triangulate the health informatics topic areas with the particular needs and concerns of NHS Connecting for Health (NHS CFH). As noted in the commissioning brief, patient safety considerations are

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often overlooked in the development and implementation of IT in healthcare. This aspect of our work built on the eHealth model developed by our team (Pagliari C, unpublished work) and involved identifying and synthesising existing frameworks for understanding dimensions of quality and patient safety taxonomies, including that developed by the World Health Organization,<sup>15</sup> to develop a framework to understand the interplay between eHealth applications of particular relevance to NHS CFH, quality and patient safety. This represented a helpful conceptual framework within which to organise thinking when considering development, deployment and commissioning of IT in healthcare applications. Based on this initial mapping of these fields, we were able to refine the scope of the review. For more details of the considerations that have informed this planning phase, please see Chapters 3 and 4.

Whilst mapping the fields of eHealth, quality and safety, it became clear that as these are areas still undergoing significant conceptual and technical development. For instance, there are major problems with the indexing of this literature in the major biomedical databases. Identifying the relevant literature therefore necessitated a considerable amount of developmental work to identify relevant MeSH and free text terms. This paid dividends though, in that it enabled us to identify a considerable body of relevant literature that was overlooked by the AHRQ review. This vast body of literature proved too voluminous to review within the context of this time and resource limited project. It will nonetheless be collated in our planned *NHS Connecting for Health Database of eHealth Studies* which we hope in due course to make available to interested parties through the Internet.

Cognisant of the key areas of interest to NHS CFH's National Programme for Information Technology (NPfIT), we focused in this initial phase of work on issues that are of particular interest to the Programme. These related to the storing, managing and sharing of data, tools to support professional decision-making and the cross-cutting issue of how to develop and implement technological interventions so as to maximise the chances that they will be successfully used. (Other important areas such as consumer informatics, telemonitoring and eLearning will be considered in the context of planned future work).

Our interest was not only on what works, but also on why things work or conversely, do not work. We thus also explored the attributes of effectiveness of interventions and critical features for success of an intervention. In addition, we sought to understand how this varies according to context.

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## 2.3 SEARCH METHODS FOR IDENTIFICATION OF EVIDENCE

The search strategy and subsequent decisions about inclusion and exclusion of studies needs to be tailored according to the review questions, so it was important that the questions were clearly articulated. Despite having well defined areas (see Section 2.4.3), searching the literature proved highly complex and laborious. This resulted from the inherent immaturity of these disciplines relative to others, the resultant flux that these disciplines are currently in and the poorly developed indexing of core concepts and technologies. Inevitably, however, the comprehensiveness, sensitivity and specificity of any search strategy for complex overviews of this kind have to be influenced by pragmatic considerations such as the time and resources available for the project.

While overviews of reviews use different methods from systematic reviews in the sense that they summarise existing reviews rather than find and collate original studies, our search strategy was developed in the same fashion as a search strategy for a systematic review. Our focus was on identifying SRs, whether exclusively of RCTs or also including studies employing other designs—technical reports and health technology assessments (HTAs) as well as RCTs. These have, together with other potentially relevant papers from our personal databases and incidentally identified studies, been logged within our Database.

### 2.3.1 TIME PERIOD

Although computer applications in medicine have existed since the 1960s the eHealth field, as we know it today, has emerged relatively recently and has been characterised by considerable change over recent years. For this reason, we confined our searches to the period 1997–2007. It was considered likely that information on major historical considerations and seminal studies conducted before this time period would have been identified by SRs appearing in this timeframe, thereby allowing a deeper awareness of the evolution of the field to emerge. Also of relevance was that a large amount of information from 1993 to the start of the time period of interest would have been captured in our earlier report on eHealth.<sup>10</sup>

### 2.3.2 SENSITIVITY AND SPECIFICITY

There is a tension between sensitivity and specificity in any search strategy and especially in one that addresses a broad question. A sensitive search strategy identifies all relevant information, whereas one that is specific ensures that only articles of relevance are captured. Sensitivity and specificity are influenced by a number of factors, these including: the time period covered; the search terms

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used; and the combination in which these are used. There is thus a trade-off between conducting an exhaustive search (with the additional resources that this requires) and undertaking a search that may miss some studies, but is unlikely to alter the overall strength of the evidence or findings.<sup>12</sup> Given concern that previous reviews may have missed large amounts of relevant literature, we decided, as agreed with our External Steering Group, to develop a highly sensitive search strategy because, even if it was not possible to review all the relevant material identified in the course of this project, the identification of this literature would nonetheless represent an important resource to the wider academic community.

Our experiences and those of others<sup>2</sup> reveal that quality improvement research, particularly if related to enhancing safety, is poorly indexed within bibliographic databases; as a result, broad search strategies using free text and allied MeSH headings needed to be used. We built on taxonomies we developed for our recent reviews, these including MeSH headings such as: Equipment Safety; Information Systems (all sets, ie Hospital, Clinical Laboratory, Clinical Pharmacy, Operating Room, Ambulatory Care); Medical Informatics; Public Health Informatics; Clinical Informatics; Decision Support; and Decision Aids. Other search terms included, Electronic Clinical Communication, Medical Computing and Medical Records Systems. These were then appropriately combined with terms that focused searches on Quality of Healthcare, Safety and Errors.

We started our search using MEDLINE, which is considered the best starting point to “get into” the literature.<sup>11</sup> An initial list of MeSH terms was compiled by our multi-disciplinary team relevant to the eHealth, quality and patient safety fields. These terms were extracted from:

- personal databases of relevant published literature already available from our teams previous work
- the AHRQ’s search strategy<sup>16</sup>
- an in-depth manual MeSH tree exploration by two researchers (TB & AB with input from JC, CP and the rest of the team); possible relevant terms were explored with regard to their potential relevance by reading the scope note which describes the MeSH term
- the keyword or index terms listings in our Reference Manager 11 (RefMan) database of SRs in the fields of eHealth, quality, patient safety, and organisational and implementation issues.

The individual MeSH terms were independently scored by two reviewers (AB & TB) according to the contribution these made to the “netting” of the references



related to the key objectives of our project, this contribution being assessed using a scoring algorithm (Table 2.1). Consensus was achieved by involving a third researcher (JC) and the resultant file of relevant MeSH terms was then circulated for comments and discussion to all other members of the team.

Table 2.1: Scoring algorithm for subjective exercise of scoring eHealth Medical Subject Heading terms possibly relevant for our project	
Score	Scope note
1	Stand alone MeSH term (not necessary to combine it with other terms) of high priority for the project
2	MeSH term requires combining with other MeSH or free text terms to result in high priority for the project
3	Combining MeSH term with other MeSH or free text terms still results in Low priority for the project
4	MeSH term falls outside of project scope or remit (to exclude)

Whilst searching for relevant literature using MeSH terms we realised that most of the eHealth field is also poorly indexed in bibliographic databases. We therefore considered it important to also devise a comprehensive list of free text terms so as to maximise the sensitivity of our search.

In order to create a broad, comprehensive list of free text terms to identify as much as possible of the relevant literature, two researchers (TB & AB) extracted potential free text terms from:

- our existing database of systematic reviews
- online glossaries
- webpages relating to patient safety and or eHealth (eg NHS CFH, National Patient Safety Agency, AHRQ and the Virginia National Centre for Patient Safety).

In addition, members of the team added terms which they considered to be important based on their own previous research experiences. Finally, free text terms were circulated for comments and discussion.

### 2.3.3 DATABASES SEARCHED

We searched the following eight electronic databases:

- MEDLINE (from 1 January 1997 to 3 May 2007)
- EMBASE (from 1 January 1997 to 8 May 2007)
- The Cochrane Database of Systematic Reviews (from 1997 to August 2007)
- Database of Abstracts of Reviews of Effects (from 1997 to August 2007)



- The Cochrane Central Register of Controlled Trials (from 1997 to August 2007)
- The Cochrane Methodology Register (from 1997 to August 2007)
- Health Technology Assessment Database (from 1997 to August 2007)
- NHS Economic Evaluation (from 1997 to August 2007).

We also searched databases of research in progress or unpublished work:

- The National Research Register
- ClinicalTrials.gov (<http://clinicaltrials.gov>)
- Current Controlled Trials (<http://www.controlled-trials.com>).

In order to make our search strategy sufficiently sensitive to avoid missing any high quality evidence we used the Boolean operator 'OR' between all relevant MeSH and free text terms relating to eHealth. We also did this with relevant quality, safety, organisational and implementation terms. In the final stage, we combined those two searches with Boolean operator 'AND' (IT search strategy 'AND' patient safety and quality, organisational and implementation issues search strategy). Although this approach inevitably yielded a large number of articles that ultimately proved irrelevant, this formative phase allowed us to develop a highly sensitive search strategy that helped to overcome a key limitation that systematic reviewers have hitherto faced, ie suboptimal indexing of papers on eHealth. Appendix 1 details our final search strategy.

## 2.4 CRITERIA FOR CONSIDERING REVIEWS

### 2.4.1 TYPES OF STUDIES

Systematic reviews, health technology assessments and RCTs were the main study designs of interest. We did, however, also draw on studies using other study designs such as descriptive or qualitative studies to understand broader contextual considerations, particularly in relation to assessing the acceptability of interventions.

### 2.4.2 TYPES OF PARTICIPANTS

In keeping with the commissioning brief, we were interested in reviews focused on reports of studies evaluating the impact of IT used by any type of a healthcare professional (eg doctor and nurse) or allied professional (eg receptionists and administrators). Reviews that reported studies focusing exclusively on the use of IT by patients and or their carers were not eligible for inclusion.

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### 2.4.3 TYPES OF INTERVENTIONS

To be eligible for inclusion, studies needed to address eHealth applications. We therefore included studies assessing the following interventions:

- use of computers in information exchange
- electronic health records
- computer-based history taking systems
- electronic booking systems and electronic referral systems
- computerised decision support systems
- artificial intelligence in healthcare (relevant to computerised decision support systems)
- computerised reminders in clinical practice
- computer-aided detection or diagnosis in medical imaging
- decision support for ePrescribing and other orders
- patient identification: bar-coding and biometric systems; biometric identification includes measuring and analysing human physical and behavioural characteristics for identification purposes (although we selected these studies their analysis has, with the agreement of the funders, not been undertaken because of time constraints; these important areas will be reviewed in the context of a project extension)
- human factors related to computing in healthcare.

In addition, studies needed to address at least one of the following: impact on safety; quality; or organisational, implementation or adoption considerations. Consequently, although studies aiming to describe the trends in the literature informed our work they were excluded as they did not assess impact on the parameters of interest to the report.

Although within the broad field of eHealth, we excluded reports that were outside the focus of the commissioning brief, these including studies of:

- computer-assisted and any other type of IT enhanced surgery
- computer-assisted therapy predominantly directed at or used by patients independently or under supervision of a healthcare professional (eg smoking cessation, cognitive behaviour therapy<sup>17</sup>)
- telemedicine<sup>18</sup>
- eLearning (the use of electronic technology and media to deliver, support and enhance learning and teaching)<sup>19</sup>
- consumer health informatics (patient-oriented eHealth)
- information literacy<sup>20–22</sup>
- point-of-care testing without CDSS or with CDSS directed at patients.<sup>23</sup>
- public health surveillance systems<sup>24</sup>

- references not having an a priori IT focus or objective but that reported on IT post retrieval of references<sup>25;26</sup>

We subsequently found that many studies employed systematic review methodology to simply describe the past and or current state of the literature for medical or health informatics in general,<sup>27</sup> or in particular geographical setting<sup>28</sup> or describe eHealth applications for a particular clinical domain without assessing patient, practitioner or organisational impact.<sup>29;30</sup> Similarly, we found a number of studies using systematic review methodology to assess study quality,<sup>31;32</sup> such as use and validity of outcome measurement,<sup>33</sup> validity of economic analysis<sup>34;35</sup> or appropriate use of statistical analysis.<sup>36</sup> We found that systematic reviews had also been conducted to provide a taxonomic description of a particular eHealth application<sup>37-39</sup> such as who is using a the application<sup>40</sup> or how language regarding a field is being used.<sup>41</sup> Some systematic reviews did not provide sufficient information on included studies to determine relevance.<sup>42;43</sup> Finally, some highly relevant literature reviews had to be excluded from data abstraction and critical appraisal due to one or more inclusion criteria not being met.<sup>44-54</sup>

#### **2.4.4 TYPES OF OUTCOMES**

The focus of this review were studies that were concerned with assessing the impact of eHealth applications on a wide range of quality of care and or patient safety indicators, as well as factors related to implementation and adoption of eHealth applications.

#### **2.5 METHODS OF THE REVIEW**

Two reviewers independently assessed the potential relevance of all titles and abstracts identified from the electronic searches (reviewers varied from database to database and included TB, MM, CU, AB, CA & JC). Full text copies of all articles judged to be potentially relevant from the titles and abstracts were retrieved. Two reviewers then independently assessed these retrieved articles for inclusion. Consensus with JC on the final list of included studies was reached, with any disagreements about particular reviews being resolved by discussion. Reference lists of included reviews were manually searched by AB and CA.

Two reviewers (MM & CU with input from TB and JC) independently reviewed titles and abstracts when needed and sorted articles that met inclusion criteria into following groups:

- SRs and or meta-analyses
- RCTs
- other study designs such as technical reports and HTAs.

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## **2.6 CRITERIA FOR CONSIDERING ARTICLES FOR THIS REVIEW**

In the process of search strategy development we considered a number of different methodological filters exploring the types of studies these yielded and the volume of this literature, eg the Cochrane Effective Practice and Organisation of Care Group filter. In the end, we decided that filters produced by SIGN<sup>55</sup> for SRs and RCTs gave the best balance between sensitivity and specificity. Using these filters, we also uncovered a number of studies using other designs and these were categorised as described above. Although we did not apply any language restrictions to electronic searches, we did not undertake critical appraisal or data extraction on studies not published in English. Similarly critical appraisal and data extraction were not performed on HTAs.

### **2.6.1 SELECTION CRITERIA FOR SYSTEMATIC REVIEWS**

In order to select relevant SRs we applied methodological filters for SRs devised by the SIGN.<sup>55</sup> This approach has been validated and is used in the development of a number of evidence-based guidelines (see Appendix 1 for methodology filters).

In order to be considered a SR, the publication needed to:

- explicitly state that the publication is a SR in the title or text; or
- search the literature in a systematic way in order to answer one or more clear questions or describe a given topic; and
- apply inclusion and or exclusion criteria or perform quality assessment

### **2.6.2 SELECTION CRITERIA FOR RANDOMISED CONTROLLED TRIALS**

In order to be considered a RCT, the publication needed to state that it was a randomised controlled study (with or without blinding) or this should have been clearly evident from the description of methods.

## **2.7 QUALITY ASSESSMENT**

We reviewed a range of quality assessment tools, but found that these were all less than ideal for our purposes, the specific issues of relevance being the narrow range of methodological approaches being considered and the failure to pay sufficient attention to contextual considerations. We therefore adapted available instruments<sup>56</sup> to produce an instrument that was suitable for assessment of SRs of eHealth (see Appendix 2) and this was then used to assess the methodological quality of all included SRs. The quality of all eligible studies was assessed by the three independent reviewers (AB, CA & UNN).

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## 2.8 DATA EXTRACTION

We developed a customised data extraction form to meet our specific needs (see Appendix 3). Where appropriate, quantitative and qualitative data were extracted from the references identified, however, in view of the breadth of literature to be summarised and the limited timescale of the project, this took the form of descriptions of the results of secondary research, eg SRs of the effectiveness or cost-effectiveness of computerised decision support systems or key trials rather than attempts to combine the results of individual studies for statistical analysis.

## 2.9 SYNTHESIS AND INTERPRETATION OF IDENTIFIED QUALITY AND SAFETY, INTRODUCTION, IMPLEMENTATION AND SUSTAINABILITY ISSUES AND FEATURES OF EHEALTH SYSTEMS INTO CONCEPTUAL FRAMEWORKS

Multiple factors may combine to influence the success of eHealth applications and for this reason such interventions can be difficult to evaluate.<sup>57</sup> While compiling available evidence, we aimed to explore the frontiers of knowledge on quality and safety of eHealth applications by evaluating functional capabilities and characteristics of eHealth solutions according to evidence from studies. Where possible though, we also used information from computer simulation<sup>58</sup> and conceptual models<sup>59</sup> that assessed the effects that could be expected from each capability in the proposed clinical environment.<sup>60–62</sup> This additional consideration of conceptual models was important as we know that reporting of errors in healthcare is poor<sup>63</sup> and many may conceivably be envisaged to happen even if not reported. Therefore, throughout the process of collection of evidence we aimed to identify (and build new where non-existent) conceptual frameworks for evaluating eHealth solutions based on their functional capabilities, functional characteristics and simulations.<sup>64–66</sup> We commented on the relevance of the evidence-base within the specific context of the NHS<sup>67</sup> aiming to incorporate findings, wherever possible, into an appreciation of the skills, knowledge, experience, attitudes and values of people (clinicians, healthcare managers, leaders, and patients); as well as the characteristics of tools (such as adaptiveness), environmental factors, tasks, goals and their inter-relationships.<sup>68</sup>

Importantly, we reported the evidence that is mounting about features that are independent predictors of improved clinical practice<sup>69;70</sup> and predictors of successful implementation.<sup>70–75</sup> For example, flexibility in incorporating information from diverse sources and adaptability to varied practice settings

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are likely to be the quality criteria by which computerised decision support systems are judged in the future.<sup>76</sup> We also aimed to consider broader factors, for example, whether external incentives are being used sufficiently in promotion of eHealth innovations.<sup>77</sup>

Our multi-disciplinary group, representing the disciplines of clinical care, informatics, patient safety, epidemiology, social science, psychology, medical education and health policy, sought, in regular Project Steering Group meetings, to engage with the data being generated and to contextualise the findings within broader considerations relating to healthcare systems' reforms, developing technologies and policy deliberations on ways of encouraging professionals to embrace innovations to improve the quality and safety of primary and secondary medical care.

We followed three main steps in conducting a narrative synthesis of these data: (1) developing a preliminary synthesis of the findings of included studies; (2) exploring relationships in the findings; and (3) assessing the robustness of the synthesis produced.<sup>7</sup> Depending on the findings from this last step, we would, if necessary, undertake further searches for evidence as described above. We aimed as far as possible for transparency<sup>78</sup> in this essentially qualitative approach to seeking "saturation" in finding new evidence or new dimensions to evidence.

In evaluating the overall strength of evidence, we considered the World Health Organization's Health Evidence Network (HEN) system for public health evidence<sup>79</sup> (adapted from Greenhalgh et al.).<sup>80</sup> This classifies evidence as:

- strong: consistent, good quality, plentiful or generalisable
- moderate: consistent and good quality
- limited to none: inconsistent or of poor quality.

Further, we judged key elements defined by the AHRQ in rating the strength of findings on the basis of considerations relating to:

- quality: the aggregate of quality ratings for individual studies, predicated on the extent to which bias was minimised
- quantity: number of studies, sample size or power, and magnitude of effect
- consistency: for any given topic, the extent to which similar findings are reported using similar and different study designs.

This classifying of the strength of evidence is presented in the Executive Summary.

While covering a vast territory of eHealth, we selected and developed exemplary case studies to develop a far richer, more context specific account of



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evidence in relation to key technologies and issues that have the potential to be of particular interest to NHS CFH (Chapters 9, 11 and 14). These, between them, clearly demonstrate the need for both theoretical understanding and empirical evidence to guide decision-making in relation to policy and practice.

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## CHAPTER 3

# NHS Connecting for Health and the National Programme for Information Technology

### SUMMARY

- The National Programme for Information Technology is the most comprehensive, ambitious and expensive eHealth-based overhaul of healthcare delivery ever undertaken.
- It is a transformation programme for the NHS that underpins system reform; it is thus, about far more than the implementation of information technology.
- This Programme has its origins in the 1998 Department of Health strategy *Information for Health*, which committed the NHS to lifelong electronic health records for everyone with round-the-clock, on-line access to patient records and information about best clinical practice for all NHS clinicians.
- Officially launched in 2002, the Programme is a 10-year initiative aiming initially to create the infrastructure, tools and environment through which it is possible to deliver:
  - a longitudinal electronic patient record (from “cradle to grave”) accessible to multiple users throughout the NHS; this (ie NHS Care Records Service) together with the dedicated National Network for the NHS (N3) and the national database on which these records will be held (the Spine); represents the backbone to the Programme
  - a service through which prescriptions can be transferred electronically from general practitioners and other prescribers to pharmacists (Electronic Prescriptions Service) and which will in time integrate with the NHS Care Records Service (Electronic Transmission of Prescriptions)
  - An electronic appointment booking service enabling general practitioners to electronically book hospital appointments (Choose and Book).
- The Programme has, however, subsequently been expanded to include amongst other things:
  - Picture Archiving and Communication System

- 
- GP2GP, which is a system that enables electronic transfer of patient records between GP practices when patients change their practice
  - Quality Management Analysis System, which automates assessment of GP practice performance against criteria included in the new GP contract.
  - Whilst these represent the headline deliverables of the Programme, our scoping of the field has identified a number of other related eHealth projects or applications, which, although officially fall within the remit of the National Knowledge Service (such as ePrescribing and computerised decision support tools), are also within the broad remit of NHS Connecting for Health and are therefore also closely inter-connected with the delivery of the Programme.
  - Originally managed directly by the Department of Health, oversight of the Programme transferred in 2005 to a newly created arm's length body, namely NHS Connecting for Health.
  - Foremost amongst the roles of NHS Connecting for Health is responsibility to nationally procure systems and services that will be needed to ensure delivery of the national Programme.
  - Given the extremely high level of public expenditure, the Programme has and continues to attract considerable public, professional, legal, financial, political and international scrutiny.
    - It is thus probably no exaggeration to say that in addition to it being the most comprehensive, ambitious and expensive eHealth reform programme in the world, it is also the most influential in that its success or failure is likely to have major domestic and international ripples for many years to come.

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### 3.1 INTRODUCTION

The National Programme for Information Technology (NPfIT) is the most ambitious and expensive IT-based overhaul of a health service ever undertaken. In this chapter we aim to give an overview of Programme currently being delivered by NHS Connecting for Health (NHS CFH). To this end, we describe the key applications that NHS CFH is implementing and the structures that have been created to deliver these. Evidence of the impact of those on quality and safety of care and how they can be best implemented is discussed in later chapters in this report (Section 3).

### 3.2 NHS CONNECTING FOR HEALTH

Currently, there are over 5,000 different computer systems in the NHS in England of variable quality and age; there is furthermore no national means to efficiently, securely and confidentially transfer healthcare information between different NHS locations.<sup>1</sup>

In July 2004, following the Review of its *Arms Length Bodies*,<sup>2</sup> the Department of Health (DH) announced the creation of a new organisation, combining responsibility for the delivery of the NPfIT with the management of the IT-related functions of the NHS Information Authority (NHSIA), which had previously been ear-marked for closure. The newly created organisation NHS CFH thus originally had and continues to retain, within its remit the national procurement of critical IT healthcare systems and then ensuring the maintenance, development and effective delivery of these IT products and services. (A more detailed background to the history of NHS CFH is available from their website).<sup>3</sup> Thus, whilst the core aim of NHS CFH is delivering NPfIT, it is also responsible for delivering a number of other programmes of work that were previously under NHSIA (see Box 3.1).

Established in April 2005 as the national IT procurer for the health service, NHS CFH is charged with providing integrated IT infrastructure and systems for the NHS in England.<sup>4</sup> It is, for example, responsible for electronically connecting 1.3 million NHS staff (of whom over 100,000 are doctors, 390,000 nurses and 120,000 other healthcare professionals) and giving patients access to their personal healthcare information. This body is thus, in a very real sense, laying the foundations to transform the way the NHS works.

NHS CFH also provides the policy focus for the DH on IT considerations for the NHS. This includes shaping the strategic infrastructure to ensure integration where necessary and, where choices are available, setting the standards required for local IT applications. This is made clear on NHS CFH's website, which



states that: ‘NHS Connecting for Health operates through a mixed economy of staff drawn from across the NHS, civil service, academia and the private sector. It utilises this rich diversity of experience—encompassing management, IT, clinical and medical skills—to deliver the National Programme and thus improve services to patients.’

### Box 3.1: NHS Connecting for Health’s work various programmes of activities

With the exception of NPfIT, other activities were previously delivered by the NHSIA until its closure in 2004. For more information on each of those see NHS CFH’s website:<sup>1</sup>

- NPfIT (main activity)
- Programme and Service Governance Office
- Business Case Support
- Data and Information Standards Programme
- National Clinical Classification Service
- National Administrative Codes Service
- Information Governance
- NHS Terminology Service
- NHS Security Team
- NSF Delivery
- GP Support Delivery – PRIMIS
- Health Informatics
- Faculty Development
- Health Informatics Specialists
- European Computer Driving Licence (ECDL)
- National electronic Library for Health (NeLH)
- Directory of Services
- Managed Message Handling Service
- NHSnet and bandwidth
- Pathology Messaging
- NHS Mail and Directory Service
- NHAIS
- NHS-Wide Clearing Service (NWCS)
- National Strategic Tracing Service (NSTS)
- NHS Numbers for Babies - Service (NN4B)
- NHS Central Register – Service
- Contact Centre
- Service Delivery NHS Support
- Morbidity Query Extract Service (MIQUEST)
- NHAIS Hosted Services
- Tracking Database
- Strategic Studies Team
- Systems Accreditation Testing
- National Business Requirements and Support
- Model Communities
- Communications and Messaging
- Information Standards Board
- National Enterprise Agreements

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### 3.3 BACKGROUND TO THE NATIONAL PROGRAMME FOR INFORMATION TECHNOLOGY

The Programme has its origins in the 1998 Department of Health strategy *Information for Health*,<sup>5</sup> which committed the NHS to lifelong electronic health records (EHRs), ensuring round-the-clock on-line access to patient records, and information to support best clinical practice for all healthcare professionals working within the NHS.

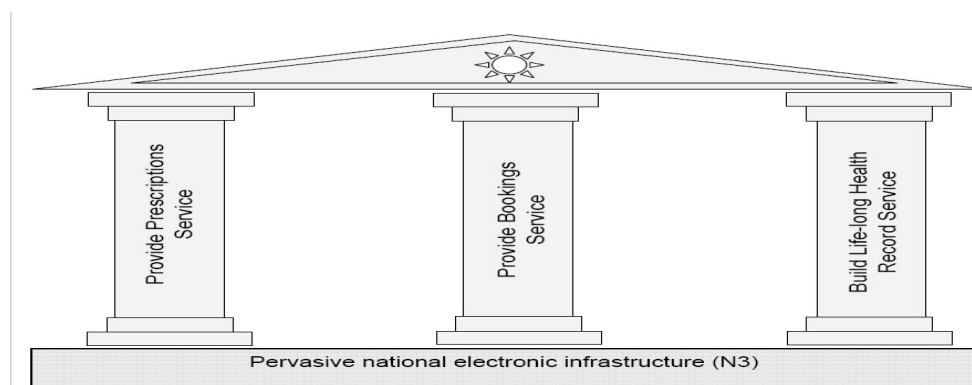
Following the development and publication of the *NHS Plan*,<sup>6</sup> a more detailed supporting document, *Building the Information Core: Implementing the NHS Plan*,<sup>7</sup> published in January 2001, outlined the information and IT systems needed to deliver the NHS Plan and support patient-centred care and services.

In March 2001, Derek Wanless, a commissioner with the Statistics Commission was asked to examine future trends affecting the health service in the UK over the next two decades. The *Wanless Report*,<sup>8</sup> published in April 2002, had several key recommendations for IT in the NHS. These included: a doubling and ring-fencing of IT spending; stringent, centrally-managed national standards for data and IT; and better management of IT implementation in the NHS, including a national programme.

The *Wanless Report* coincided with the publication of *Delivering the NHS Plan*,<sup>9</sup> which developed the vision of ‘...a service designed around the patient’, offering more choice of where and when they accessed treatment.

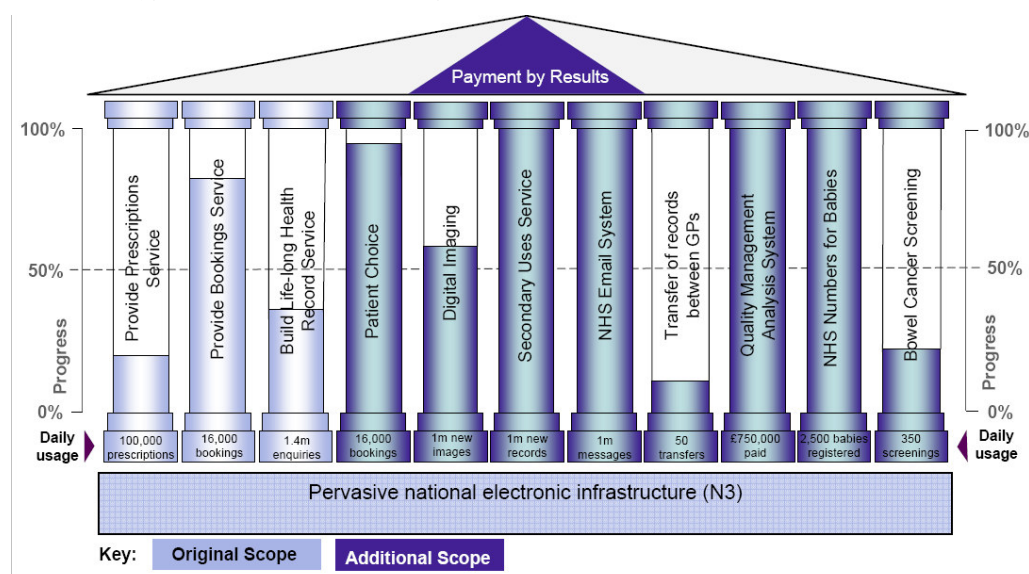
In June 2002, following the *Wanless Report* and *Delivering the NHS Plan*, the Department of Health published its new strategy for developing IT in the NHS *Delivering 21st Century IT Support for the NHS – A National Strategic Programme*.<sup>10</sup> This strategy laid out the first steps for the Programme, including the creation of a ministerial taskforce and the recruitment of a Director General for the NPfIT. Formally established in October 2002, it had a mandate to centrally control specification, procurement, resource management, performance management and delivery of the IT agenda and implement modern, integrated IT infrastructure and systems for all NHS organisations in England by 2010. The original scope is presented in Figure 3.1. The significantly expanded scope is in contrast presented in 3.2.

**Figure 3.1: Original scope for the National Programme for Information Technology in 2002.**



Source: *Connecting For Health (2007)*<sup>1</sup> Reprinted with permission from NHS Connecting for Health. Crown copyright.

**Figure 3.2: NHS Connecting for Health and National Programme for Information Technology overview in February 2007.**



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### 3.4 PROGRAMME SCOPE, FUNCTION AND KEY ACTIVITIES

The NPfIT's (and NHS CFH's) scope continues to evolve, as does the terminology associated with it, such that it is difficult for an outside observer (or indeed those “inside” the organisation) to have a full picture of the Programme's activities. Broadly, it comprises clinical change, clinical systems, and the underlying infrastructure for the NHS in England, which currently serves a population of over 50 million.

A key aim of the NPfIT is to support clinicians in providing care by giving them better access to patient information and supporting them in decision-making whenever and wherever this support is needed. The Programme is an essential element in delivering the NHS Plan<sup>6</sup> as it is creating the infrastructure that it is hoped will facilitate improved patient care by enabling clinicians and other NHS staff to increase the efficiency, effectiveness and safety of healthcare provision. As presented in Figure 3.1, the core original deliverables of the Programme are:

- An electronic NHS Care Records Service (NHS CRS) that aims to improve the sharing of patients' records, with their consent, across the NHS; beginning with the limited rollout of a Summary Care Record (SCR), this will then also extend to a Detailed Care Record (DCR). An essential component of NHS CRS is the Spine—a central storage and communication service for records that also supports other core systems and services, including Choose and Book and the electronic prescription service.
- An electronic prescription service (EPS), this being implemented through the Electronic Transmission of Prescriptions (ETP) programme, which allows for the transmission of prescriptions from GPs and other prescribers to pharmacies. Prescriptions are also sent electronically to the Prescription Pricing Authority, the organisation that reimburses dispensers, ie community pharmacies for the medication they have supplied to patients.
- An electronic booking service, Choose and Book, which aims to make it easier and faster to book convenient and accessible hospital appointments for patients.
- A National Network for the NHS (N3)—the largest virtual private network (VPN) in Europe—and will provides the IT infrastructure to meet NHS needs now, and in the future, with fast, reliable, high-bandwidth connectivity.

As noted above, this original list of deliverables has, however, expanded and currently includes the following:

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- GP2GP, which is a system designed to allow direct secure transfer of patient records between GPs when patients change practice.
  - The Quality Management and Analysis System (QMAS) collects data on quality of care provided by general practices, measured against national Quality and Outcomes Framework targets described in the Revisions to the General Medical Services Contract.<sup>11</sup>
  - HealthSpace has been developed with a wide scope including support of Choose and Book. This is a secure online personal health organiser, which is accessible to anyone aged over 16 and living in England.
  - Picture Archiving and Communications Systems (PACS), which enables images such as x-rays and scans to be stored electronically and then viewed through any computer or screen linked to the PACS system.
  - NHSmail provides an email service for NHS staff accessible using web browsers or commonly used email clients.
  - A linked Directory Service contains details of all NHS staff, including a user interface to facilitate searching for people and browsing of the NHS organisational structure. Directory and NHSmail services also have an integrated outbound fax service and outbound short message service (SMS).

The Programme involves major clinical and operational changes as part of systems implementation. Realising the full potential of the Programme thus also requires a focus on the human elements of change and its impact on those who will actually use the new technology. The Programme should thus provide support to the NHS to help it to:

- Realise the benefits and achieve real performance improvement through synergy with other change programmes and system reform, using the Integrated Service Improvement Programme (ISIP) framework.
- Enable local change through education, training and development.
- Optimise the use of technology to manage knowledge and information to improve care and treatment, safety and clinical governance.
- Design processes to improve patient, clinician and managerial satisfaction.
- Help patients and clinicians make best use of new processes, systems and knowledge.
- Actively contribute to system development and implementation activities.

Below we consider in more detail some of the above described core deliverables of the Programme.

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### 3.4.1 NHS CARE RECORDS SERVICE

It is important to note that most English GPs and primary care providers already use (at least some form of) EHRs (see Chapter 6). Whilst useful, these records are however currently only available from local primary care providers (ie the practice with which the patient is registered). The NHS CRS in contrast aims to provide a live, interactive patient record service, which is accessible to healthcare professionals at all times, irrespective of wherever they work in the NHS.<sup>12</sup> Though still in development, an early version of a SCR system that achieved these aims has been introduced into selected ‘Early Adopter’ practices in 2007. Through the use of an electronic SCR service, clinicians can access key details from a patient’s medical record, such as allergies, current prescriptions, date of birth, and address.<sup>12</sup> The SCR is however just the first step toward what will eventually be a service to provide safe, secure access to up-to-date detailed healthcare records for every patient in England. The plan is to enable clinicians to access patients’ records securely using a Smartcard, when and where needed, via a nationally maintained information repository. Once fully implemented (projected date is 2010), the NHS CRS will function across care settings and organisations and will support planned, emergency and unscheduled care. For more detailed information on how this is likely to affect front-line NHS staff, we recommend *Guidance for the NHS about Accessing Patient Information in New and Different ways and what this Means for Patient Confidentiality*.<sup>13</sup>

While the online care record will eventually be—depending on individual access rights—available in full to dedicated NHS staff who care for the patient, patients will also for the first time have access to a summary of their healthcare records through HealthSpace. NHS CFH has developed an extensive public awareness campaign to introduce this radically new way of sharing and storing patient information to the public this involving, amongst other things, information leaflets,<sup>14;15</sup> and a patient video.<sup>16</sup> In an attempt to allay concerns regarding possible breaches of patient confidentiality, the NHS has published its commitments to maintain security of data in its *NHS Care Records Guarantee* (see Chapter 16 for a fuller discussion of these issues).<sup>17;18</sup>

#### *The Spine*

The Spine is the national database of key information about patients’ health and care. It forms the quintessential core of the NHS CRS, but will also support other key elements of the Programme such as C&B and ETP, each of these using the Spine’s messaging capabilities as part of their own services. The Spine is made up of the following components:



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- Personal Demographics Service (PDS), which facilitates unique linkages of patient data from a variety of sources. As the name implies, this contains patient's demographic information, including a unique NHS number, name, address and date of birth.<sup>19</sup> The PDS does not however contain any clinical data or information that may be considered particularly sensitive, such as on ethnicity or religion.
  - Personal Spine Information Service (PSIS), which is the central database containing patients' clinical records.
  - Transaction Messaging Service (TMS), which supports transfer of information between different parts of the NHS (eg in relation to C&B).
  - Secondary Uses Service (SUS), which provides timely, anonymous patient data for non-clinical care purposes. This includes public health, policy and planning and research purposes (eg monitoring trends of use of service).<sup>20</sup> SUS aims to support national initiatives, such as Payment by Results. Where possible, SUS captures data automatically through the Programme's NHS operations systems. The initial content for SUS will be person-specific, building on existing flows such as commissioning datasets, cancer waiting times, clinical audit, central returns and supporting demographic data. It has scope in the future however to include non-person-specific data such as finance, workforce and estates
  - Clinical Spine Application (CSA), which is a web-based application that will in time provide healthcare professionals with access to the NHS CRS to gain controlled access to patient information provided by the PDS and the PSIS. CSA is intended for clinicians who would not have access to local NHS CRS compliant systems to send and receive information to and from the Spine.
  - Spine Directory Service, which comprises the Spine User Directory and Spine Accredited Systems and Services, which ensure that transactions or messages are only processed from authorised users and systems. It is therefore a key component of the security of the Spine.<sup>21</sup>
  - Access Control Framework, which controls access to clinical records of patients and registers and authenticates all users storing type of relationship between healthcare professionals and patients, as well as patient preferences on information sharing (for example, whether sensitive information is restricted from sharing).

#### *National Network for the NHS*

The National Network for the NHS, better known as N3, connects all NHS



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organisations and provides the NHS's IT infrastructure, network services and broadband connectivity requirements.<sup>22</sup> The networking solutions provided by N3 are already delivering the systems and services that enable the fast, secure sharing of information, files and data between NHS sites (see Chapter 5 for further details on health information exchange and interoperability).

Fast access to up-to-date patient records, the streamlining of clinical practice and a reduction in administrative tasks are all expected from the combination of the latest networking technology and the bespoke applications of the Programme. N3 provides support for NHS organisations in implementing new services, such as the use of video conferencing for appointments with consultants. It also offers substantial savings on the cost of telephony by enabling NHS organisations to converge their voice and data networks.

As of November 2007, approximately 1.2 million NHS employees had access to the N3<sup>23</sup> with 20,917 connections to the Network. Furthermore, over 99 per cent of GP practices are now connected to N3, making this one of the largest VPNs in the world. It is estimated that N3 can, relative to previous NHSnet contracts, save the NHS £900m over seven years.<sup>24</sup>

#### **3.4.2 CHOOSE AND BOOK**

Driven by the Government's agenda to give public and patients more choice, Choose and Book has been introduced as a national electronic referral service to allow patients a choice of place, date and time for their first out-patient appointment. Patients can, if appropriate, choose a hospital or clinic, and book their appointment to see a specialist either in conjunction with a member of the practice team or, if more convenient, from home either by telephone or over the Internet.<sup>25</sup>

When a GP refers a patient to a specialist, Choose and Book helps identify relevant clinics together with details about availability. After considering individual preferences and clinical requirements, members of the primary care team can assist patients in making their appointment at the time of referral. Patients then receive confirmation of the time, date and location of their appointment. Some patients may want or need more time to consider their choices and, if so, they can take the appointment request letter away with them and book the appointment later, either online or over the phone. Choose and Book thus allows them to discuss options with family members and make any necessary arrangements before scheduling the appointment.

Choose and Book allows patients to make appointments at a convenient time and location, which will, it is hoped, result in higher patient satisfaction and

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improved attendance. Choose and Book also has a function that enables patients to cancel, reschedule or check the status of an existing appointment (through telephone or via the Internet through their personal HealthSpace website). It is anticipated that the ability to better integrate medical appointments with other commitments will contribute to improving patient outcomes.

This new initiative also has the potential to bring benefits to NHS staff. The NHS CFH website, for example, refers to the availability of a complete full directory of all the secondary care services commissioned in the primary care trust (PCT) available via the Directory of Services to GPs. Furthermore, GPs can readily see which services have the shortest waiting times. Hospital specialists also have potential gains as they are able to make available clinic specific details to GPs before referral, thereby in theory facilitating more appropriate referrals and also enabling better quality referral information.

The rollout of Choose and Book began in the summer 2004 and will continue until it is available to all patients.<sup>25</sup> As of the end of November 2007, Choose and Book was being used for over 45 per cent of NHS referral activity from GP surgery to first out-patient appointment and over 85 per cent of all GP practices had some experience of using Choose and Book to refer their patients to hospital. The system is currently being used to process approximately 100,000 referrals a week and has thus far been used for a total of over six million bookings.<sup>24</sup> Despite this volume of traffic, NHS CFH has not yet met its goal of Choose and Book being used for 90 per cent of all referrals, missing two deadlines, the most recent in March 2007.<sup>25</sup>

### **3.4.3 ePRESCRIBING**

In 2003 NPfIT commenced a stakeholder engagement and planning process in relation to perhaps one of the most important eHealth applications, namely implementation of electronic prescribing (hereafter referred to as ePrescribing) in hospitals.<sup>26</sup> ePrescribing is defined by NHS CFH as ‘. . .the utilisation of electronic systems to facilitate and enhance the communication of a prescription, aiding the choice, administration or supply of a medicine through decision support and providing a robust audit trail for the entire medicines use process.’ As defined, NHS CFH’s vision of ePrescribing clearly incorporates computerised decision support system functionality (CDSS) (see Chapters 8 and 10 for detailed discussions on electronic prescribing and CDSS).

While UK GPs have been using ePrescribing for close on two decades (with varying degree of functionality, but constantly increasing in sophistication), this has not been the case within the acute sector in the UK. Diversity of different

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clinical specialty requirements and complexity of prescribing in hospitals has often been cited as one of the major barriers to implementation.<sup>27</sup>

ePrescribing (short for electronic prescribing) is now facilitating the development of a national system that has improving the quality, effectiveness and safety of prescribing in hospital as its primary objective. ePrescribing systems will in time electronically support the entire medicines management process, beginning with choosing and then prescribing the medication, right through to administration.

ePrescribing should facilitate wider improvements in prescribing and administration processes, including reductions in paperwork, improved audit trails for medication and enhanced communication (for example, between hospital departments and pharmacies).

ePrescribing, with its built in functionalities—such as decision and knowledge support, alerts for contra-indications, allergic reactions and drug interactions, formulary guidance or management, training and guidance for prescribers, reminders, and audit trails of medication administration—represents one of NHS CFH's key activities designed to reduce risk of iatrogenic harm and thereby improve patient safety. Ultimately, the goal is to integrate it seamlessly with EHRs and other computer systems.

#### **3.4.4 ELECTRONIC TRANSMISSION OF PRESCRIPTIONS**

As described above, virtually all UK GPs are already using ePrescribing and use this technology to issue approximately 1.5 million prescriptions on each working day. Given that the annual number of prescriptions issued in England is expected to grow at about five per cent per year, it is clear why the ability to automate repeat prescribing has proven so popular with GPs.

Building on these existing primary care computer capabilities, ETP introduces important new add-on functionality. Instead of printing 'electronically prescribed' prescriptions (ie prescribed with the support of ePrescribing system), GPs will be in a position to electronically send the prescription to the dispensing pharmacist. It is expected that the new system will lead to significant time savings, especially in-so-far as it enables the more efficient processing of repeat prescriptions, which now make up about 70 per cent of all prescriptions issued. The sending of repeat prescriptions using ETP will in due course happen (semi-)automatically.

Electronic Transmission of Prescriptions forms the basis of the Electronic Prescription Service (EPS), which allows primary care prescribers to create and transmit prescriptions electronically.<sup>28</sup> These electronic prescriptions are

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received by the EPS, a secure information hub, from which they can then be downloaded by participating dispensers. True paperless prescribing will occur in a later release, when patients will be able to choose (or “nominate”) a particular dispensing contractor, ie pharmacy to automatically receive their electronic prescriptions. In time, the electronic submission of reimbursement claims by these dispensers will also be supported by the EPS system.

The EPS is being introduced in primary care settings, such as GP practices and community pharmacies, all across England, and will continue to expand to other settings in which primary care prescribing takes place.<sup>26</sup> The first iteration of the EPS, known as Release 1, which is mostly invisible to patients and end users, went live in February 2005.<sup>29</sup> Release 2 will be more prominent, and is scheduled to be deployed in two main phases: Stage one will be the ‘transition’ phase, and stage two will be the ‘full EPS’ phase. In the ‘transition’ phase, prescribers and dispensers will gradually begin replacing most paper prescriptions with electronic prescriptions. This is when EPS will really begin to demonstrate its worth, as it becomes possible for patients to nominate dispensers to receive their electronic prescriptions, and for dispensaries to electronically submit reimbursement claims. Some hand-signed FP10 prescription forms will continue to be required in this phase as only those dispensers working with nominated prescriptions will be able to accept electronically-signed prescriptions. By the ‘full EPS’ phase, most sites will be using Release 2. At this point, all within-scope prescriptions (eg controlled drugs) will be able to be sent, signed and received electronically— whether nominated or not.<sup>30</sup>

The plan is that in time, the EPS will be integrated with NHS CRS. Information on what has been prescribed and dispensed will be able to be automatically recorded in the patient’s care record. Access to more accurate (or entirely new) information about what has been prescribed and dispensed will be of great assistance to the healthcare professionals who need it (for example, a doctor in an accident and emergency department or a GP a patient visits while away from home), thus helping to improve standards of care.

As of the end of November 2007, EPS was being used for over 17 per cent of daily prescription messages. Technical upgrades to the new system had occurred at 6,959 GP practices and 7,308 pharmacy systems, and EPS was actively operating at 4,523 GP practices and 5,067 pharmacy systems. Over 50 million prescription messages had been electronically transmitted, including nearly 1.5 million in the preceding week alone.<sup>24</sup>

*Connecting for Health Evaluation Programme* has recently commissioned an

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evaluation project to evaluate the impact of the new service on quality and safety of care.<sup>31</sup>

#### **3.4.5 PICTURE ARCHIVING AND COMMUNICATIONS SYSTEMS**

Picture Archiving and Communications Systems (PACS) capture, store, distribute and display static or moving digital images such as x-rays or scans, thereby potentially enabling more efficient diagnosis and treatment. The ability to store digital images will form an essential part of every patient's electronic record, thereby removing the need to print on film and to file or distribute images manually.

These images can then be sent and viewed at one, or across several, NHS locations. This should in turn result in increased capacity of diagnostic services and should furthermore speed-up the time to diagnosis. For patients, this should also mean fewer delays, fewer wasted appointments due to lost or low quality images, and less re-testing, which in turn should reduce the total lifetime radiation dose.<sup>32</sup> Patient care also has the potential to benefit as clinicians and care teams have the ability to work together viewing common information across one or more locations. PACS has been procured to provide full access to digital images in NHS organisations throughout England.

As of the end of November 2007, there were 121 NHS CFH PACSs live across England. These systems deployments are now over 95 per cent complete and over 437 million images had been stored using these systems. PACS has been used for almost 19 million patient studies.<sup>24</sup>

#### **3.4.6 THE NHSMAIL EMAIL AND DIRECTORY SERVICE**

Historically, there have been many different local email systems operating in the NHS. The quality and reliability of these services varied substantially and they incurred substantial costs. In addition, none of the services were secure enough to allow the transmission of patient information resulting in information being sent frequently via mail or fax incurring further costs for paper, printing and postage as well as slowing down the process.

The NHSmail service was launched in October 2004 to replace these disparate email services with a standardised platform that was capable of being used for the transmission of patient information. NHSmail provides a central, secure email service, thus reducing the overall email costs to the NHS and providing a swift and secure means of exchanging information across the NHS.

The NHSmail platform is a centrally funded service that's free at the point of use, and offers a helpdesk that is available to support users 24 hours a day, seven

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days a week. It preserves patient confidentiality and is protected by both anti-virus and anti-spam software. NHSmail is the only system approved by the DH and the British Medical Association for NHS users to securely exchange patient data. NHSmail aims to improve workflow by allowing authorised users to log on from anywhere, at any time, giving them access to the NHS Directory, with contact details for over one million NHS staff. NHSmail also includes features that allow users to send free SMS and fax messages directly from the system, and to share calendars and mailboxes with other NHSmail users.<sup>33</sup>

As of the end of November 2007, NHSmail had 299,098 registered users and an average of 983,152 messages were sent or received across the NHSmail platform every day. The number of NHSmail users continues to grow, and when migration to the system is complete, they will number over one million, making NHSmail ‘. . .the largest private, fully-featured, secure, single-domain e-mail service in the world.’<sup>24</sup>

Although NHSmail is secure for transfer of confidential patient information, it is not currently being routinely used for communication by clinicians about patients. Furthermore, there are no standards for how this should happen. As the system is increasingly used by clinicians this is a logical next step in its evolution.

### **3.4.7 SUPPORT FOR PRIMARY CARE**

#### *GP Systems of Choice*

It is worth mentioning here the NHS CFH scheme through which the NHS funds the provision of GP clinical IT systems in England. GP Systems of Choice (GPSoC) allows practices and PCTs to benefit from a range of quality assured GP clinical IT systems purchased from existing suppliers who are contracted to work within the NPfIT.

Practices can choose between systems provided by their local service provider or by suppliers that are contracted to offer systems on the GPSoC Framework. GPSoC introduces standards which will improve the quality of service that practices receive from their GPSoC framework supplier.

#### *The Quality Management and Analysis System (QMAS)*

The new GMS contract was introduced in April 2004. A key component was the Quality and Outcomes Framework (QOF) of national achievement targets describing how GP practices would be rewarded financially based on their achievement in up to four domains: clinical; organisational; patient experience; and additional services.



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To support the QOF and the GMS contract, the Programme developed a single, national IT system, known as Quality Management and Analysis System (QMAS). QMAS tracks the performance of each practice, comparing it against QOF goals allowing for the fair and uniform application of financial incentives based on quality of care.<sup>34</sup> The system is also used to compute national disease prevalence rates for a range of conditions.<sup>35</sup> QMAS last underwent a major upgrade in August 2006, in support of the 2006–07 GMS contract.<sup>34</sup>

### *GP2GP*

When patients transfer from the care of one GP to another, it is clearly important that their medical records be transferred as swiftly as possible. Ensuring that medical records arrive in time for the patient's first consultation may have significant clinical benefits, as it has been estimated that not having this information could threaten the quality of care in over 50 per cent of consultations.<sup>36</sup> Using the traditional paper-based system, the transfer of patient records may take weeks or months leaving clinicians without the information they need to provide the best possible care for patients.<sup>36</sup>

GP2GP is designed to address this problem. It enables the transfer of the electronic component of a GP patient health record. When a patient registers with a new practice, GP2GP will move the patient's current EHR from their previous general practice to their new one. On receipt of the EHR, the new practice will undertake certain housekeeping activities, eg authorise current repeat prescriptions listed in the EHR, and will have the clinically important medical history in hand at the time of the patient's first consultation (see Chapter 5).<sup>36</sup> The GP2GP system includes a feature called "autosend", which allows the EHR to be sent without any action on the part of the sending GP. Not only does this cut down on the administrative cost to the sender, but it also ensures that the patient's new GP will receive the records quickly—within minutes or hours.<sup>37</sup>

The GP2GP system met its March 2007 implementation goal of achieving rollout in 500 practices<sup>38</sup> and is currently engaged in a nationwide rollout among practices meeting certain 'entry and readiness criteria'.<sup>36</sup> As of the end of November 2007, 42,059 medical records had been sent using the GP2GP system and 2,624 practices were actively using GP2GP.<sup>24</sup>

### *3.4.8 HealthSpace*

HealthSpace provides the public with a personal health organiser allowing users to record information such as weight, medications and alcohol intake. It will



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also soon allow patients in the ‘Early Adopter’ locations for the NHS CRS (see 3.4.1) to their SCRs online.<sup>39</sup>

Apart from the aforementioned NPfIT deliverables, NHS CFH is involved in a number of other work-streams and deliverables with regards to IT implementation.

### **3.5 MANAGEMENT OF NATIONAL PROGRAMME FOR INFORMATION TECHNOLOGY**

Operating through a mixed economy of staff drawn from across the NHS, civil service, academia and the private sector, NHS CFH brings together a range of expertise and experience from healthcare, IT and management. This skill-mix is needed to manage a Programme of this complexity.

Governance and accountability for the Programme operates at three levels with clear reporting lines and links to other groups. The top level of governance is provided by the DH’s Departmental Management Board. The operational management team chaired by the chief operating officer who reports to the National Programme Board manages the programme. Agencies that audit or review the Programme such as Her Majesty’s Treasury, the National Audit Office, and the Office of Government Commerce are all represented on the National Programme Board.

NHS Connecting for Health implements the key products, systems and services in planned phases by working with its suppliers and the NHS. National Application Service Providers (NASPs) are responsible for purchasing and integrating IT systems common to all users nationally. Local Service Providers (LSPs) deliver IT systems and services on a local level for five regional clusters of Strategic Health Authorities (SHAs). They supply and integrate systems to perform functions in the local setting and to interface with the national system.

### **3.6 IMPLEMENTATION, DELIVERY AND NATIONAL PROGRAMME SUPPORTING SERVICES**

The Programme is for implementation purposes divided into three geographical regions. These were created after consultation with the SHAs on how best to deliver local IT services as part of the Programme.

The LSPs work directly with NHS frontline services to deliver IT systems to support the modernisation of the NHS. The NPfIT Local Ownership Programme (NLOP) provides a critical point in bringing together the efforts of the National Application Suppliers, LSPs and NHS service organisations.

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In addition to the LSP delivery channel, some NHS CFH services are made available to users via their existing systems. Existing systems comprise both systems used within the NHS (that will ultimately be replaced by new LSP services) as well as systems such as those used by Community Pharmacy or Independent Sector providers that are not within LSP contract scope. The necessary development and upgrade of these existing systems is coordinated by the NHS CFH Existing Systems Programme.

Cluster teams co-ordinate the implementation of many thousands of IT installations designed to improve the safety, efficiency and quality of patient care. They also work with staff across the NHS to upgrade the many thousands of existing systems in support of the introduction of Choose andBook, EPS and GP2GP.

Successful implementation relies on the thousands of NHS staff working in local project teams, clinical groups or as recipients of new IT services. The Service Implementation (SI) Team (see 4.4.2) is focused on engaging with the people who will use the new technology: GPs, nurses, managers, allied health professionals, hospital doctors, booking clerks, surgeons and receptionists—in short, everyone who works in the NHS. The SI team, including a number of clinical leads, is responsible for involving key clinical communities in the design of Programme technologies and developing their understanding of what benefits they can expect in their areas of clinical practice.

Implementing such a Programme is exceptionally complex and involves widespread activities. This is even truer because the implementation of IT aims also to transform or change many clinical processes and in many respects also organisational culture. Implementation is defined by NHS CFH as ‘. . .the activities required to be carried out locally to deliver the National Programme products and services.’ It starts with local and national testing to ensure that systems satisfy defined requirements and then follows through a range of steps that aim to end with transition to “business as usual” in a new way. Key roles and implementation responsibilities are described in Box 3.2 and are supported by a detailed *Implementation Guide* and The National Standard for Implementation Framework.<sup>40</sup> The key support structures are:

- Communications and Engagement
- Service Implementation
- Office of the Chief Clinical Officer
- National Deployment Support
- The NHS CFH Central Design Authority and Technology Office.

### Box 3.2 Overview of the key roles and implementation responsibilities

- **PCTs as commissioners**, both having their own comprehensive IM&T plan, and working with all providers in their LHCs to align IM&T plans and enable patient-centric service transformation
- **SHAs**, now accountable for implementation and realisation of the benefits from the NPfIT, assuring that the local NHS has the capability and resources to deliver their plans
- **LHCs (working with SHA CIOs and NHS CFH National Programmes)** will develop the local implementation arrangements, including prioritisation, timing of system replacements and alignment of local IT strategies with the programme plan and capacity. These plans will ideally be consistent with priorities identified in the Local Delivery Plans and in ISIP plans
- **LPfIT, SPfIT and NMEPfIT Programme Directors** will be responsible for any implementation dependencies placed on LHCs by either National or Local Service Providers
- **The National Programme Service Implementation team** exists in order to support the NHS in maximising the value gained from the investment in the National Programme
- **The Integrated Service Improvement Programme (ISIP)** is aligned with the Local Delivery Planning process, providing the connection between National Programme benefits realisation and fulfilment of accountability for NHS targets
- **The central National Programme teams** provide products and services, general guidance and support. Some also provide funding for specifically agreed activities
- **The NHS CFH Deployment Support Team** will provide specialist knowledge and expertise to help organisations resolve particular deployment issues at local or more strategic levels or to transfer knowledge such that the organisation is enabled and prepared to successfully complete deployment activities
- **NHS CFH Requirements, Design, Build and Test (RDBT)** team is responsible for monitoring and assuring the planning, design and development of LSP solutions to meet the requirements and priorities of the NHS. They will also assure the delivery of LSP solutions and associated functionality to meet NHS business targets in line with agreed plans and contractual commitments.
- **National Application Service Providers** are responsible for the delivery of national applications such as the core elements of the NHS CRS, Choose and Book, EPS, GP2GP, NHSmail and SUS
- **The National Infrastructure Service Provider** is responsible for providing networking and support services (specifically the N3 facilities)
- **LSPs** are responsible for the development and implementation of a range of IT related services within the NHS Programmes for IT. These services are contractually agreed and will meet minimum national standards and requirements. The LSPs are also responsible for the development and deployment of PACS reference solutions in cooperation with their respective sub-contractors in the NHS Programmes for IT.
- **Existing System Providers** are responsible for providing compliant systems for integration and deployment within the trusts.
- **The NHS CFH Central Design Authority and Technology Office** develops and controls standards for the NHS IT systems of the future. It supports the National Programme for IT (NPfIT) and the introduction of new computer systems that deliver faster, safer and more convenient patient care in England.

*Adapted from: Connecting for Health. The National Programme for IT Implementation Guide. (2007)<sup>40</sup>*

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### **3.6.2 COMMUNICATIONS AND ENGAGEMENT TEAM**

The Communications and Engagement Team fosters dialogue between NHS CFH and the NHS as well as other stakeholders. Local NHS organisations are responsible for communication of the national Programme to NHS staff and patients and promoting their engagement. The engagement effort is divided into two parts: clinical engagement, and public engagement.<sup>41</sup> The clinical engagement effort is led by the national Communications and Engagement Team, which develops implementation strategies and supporting materials and includes National Clinical Leads that focus their respective professions (ie GPs, hospital doctors, allied health professionals and nurses) as well as the public.<sup>41</sup> The clinical leads serve as a conduit for two-way communication between clinicians and NHS CFH, and use networks to communicate with frontline clinicians and professional organisations.<sup>42</sup> The public engagement effort encompasses a variety of activities to involve the public in all stages of the health IT effort, including research, workshops and co-ordination with voluntary agencies.<sup>43</sup> The Communications and Engagement Teams exist also on the cluster level to provide a more local focus in implementation strategies.

### **3.6.3 SERVICE IMPLEMENTATION TEAM**

The SI Team is built of a leadership team and clinical leads. It works with NHS staff and developers of new IT solutions to ensure the potential of the new technology is exploited (See Box 3.3). The SI Team's work is performed in synergy with other change programmes and system reform using the Integrated Service Improvement Programme (ISIP). Team works on a number of levels ranging from local engagement and implementation activities to contribution to system development at national level. The work of the SI Team is delivered through the following work streams (of which we describe first four in more detail):

- Capability and Capacity (including the ISIP Framework)
- Education, Training and Development
- Evaluation Programme
- National Knowledge Service
- Mainstreaming IM&T Strategy Planning and Benefits
- Access Control.

### Box 3.3 The three key projects of the Service Implementation Team

#### **Knowledge, Process and Safety**

*Work-streams* 2010—The Busy Clinician, The Constant Patient, The Connected Healthcare Team;

*Deliverables*—National Knowledge Service: Map of Medicine, National Library for Health

#### **Modernisation**

*Work-streams*—Realising Benefits and Implementation; Education Training, and Development;

*Deliverables*— guidance on benefits planning, a standard set of measures, a detailed report from the five NHS Connecting for Health service implementation pilots, Frontline Connect (FLC)

#### **Communications and Engagement:**

*Work-streams*—Corporate Communications, Stakeholder Engagement (Clinical Leads), Public Engagement, Media Relations

*Deliverables*—website, communications, improved links with stakeholder and communications leads, the *Making IT Work* stakeholder newsletter, better research, a programme of meetings, a public information campaign, media visits and demonstrations for reporters.<sup>44</sup>

### 3.6.4 CAPABILITY AND CAPACITY TEAM

In April 2007, NHS CFH started transferring accountability for the delivery of the NPfIT to the 10 SHAs, as part of the NPfIT Local Ownership Programme (NLOP).<sup>45</sup> NLOP provides the NHS Chief Executives and the NHS Management Board with information and evidence about NHS CFH, SHAs and Trusts capability and capacity to deliver their new NPfIT responsibilities and accountabilities across the entire implementation plan and furthermore how to address shortage of or gaps in capability and or capacity. To achieve this goal, the Capability and Capacity Team focuses on: Organisational Readiness Assurance; Resource Modelling; Programme and Project Management Improvement; Enhancing Executive Leadership of IT enabled change; Health Informatics Development; and Evidence-based Implementation Support.

In the Capability and Capacity stream of work the ISIP is used to develop an integrated approach to service improvement planning and benefits management within the NHS.<sup>46</sup> ISIP's actions in support of these aims include the ISIP Roadmap for Transformational Change (RTC), an integrated service improvement framework; the development of standard benchmarks and measures, the definition and dissemination of good practice throughout the NHS, and the integration of the ISIP approach with NHS and Department of Health activities.<sup>46</sup>

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### *Education, Training and Development*

The ETD Team's activity is at the core of success of NPfIT.<sup>47</sup> Its mission is to '... encourage and accelerate the uptake, spread and creative use of technologies and software applications that support high-quality patient-led healthcare.'<sup>47</sup> The ETD Team supports learning and acquisition of new knowledge, attitudes and skills related to IT in healthcare through a range of activities. The ETD Team also supports professional development<sup>48</sup> and professional recognition<sup>49</sup> programmes for health IT personnel with a view to promoting quality of care provision.

### *NHS Connecting for Health Evaluation Programme*

In 2006, NHS CFH commissioned a new programme of evaluation through the Department of Health Research & Development Directorate. This is directed by Professor Richard Lilford at the University of Birmingham and aims to ensure independent research and evaluation of NHS CFH to critically ensure current best evidence for implementation of NPfIT. NHS Connecting For Health Evaluation Programme's (NHS CFHEP) functions and core tasks are described in Box 3.4.<sup>50</sup> This is an important development as research from other countries (in particular the US) has demonstrated rigorous evaluation and research into implementation is key to success of any programme of IT in healthcare.

NHS CFHEP has to date commissioned four projects (including the one that has led to the production of this report).<sup>51</sup> Other projects thus far commissioned include:

- evaluation of the 'Early Adopter' implementation of the NHS SCR
- evaluation of the pilot implementation of an IT specification for a blood tracking systems
- evaluation of the EPS in primary care.

A fifth and final call evaluating the adoption of the NHS CRS in secondary care has recently been advertised.



### Box 3.4 Functions and core tasks of NHS Connecting for Health's Evaluation Programme

- To commission, manage and bring to a successful conclusion, a programme of urgent research on behalf of National Programme for Implementing Information Technology (NPfIT) and its stakeholder communities, using its own funding.
- To influence the longer-term national research programmes to develop capacity in relevant areas and to commission related work.
- To assist the DH and Co-ordinating Centre for CRC UK in providing access to information collected on computer systems installed under NHS CFH.

These functions are to be achieved through the core tasks of the NHS CFHEP:<sup>50</sup>

- Assess the usability, actual usage, functions and impact of pilot and delivered systems and services.
- Provide informative, timely feedback to NHS CFH, contractors, Trusts and other relevant parties about what works, for whom, when and how systems can be improved.
- Disseminate important results to stakeholders in and beyond the NHS.
- Promote an evaluative culture in NHS CFH and the NHS and help build the capacity to carry out good quality evaluation studies on NHS IT.

*Adapted from: University of Birmingham. NHS Connecting for Health Evaluation Programme (2007)*<sup>50</sup>

### National Knowledge Service

Created in 2002<sup>52</sup> as a response to the *Bristol Royal Infirmary Inquiry*,<sup>52;53</sup> the National Knowledge Service was charged with the mission to ‘. . .collect, organise, and deliver knowledge where and when it is needed’<sup>52</sup> to support the safe, effective and efficient delivery of the highest quality healthcare (see Box 3.5).<sup>54</sup> The National Knowledge Service has now transferred to The NHS Institute for Innovation and Improvement.<sup>55</sup>

### Box 3.5 Work streams of National Knowledge Service

- **The National Library for Health:** Intended ‘. . .to organise the best current knowledge to ensure not only easy immediate access to the knowledge needed, but also the incorporation of best current knowledge in clinical decision tools and the workflow of the NHS’
- **The Best Current Knowledge Service:** Intended ‘. . .to ensure best current knowledge is available to meet the needs of patients, the public and NHS staff’
- **The National Clinical Decision Support Service:** Intended ‘. . .to realise the potential offered by the National Programme for IT, to deliver high quality decision aids to clinicians and patients’
- **The National Knowledge Management Network:** Intended ‘. . .to promote the spreading, sharing and implementation of best current knowledge’.<sup>56</sup>



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### *Mainstreaming IM&T Strategy Planning and Benefits*

This programme contains the NHS CFH work on benefits, key to an evaluation of eHealth in the NHS. The programme is undertaken in four work-streams:<sup>57</sup>

1. IM&T Strategy and Policy
2. IM&T Planning
3. IM&T Performance Management
4. Benefits from investment in IM&T and related service improvement

The first work-stream aims to build and strengthen top level leadership, establish capacity for defining at a strategic level the IM&T required by the NHS to support delivery of national health priorities. It also identifies products, services and standards that should be developed at a national level.

More specifically this work-stream includes a Board of senior stakeholders who provide support for the NHS Chief Executive in his role as Senior Responsible Officer for the NPfIT; strategic oversight of IM&T requirements for the NHS; and oversee and drive a refresh of the current NHS IM&T Strategy.

The second work-stream (IM&T Planning) aims to establish a framework within which NHS organisations plan implementation and benefits realisation of IM&T. This is part of the national planning cycle for achieving local business objectives and meeting national expectations.

More specifically, the second work-stream aims to align NPfIT closely with DH and NHS strategic priorities and supports detailed planning and delivery of the NHS Operating Framework. Operating Framework sets out the specific business and financial arrangements for the NHS for each year and is addressed to all NHS Chief Executives.

Importantly, this work-stream also undertakes a cost benefit appraisal and identification of preferred option for sign off by the NHS Management Board prior to any commercial re-negotiation with LSP suppliers by NHS CFH on behalf of the NHS.

The third work-stream (IM&T Performance Management) aims to establish a framework and capacity to monitor and report on NHS delivery against IM&T accountabilities, expectations and priorities, as they are set by the NHS Management Board and the annual planning cycle.

More specifically, this work-stream develops indicators of performance and deployment, it establishes process for their collection; and that from these lessons are learnt and resources re-prioritised accordingly.

The fourth work-stream (IM&T Benefits Work-stream) aims to establish, in collaboration with SHAs, a framework and programme to support, monitor and measure effective and rigorous benefits realisation from investment in IM&T

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at national and local levels. This is critical so that the NHS understands and ambitiously pursues the potential benefits enabled by implementing modern and appropriate information technology, in particular those products provided by the NPfIT, and that there is rigorous and methodical identification, measurement and realisation of benefits enabled by the deployment of information technology across the NHS.

Specifically, this work-stream includes a benefits register for National NPfIT products, linked to the NPfIT product catalogue and establishes and collects metrics for benefits directly attributable to deployment of NPfIT products.

### **3.6.5 OFFICE OF THE CHIEF CLINICAL OFFICER**

Healthcare needs to be a risk-averse industry where no compromise on safety can be tolerated. The key objective of The Office of the Chief Clinical Officer (OCCO) is to secure safety and quality, which are central to NHS CFH's activity. To meet this objective the Office's programmes of work and projects are continuously developing and include:

- **Governance of Clinicians:** work-stream to support the continued professional development of clinicians working on the Programme
- **Clinical Stakeholder Management and Clinical Communications:** work-stream to co-ordinate clinical communications with clinical, patient and public stakeholders
- **Clinical Content:** work-stream that aims to ensure clinical input into content design and implementation and provide toolkits for these activities
- **Clinical Safety:** work-stream that promotes and embeds safer working practice methods and solutions across the NHS. It makes sure that systems planned and delivered through the National Programme have been through a safety assurance process excluding or minimising risks to patients' safety. This stream of work is led by Dr Maureen Baker, the National Clinical Lead for Clinical Safety. The Clinical Safety Management System has been developed analogous to those in other safety-averse industries. This work-stream liaises closely with the National Patient Safety Agency.
- **Nursing and Midwifery:** work-stream that focuses on critically important involvement and engagement of the nursing and midwifery professions. This work-stream also advocates on behalf of nurses and midwives ensuring that they have a voice in the NPfIT.<sup>58</sup>

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#### **3.6.4 NATIONAL DEPLOYMENT SUPPORT**

The NHS CFH Deployment Support Team provides specialist focused support to NHS organisations around deployment issues related to LSP and NASP solutions. National Deployment Support is also responsible for monitoring the effectiveness of the resources provided.

#### **3.6.5 THE NHS CONNECTING FOR HEALTH CENTRAL DESIGN AUTHORITY AND TECHNOLOGY OFFICE**

The NHS CFH Central Design Authority and Technology Office develops and controls standards for NHS IT systems. In the past, IT systems were developed locally and would often differ significantly in terms of their specifications, functionality or quality. For NHS CFH, IT systems are developed for the whole NHS wherever possible on the basis of National Service Frameworks (NSFs) definitions of best care. The NHS CFH Central Design Authority and Technology Office specifies and quality assures the IT requirements in several key work areas including: testing, technical assurance, LPfIT, SPfIT and NMEPfIT Technical Architects, demographics,<sup>59</sup> NHS Data Standards and Products, NHS Terminology Service, NHS Classifications Service, NHS Data Model and Dictionary Service, National Administrative Codes Services (NACS), The Spine Directory Service (SDS), Information Quality Assurance Programme (IQAP),<sup>60</sup> and Communications and Messaging.

### **3.7 CONCLUSIONS**

As is evident from the above description, NHS CFH and its national Programme are complex ambitious endeavours that have the potential to impact on almost all aspects of NHS care provision (See Box 3.7 for more information). Whilst clearly multi-faceted, the core aspirations of this modernisation agenda relate to improving data storing and management and supporting professional decision-making. We focus on these issues in the next chapter and the potential these have to impact on the quality and safety of healthcare provision.

### Box 3.7 Key documents and websites about NHS CFH and the National Programme for IT

The NHS Plan<sup>6</sup>

[http://www.connectingforhealth.nhs.uk/resources/policyandguidance/nhs\\_plan.pdf](http://www.connectingforhealth.nhs.uk/resources/policyandguidance/nhs_plan.pdf)

Delivering the NHS Plan<sup>9</sup>

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4005818](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005818)

Building the Information Core: Implementing the NHS Plan<sup>7</sup>

[http://www.dh.gov.uk/dr\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4066946.pdf](http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4066946.pdf)

Delivering 21st century IT support for the NHS: national strategic programme<sup>10</sup>

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4008227](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008227)

Better information, better choices, better health: Putting information at the centre of health<sup>61</sup>

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4098576](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4098576)

Securing Our Future Health: Taking a Long-Term View<sup>8</sup>

[http://www.hm-treasury.gov.uk/Consultations\\_and\\_Legislation/wanless/consult\\_wanless\\_final.cfm](http://www.hm-treasury.gov.uk/Consultations_and_Legislation/wanless/consult_wanless_final.cfm)

Connecting for Health home page<sup>62</sup>

<http://www.connectingforhealth.nhs.uk/>

Information about Connecting for Health's streams of work<sup>63</sup>

<http://www.connectingforhealth.nhs.uk/systemsandservices>

Information about Clinical Engagement in NHS CFH<sup>42</sup>

<http://www.connectingforhealth.nhs.uk/engagement/clinical>

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## CHAPTER 4

# Exploring, describing and integrating the fields of quality, safety and eHealth

### SUMMARY

- eHealth is a relatively new and rapidly evolving field and so many of the concepts, terms and applications are still in a state of flux.
- There is furthermore no agreed definition of eHealth, with some researchers using this to relate primarily to the area of consumer informatics, whereas others use it more generically to refer to any of the ways in which information technology can be employed to improve delivery of healthcare. For the purposes of this review, we considered it important to use an inclusive definition and chose to use Eysenbach's definition as the basis for our work, as adapted by Pagliari:

'eHealth is an emerging field of medical informatics, referring to the organisation and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterises not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally and worldwide by using information and communication technology.'

- Whilst the number of eHealth applications is potentially endless, these can nonetheless be divided into three broad domains relating to key activities they support:
  - storing, managing and sharing data
  - informing and supporting clinical decision-making
  - delivering expert professional and or consumer care remotely.
- Most frameworks of quality currently in use do however incorporate the following key dimensions of care: effectiveness of treatments and appropriateness of means of delivery; acceptability; efficiency; and equity.
- Whilst there are no internationally agreed definitions of patient safety, adaptations of the National Patient Safety Agency's definition of *Patient Safety Incidents* is increasingly being used. This, in its original definition,

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states that a ‘...patient safety incident is any unintended or unexpected incident which could have harmed or did lead to harm for one or more patients being cared for by the NHS.’

- There are a number of patient safety taxonomies currently in existence, however, our scoping of this literature found that the Joint Commission on Accreditation of Healthcare Organizations *Patient Safety Event Taxonomy* and the related World Health Organization Classification are the most comprehensive and clinically relevant in that they incorporate five key areas:
  - impact of medical error
  - type of processes that failed
  - domain, ie the setting in which an incident occurred
  - cause or factors leading to the safety incident
  - prevention and mitigation factors to reduce risk of recurrence and or improve outcomes in the case of a further incident.
- Integrating the fields of eHealth, quality and safety clearly demonstrates the numerous ways in which technology has the potential to improve the efficiency of many facets of healthcare delivery through, for example, helping clinicians to readily access comprehensive information on their patients, aiding monitoring of their conditions and the treatments being issued, reducing inappropriate variability in healthcare delivery, and proactively identifying and alerting clinicians to threats to patient safety.
- The integration of these domains however also highlights the many ways in which introduction of new eHealth applications can inadvertently introduce new risks.

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## 4.1 INTRODUCTION

In order to help identify the focus of our work and also to place some boundaries around the potentially very large field of enquiry, during the formative phase of this study, we undertook mapping of the domains of eHealth, quality and safety, looking particularly for areas at the intersection of these fields of enquiry. This proved challenging for several reasons, not least that eHealth, quality and safety are relatively nascent and hence understandably contested areas that are at present still rapidly evolving. This chapter summarises our attempts at this underpinning conceptual work and provides the framework within which we interpreted the findings chapters in Section 2 of this report.

The analytic framework that we have developed thus draws on the following main strands:

- exploration of notions of constructs of quality and its assessment
- a classification of patient safety risks, derived from the WHO International Classification for Patient Safety<sup>1</sup> and a systematic overview of safety taxonomies by the Joint Commission on Accreditation of Healthcare Organizations<sup>2</sup>
- the core applications of eHealth, represented within the conceptual model developed by Pagliari et al.<sup>3</sup>
- the headline deliverables of NHS Connecting for Health and other key elements of the National Programme for Information Technology (See Chapter 3)

These strands encompass a number of cross-cutting themes around behavioural and organisational change, usability and interoperability of technology and its evaluation.

## 4.2 QUALITY OF HEALTHCARE

Modern medicine faces important challenges. Never before has scientific development impacted so profoundly on human health and our knowledge on how to impact on disease and health grown so rapidly. The number of scientific articles that in one way or another propose improvements to health and to the delivery of healthcare now counts several hundred thousand annually. From the first randomised controlled trial (RCT) conducted some 60 years ago the number has now grown to over 10,000 annually.<sup>4;5</sup> This in turn creates a constant need for change—quality improvement.

However, despite these advances in our ability to use new medicines, procedures and approaches to improve the health of individuals and populations, there is a growing body of knowledge that demonstrates that translating these

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insights into practice frequently falls short of the mark.<sup>6–10</sup> During the last decade hundreds of authoritative studies have clearly revealed the very considerable variations in the extent to which the performance of healthcare professionals and healthcare systems vary,<sup>6–10</sup> this typically manifests as the population receiving only about 50 per cent of and expected standard of care.<sup>11</sup> Moreover, there is the continuing paradox of the inverse care law, this describing how those most in need are typically least likely to receive care<sup>12</sup> with this gap is unfortunately growing.<sup>13</sup>

The origins of the attention to quality are over hundred years old.<sup>14</sup> Over forty years ago Avedis Donabedian,<sup>15</sup> widely considered the father of quality movement,<sup>16;17</sup> invigorated focus on quality of healthcare as a measure of the pursuit of best care. In a broader sense, the focus on quality is a result of a complex convergence of scientific, political, economic and social issues. But despite this long history of focusing on quality considerations, the response by the medical profession has always been mixed.<sup>18</sup>

Maximising patient safety is an essential component of the wider quality improvement agenda. Although these topics are often considered separately, reports such as the Institute of Medicine's *Crossing the Quality Chasm*<sup>8</sup> and *To Err is Human*<sup>7</sup> clearly align safety and quality, clearly emphasising the potential of information technology (IT) to improve both the quality and safety of care. Of note is that analyses of safety incidents has been a catalyst to the integration of the fields of informatics, human factors engineering, cognitive and social psychology, have been within the quality discipline.<sup>19</sup>

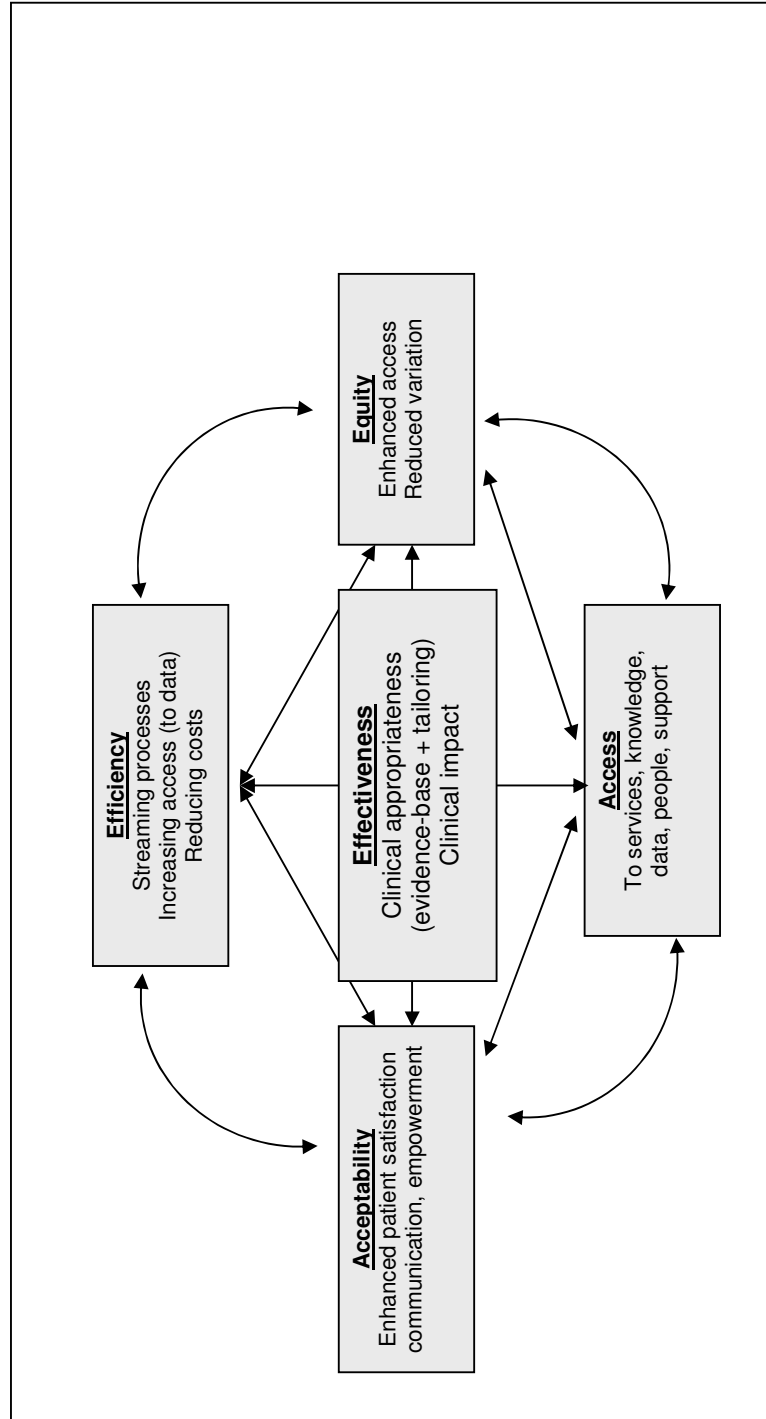
#### **4.2.1 DEFINING AND MEASURING THE QUALITY OF HEALTHCARE**

Experts have struggled to formulate a concise, meaningful, and generally applicable definition of quality healthcare.<sup>18</sup> As with safety (discussed below), there remains no single agreed definition of quality, although many have attempted to elucidate the concept and a number of broad frameworks for understanding it have been proposed.<sup>15;20–31</sup> While trying to capture the essence of this elusive construct, all definitions agree that quality care is that which helps an individual and or population to maximise their welfare, quality or (preferably and) duration of life, and which leads to desired health outcomes. For example, Donabedian defines it in terms of the structures, processes and outcomes of care;<sup>15</sup> Maxwell<sup>20</sup> in terms of accessibility, effectiveness, efficiency, acceptability, equity and relevance; and Schuster in terms of the underuse, misuse and overuse of services.<sup>23</sup> Others have presented a detailed list of condition-specific quality of care indicators.<sup>30</sup> The simple and widely-quoted framework developed

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by Campbell et al. draws on several of these characterisations and considers quality in terms of its relevance to the individual—access and effectiveness (of clinical care and inter-personal care) and the public or populations—access, effectiveness, equity, efficiency and cost.<sup>25</sup> We have integrated these within the conceptual map shown as Figure 4.1, which highlights the core domains of effectiveness, efficiency, equity, acceptability and access, illustrating their inter-dependencies (shown by the arrows and repetition of sub-terms). This integration also recognises the central role of effectiveness in both the quality and safety debate, echoing the assertion that ‘. . .quality-improvement efforts based on evidence of effectiveness are likely to be more readily embraced and may save more lives than will efforts to improve safety that cleave to the concept of accidental death and lack a solid evidence-base.’<sup>19</sup> Cost is subsumed within efficiency, although the effectiveness, equity, accessibility and acceptability of care also have downstream cost implications. One of the most widely adopted definitions of quality is the Institute of Medicine’s, which defines quality as the ‘. . .degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.’<sup>8</sup> This is the definition we have adopted in our report.

Figure 4.1 Map of quality concepts



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### *Measures and indicators of quality of care*

Lilford et al. highlight how:<sup>32</sup>

‘The distinction between a measure of quality and an indicator of quality is important. Generally speaking we have very few real measures of quality. For example, post-operative length of stay is a measure of the patient’s hospital stay, but only an indicator of quality, eg a patient’s long stay might represent postoperative complications or poor discharge arrangements. Thus, the term indicator is preferable.’

Quality has numerous aspects and indicators measured depend on the setting, patient and provider. Quality indicators assess aspects of care associated with positive patient outcomes in a variety of domains. Broadly, indicators can be summarised into the technical excellence of provision of care and the excellence of interactions between provider and patient. Concepts such as effectiveness, access, capacity, safety, patient-centeredness, equity and disparities include just some of most commonly used to describe an aspect of either technical or inter-personal excellence.

Measuring quality of care or interventions to improve it is thus far from simple<sup>33</sup> and needs adjusting for, amongst other things, treatment refusal.<sup>34</sup> Different methods of measurement of the quality of care do not necessarily provide the same answers.<sup>32;35</sup> Complexity (and the vagueness) of definitions of quality means that researchers and practitioners often find it difficult to understand and relate to it. The very language and terminology of quality of care leaves many healthcare professionals somewhat bewildered. Terms such as desired patient outcomes, measures, criteria, standards, profiles, observed and expected mortality, case-mix and case-severity adjustments, charts, tables, leagues, quality control, continuous quality management, quality improvement, quality assurance are all poorly understood. Moreover, what constitutes quality often changes and adapts depending on the goal of the measurement.<sup>36</sup>

One overarching benchmark for quality however, as defined by the Institute of Medicine, is current best knowledge. Broadly speaking, measures of quality can be classified into those that measure processes and those that measure outcomes. As a process, the quality of care can be measured according to whether patients were offered recommended services. As an example, a study of processes found that quality of care increases as a patient’s number of chronic conditions increases.<sup>37</sup> Process measures are strictly valid when there is a proven relationship to health outcomes. For example, receiving warfarin reduces mortality in a number of conditions and measuring the number of



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patients who receive treatment and maintain therapeutic range of international normalized ratio (INR or a measure determining the clotting tendency of blood) is thus a valid process measure of quality (see Chapter 11). Another commonly measured process measure of quality of care is rate of admissions to hospital.<sup>38;39</sup> A high rate of admissions to hospital is generally considered to be a reflection of suboptimal community-based patient care.

Outcome measures of quality are on the other hand only valid if they are modifiable as a result of a process that aims to improve this outcome. So deaths from causes that are not modifiable cannot be considered measures of quality of care.<sup>40</sup>

There is also a clear recognition of importance of patients' or consumers' perspective in what constitutes quality healthcare. Language has adapted to reflect patient-centredness and researchers talk about 'desired health outcomes' (ie those desired by the patient and not necessarily doctor); another related outcome being "expectations".

Variability in measured quality of care poses a great challenge for policy-makers, healthcare professionals and patients alike with outcomes'...influenced by definitions, data quality, patient case-mix, clinical quality of care and chance.<sup>32</sup> For example, an association between a higher volume of activity and improved outcomes in hospital care is now supported by evidence from more than 300 studies across a wide range of procedures and conditions.<sup>41</sup> Nevertheless, evidence is far from uniform.<sup>42-44</sup> The clinical and policy significance of these findings is complicated by the methodological shortcomings of many studies. Differences in case mix and processes of care between high- and low-volume providers may explain part of the observed relationship between volume and outcome.<sup>45</sup> Yet how should we act on this finding that high volume is associated with better outcomes?

While measurable differences do not necessarily translate into clinically meaningful differences in patients' lives,<sup>46</sup> measuring quality of care is nonetheless an essential prerequisite to quality improvement. Only by measuring outcomes of quality improvement initiatives and interventions can we know whether they actually result in an improvement. The UK Quality and Outcomes Framework is an example of a national policy initiative aimed at measuring indicators of the quality of primary care.<sup>47</sup> In 2006, in an attempt to improve the quality of care, the US Congress signed a pact with the American Medical Association which pledged to develop over 100 standard measures of doctors performance that will be reported to the federal government.<sup>48</sup>

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#### 4.2.2 IMPROVING QUALITY OF CARE

Problems with quality have traditionally been classified into three areas: shortage of technical and interpersonal competence; overuse or unnecessary or inappropriate use of services; and underuse of or lack of access to needed and appropriate services. Appropriateness is at the heart of defining quality of care (see Figure 4.1).<sup>49</sup> Yet defining what is appropriate is far from easy<sup>50;51</sup> and indicators of quality of care cannot simply be transferred between countries or indeed clinical settings as variation in professional culture or clinical practice play important roles.<sup>52</sup>

Improving quality of care is complex and includes approaches such as: implementation of evidence-based practice (where possible catalysed by the development of clinical practice guidelines for example),<sup>53</sup> leadership commitment,<sup>54</sup> continuous quality improvement<sup>55</sup> continuing medical education and professional development,<sup>56</sup> regulation, assessment and accountability, competition, continuous quality improvement (industrial quality management technique),<sup>57;58</sup> audit and feedback,<sup>59</sup> and patient empowerment, creating public pressure by publishing performance data.<sup>60;61</sup> The UK is now seen as one of leaders in using financial incentives as drivers of quality improvement<sup>47</sup> and response of practitioners has been overwhelming.<sup>62</sup> An example of a national initiative is *The 100 000 Lives Campaign* and building on this, the *5 Million Lives Campaign*.<sup>63;64</sup>

Although attempts to improve quality are numerous, the strength of the evidence in support of most of these initiatives is either weak or absent.<sup>6;65</sup> We lack an understanding of which approaches are most appropriate for what types of improvement in what settings and of the determinants of successful performance change and none of the popular models for improving clinical performance appear to be superior.<sup>6</sup>

It is only recently that it has been recognised that quality needs to include mechanisms to also measure and monitor potential harms.<sup>46</sup>

#### 4.3. SAFETY

Approximately 850,000 medical errors occur in NHS hospitals every year resulting in an estimated 40,000 deaths.<sup>66;67</sup> These are, by any standard, shocking statistics and reflect an unacceptable state of healthcare.<sup>68</sup>

Safety is an intricate feature of high quality care although it has only begun to receive attention as a quality parameter in recent years. The Institute of Medicine's landmark reports on healthcare safety and quality, *To Err Is Human*<sup>7</sup> and *Crossing the Quality Chasm*<sup>8</sup> and equivalent reports in the UK<sup>66;69</sup> have

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articulated a broad agenda for quality and safety improvement in healthcare that needs to be based on evidence,<sup>70</sup> recognising the current unacceptable state of identifying, analysing and learning from medical mishaps.<sup>71</sup>

#### **4.3.1 DEFINING THE SAFETY OF HEALTHCARE**

One of the most fundamental challenges of patient safety is the variety of different concepts underlying this broad construct and the lack of a single agreed definition; the range and number of classification schemes<sup>72–81</sup> characterising incident reporting systems and patient safety research reflects these underlying tensions. Diverse understanding of patient safety related terminology<sup>82–84</sup> impacts importantly on how we are able to learn from potentially dangerous events<sup>85</sup> when attempting to interpret or synthesise the results of published studies, which address somewhat different theoretical propositions (eg, avoidance of error, risk prevention, reporting or investigation of incidents) and use different outcome measures. Patient safety encompasses aspects such as harm to patients, incidents that lead to harm, the antecedents or processes that increase the likelihood of incidents, and the attributes of organisations that help guard against harm and enable rapid recovery when risk escalates.<sup>86</sup>

Most definitions of patient safety and medical error recognise that organisational factors interact with human factors to facilitate and mitigate errors.<sup>87</sup> There is, however, a tension between focusing on individual practices and seeing safety primarily as a systems' problem.<sup>88</sup> The latter approach focuses on developing systems that prevent errors and, equally importantly, ensures that clinicians provide effective care.<sup>89;90</sup>

Shojania et al. have defined a patient safety practice as '...a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the healthcare system across a range of diseases and procedures.'<sup>91</sup>

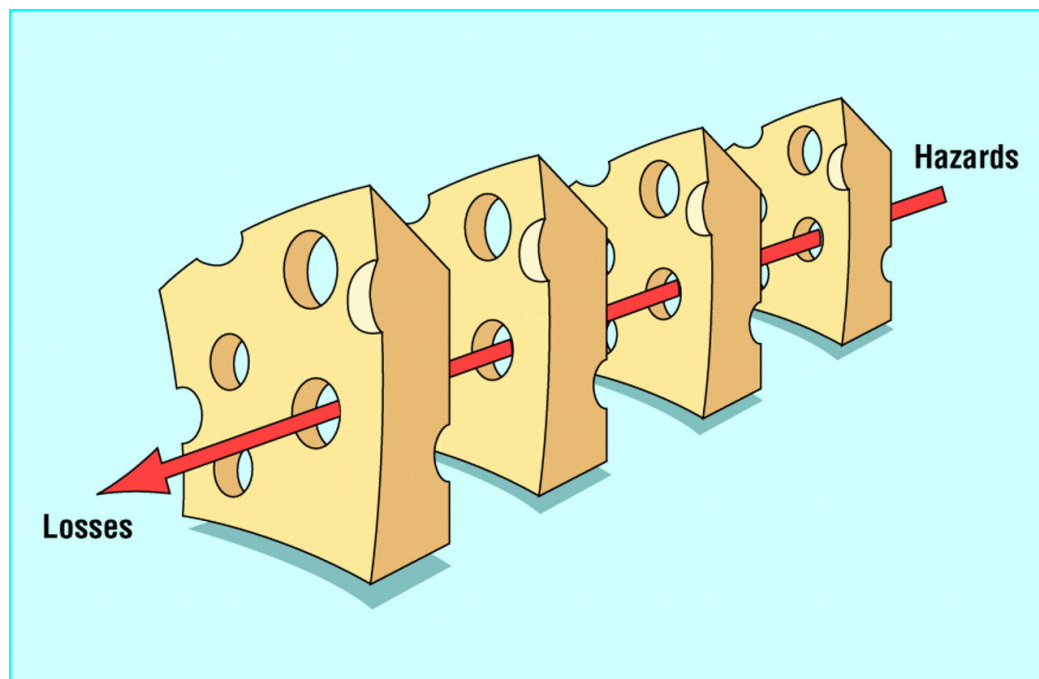
In conceptualising patient safety we found it helpful to focus on the goal of patient safety. Battles and Lilford<sup>92</sup> specify how the '...goal of patient safety is to reduce the risk of injury or harm to patients from the structure and process of care. This can be accomplished by eliminating or minimising unintended risks and hazards associated with the structure and process of care.' and '...a vision for patient safety would be zero health care associated injuries or harm.'

In an attempt to systematically organise and represent patient safety theory we considered various other definitions and constructs of safety related terminology.<sup>72–81;93</sup> What became evident is that in the past efforts to define and classify "errors" or "mistakes" were somewhat theoretically and methodologically

flawed.<sup>74</sup> Contributions to learning from risk-averse industries such as aviation<sup>94–96</sup> have been seminal in recognising key safety principles, such as: that errors can never be completely eradicated and generally derive from faulty system design not from negligence; that major safety incidents are only the “tip of the iceberg” of procedures and processes that indicate possibilities for organisational learning; and most importantly that prevention of safety incidents should be an ongoing process based on open and full disclosure and reporting. The key objective of designing safe systems is to make it difficult for the individual to err and to design systems that absorb errors, mistakes, slips and lapses that inevitably occur due to a characteristic of human nature—fallibility.<sup>96</sup>

Among many safety models Reason’s *Swiss Cheese Model* has become the dominant paradigm for analysing medical errors and patient safety incidents (See Figure 4.2).<sup>97;98</sup> The holes in the defences arise for two reasons: *active* failures (eg shortage in communication or improper ventilation technique); and *latent* conditions (eg inadequate patient monitoring, or inadequate staffing skills mix). Nearly all adverse events involve a combination of these two sets of factors.

**Fig 4.2 The *Swiss Cheese Model* of accident causation – model of how defences, barriers, and safeguards may be penetrated by an accident trajectory**

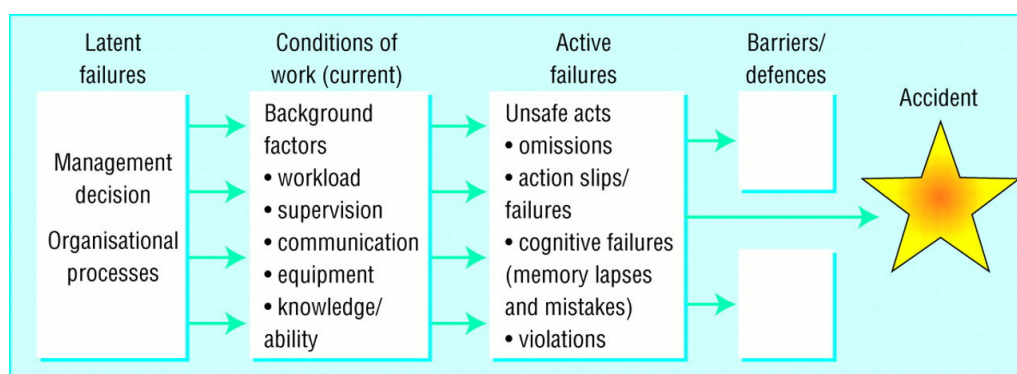


Source: Reason (2000)<sup>99</sup> Reprinted from Reason (2000) with permission from British Medical Journal.

Vincent et al. have adapted and further developed Reason's model and describe the people who are directly involved as the inheritors, rather than the instigators of an accident sequence (see Figure 4.3).<sup>80</sup> These frameworks facilitated systematic and conceptually driven approaches to organisational risk assessment.

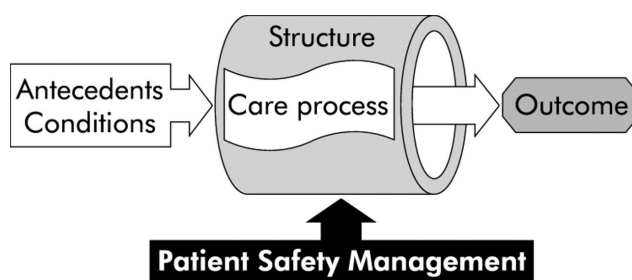
When we approach quality and safety as intricately related we then see how safety incidents can lie either in the structure or the process of care. Figure 4.4 illustrates the process as occurring within the structure of healthcare.<sup>92</sup>

**Figure 4.3 The figure shows the anatomy of an organisational accident**



Source: Vincent et al. (1998)<sup>100</sup> Reprinted from Vincent et al. (1998) with permission from British Medical Journal.

**Figure 4.4 A structure and process model for patient safety based on Donabedian**



Adjust structure and process to eliminate or minimize risks of health care associated injury before they have an adverse event that impacts on the outcomes of care

Source: Battles et al. (2003)<sup>92</sup> Reprinted with permission from J Battles.

Recognising the problem of multiple definitions of patient safety related concepts, a number of organisations have advocated the use of a standard taxonomy and terminology.<sup>101</sup> The National Patient Safety Agency's (NPSA)



definition of *Patient Safety Incidents* states that a ‘...patient safety incident is any unintended or unexpected incident which could have harmed or did lead to harm for one or more patients being cared for by the NHS.’ Most recently the World Health Organization’s (WHO) World Alliance for Patient Safety has produced a conceptual map and classification scheme in collaboration with a number of high profile international organisations, including the UK’s NPSA.<sup>1</sup> This builds on the taxonomy developed by the Joint Commission on Accreditation of Healthcare Organisations (JCAHO), on behalf of the WHO, which was based on systematic review and expert consensus.<sup>74</sup> Homogeneous elements of models—which comprise terms and the relationships between terms that make up the building blocks of a classification scheme—were categorised into five complementary root nodes or primary classifications (See Box 4.1).

For the purposes of our review we have found a combination of the original JCAHO taxonomy<sup>2</sup> and the WHO conceptual map and classification scheme<sup>1;102</sup> to be most useful for understanding the potential role of eHealth solutions in facilitating safer patient care, as well as their unintended consequences (See Box 4.1 and Figure 4.9). These differentiate types of problem (communication, patient management, clinical practice), cause (organisational, technical, human), impact (medical and non-medical), issues for prevention (accuracy, communication, alarms) and domain (setting, target, people). In so doing they recognise that adverse events may result from multiple systemic features operating at different levels, such as the task, the team, the work environment and the organisation.<sup>80</sup> They also recognise the importance of psychological and human factors in the nature, mechanisms and causes of error and the fact that liability to error is strongly affected by the context and conditions of work, as has been argued by Leape and others.<sup>79</sup> These are further discussed below when combined and integrated with eHealth map in Section 4.5.

#### Box 4.1 Five complementary primary classifications of patient safety developed by the JCAHO

1. **Impact:** The outcome or effects of medical error and systems failure, commonly referred to as harm to the patient.
2. **Type:** The implied or visible processes that were faulty or failed.
3. **Domain:** The characteristics of the setting in which an incident occurred and the type of individuals involved.
4. **Cause:** The factors and agents that led to an incident.
5. **Prevention and mitigation:** The measures taken or proposed to reduce incidence and effects of adverse occurrences.

Source: Chang et al. (2005)<sup>2</sup> Reproduced with permission from Oxford Journals.

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#### 4.3.2 IMPROVING SAFETY OF HEALTHCARE

Two approaches to the problem of human fallibility exist: the person and the system approaches.<sup>98</sup> The explanation for safety incidents is often messy and multi-faceted, resisting a clean, simple fix.<sup>103</sup> In essence approach to safety incidents is based on examining the chain of events that led to an accident or near miss and considering all acts of those who were in any way involved, and then, vitally, by looking further back at the working conditions of staff and the organisational context of the incident trying to understand why it occurred.

A number of studies emphasise the limitations of voluntary reporting by healthcare providers as the principal means for detection of safety incidents.<sup>104</sup> Among all types of medical errors, cases in which the wrong patient undergoes an invasive procedure warrant special attention. Nonetheless, such procedures are under-reported and almost never discussed.<sup>105</sup> To facilitate the process of learning and as a response to high profile policy reports<sup>66;69</sup> that urged the health service to improve patient safety In the UK, the NPSA was created and the national reporting and learning system based on involvement of healthcare professionals in reporting of patient safety incidents, including ‘near misses’ which cause no actual harm.<sup>106</sup> It is recognised that a system, which does not criminalise mistakes<sup>107</sup> is needed and the focus on learning from safety incidents.<sup>108</sup> There is also a need to learn how to accurately submit information to better prioritise, organise and streamline event analysis.<sup>109</sup> Experience from the aviation industry shows that as reporting rises, the number of serious events begins to decline. Paradoxically, an increase in reporting of patient safety incidents will be a sign that the NPSA has been successful in promoting an open and fair culture in which we can all learn from the mistakes of others, truly an “organisation with a memory”.<sup>106</sup>

Yet reporting systems are far from fully effective in monitoring more serious violations, usually only providing information after a violation has caused some harm.<sup>110</sup> New approaches and methods are needed to study violations in healthcare and IT will play a key role in these; for example by monitoring, in real-time, variability in quality—this can identify threats to patient safety<sup>111</sup> or through tools, such as event monitoring and natural language processing that can inexpensively detect adverse events in clinical databases.<sup>112</sup> Before we describe in more detail how eHealth, quality and safety interact we briefly consider key conceptual considerations in the field of eHealth.



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#### 4.4. DEFINING THE FIELD OF EHEALTH

Drivers for increased use of IT in healthcare are multiple,<sup>113</sup> but can be summed up in one overarching message: increased use, indeed pervasiveness of IT in all areas of society in personal, business and public life.

eHealth for healthcare delivery is now one of the main priority areas for most developed and indeed developing countries and the stakes for eHealth are high. During the 58th World Health Assembly in 2005, the ministers of health of the 192 member states of the United Nations, approved the so-called *eHealth Resolution WHA58.28eHealth* (a resolution is the highest legal entity possible in the United Nations system).<sup>114</sup> For an extract from the resolution see Box 4.2.

Such strong support for eHealth, in spite of scepticism of some agencies and member states, shows global political commitment that has translated in unprecedented investment in IT within healthcare.

eHealth is a new term that in a very simple way aims to describe, that something now happens or is assisted by IT, that it happens “electronically”. For example like “e” before mail, where mail is sent electronically and not anymore by post and in the case of eHealth, IT has automated many aspects of the delivery of healthcare.

This “e” nevertheless means much more than the technological development of the use of information technology. In a broader sense, eHealth encompasses a paradigm shift in healthcare resulting in increased efficiency, enhanced quality and safety, encouragement, empowerment, improved equity and evidence-based care.<sup>115</sup>

The term eHealth has over 50 different definitions.<sup>116</sup> It is now widely used in different domains of society from academic<sup>117;118</sup> to policy.<sup>113;119</sup> Questions remain about how the differing concepts and understandings of the term eHealth affect different stakeholders.<sup>116</sup>

Nevertheless, there is a trend to use eHealth in an encompassing way for any use of information technology related to health. A recent analysis of the literature suggests the concept is best understood as the application of predominantly networked digital information technologies to support the organisation and delivery of care.<sup>3</sup> It sits within the broader field known as health informatics, which encompasses additional hardware, software and other technological issues.

For the purposes of this review, we considered it important to use an inclusive definition and chose to use Eysenbach’s definition as the basis for our work, as adapted by Pagliari:<sup>115;117</sup>

‘eHealth is an emerging field of medical informatics, referring to the

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organisation and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterises not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.'

The conceptual map shown in Figure 4.5 is derived from an extensive review of eHealth research and commentary, conducted for the NHS Service Delivery and Organisation (SDO) Programme by Pagliari et al.<sup>3</sup> It represents a synthesised overview of the important application domains within eHealth, set within the context of the broader field of Medical (or Health) Informatics applications. This illustrates the overlap between the two topics (which are often treated as being equivalent) but also emphasises the pervasive role of networked information and communications to eHealth, as distinct from more independent applications of computers and digital devices. In addition, it reveals the overlap with related subfields such as biomedical informatics, eBusiness, eLearning and public health informatics, with the generic areas of computing and telecommunications, and medical equipment. Development of the map drew on the Medical Informatics Scientific Content Map developed by the International Medical Informatics Association<sup>120</sup> and structural elements of Medline's MeSH tree for Medical Informatics.

#### Box 4.2 An excerpt from the United Nations *eHealth Resolution*

'The Fifty-eighth World Health Assembly. . . Noting the potential impact that advances in information and communication technologies could have on health-care delivery, public health, research and health-related activities for the benefit of both low- and high-income countries; Aware that advances in information and communication technologies have raised expectations for health;

. . .

Stressing that eHealth is the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research,

1. URGES Member States:

(1) to consider drawing up a long-term strategic plan for developing and implementing eHealth services in the various areas of the health sector, including health administration. . .

(2) to develop the infrastructure for information and communication technologies for health as deemed appropriate to promote equitable, affordable, and universal access to their benefits, and to continue to work with information and telecommunication agencies and other partners in order to reduce costs and make eHealth successful;

. . .

(6) to establish national centres and networks of excellence for eHealth best practice, policy coordination, and technical support for health-care delivery, service improvement, information to citizens, capacity building, and surveillance;

(7) to consider establishing and implementing national electronic public-health information systems and to improve, by means of information, the capacity for surveillance of, and rapid response to, disease and public-health emergencies'

The core applications of eHealth, according to this map, are summarised as:

- **Informing and supporting decisions:** this includes applications to aid professionals, namely clinical decision support tools and systems, with on-line access to research evidence, guidelines and professional development tools. It also includes consumer health informatics applications such as on-line patient information, decision aids, targeted educational interventions or therapy, personal health records and online peer support.
- **Storing and managing data:** this refers to electronic health records (EHRs) and records systems, including clinical and administrative data (and stored images), at both the patient and population levels.
- **Providing expertise or care at a distance:** this includes, firstly, telemedicine applications, which chiefly concern professional-to-professional interaction for advice or case conferencing and also remote

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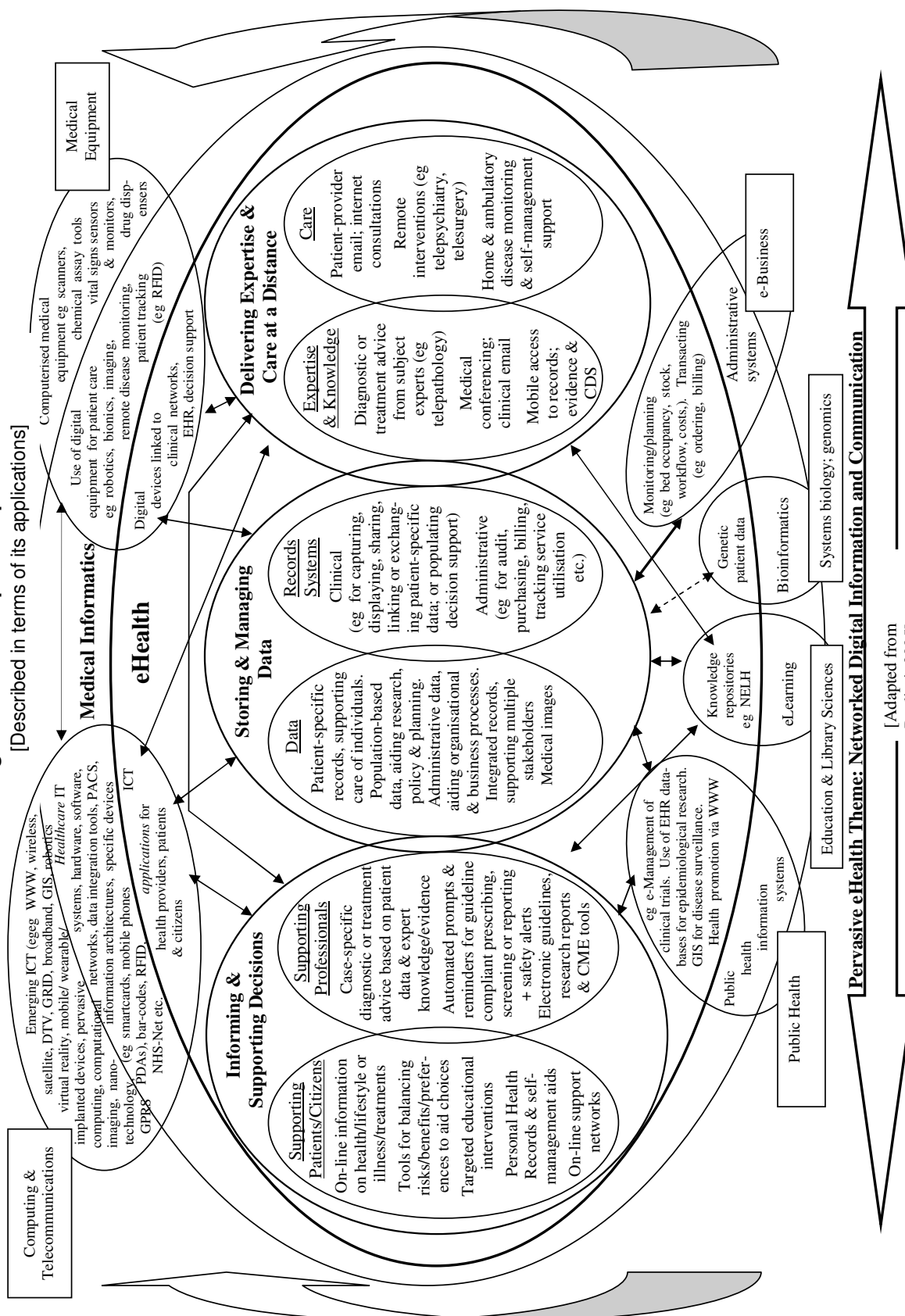
access to health records and decision support. It also includes telecare applications, which represent an increasingly important part of the eHealth landscape and concern the provision of remote professional-patient communication and support, as well as the use of technology to promote supported self-care in the home (including self-monitoring, education etc.).

Each of these three areas overlaps with the others, to a greater or lesser extent, and there is considerable interplay between the individual applications, reflecting both the complexity of the area and the pervasive theme of networked data and technologies. For example, telecare applications may integrate decision aids and online information, in addition to telemonitoring and remote clinician advice, while the effectiveness of both computerised decision support systems (CDSSs) and telecare is highly dependent on valid electronic health records. Likewise, computerised provider order entry (CPOE) is conceptually related to the EHR, since it concerns electronic documentation and data transfer, but it also often integrates CDSS, which may in turn accommodate both prompts for guideline-compliant prescribing, error alerting and or linkage to incident reporting systems. While digital devices, per se, are not within the scope of eHealth, the application of networked devices linked to an EHR is for example. This might include radio-frequency identification bracelets linked to patient records and CPOE.

The figure has been elongated to fit the page and the upper, bold, arrow is designed to illustrate the overlap between the outer two circles. Nevertheless, the display is useful in that it emphasises the central importance of the EHR in maximising the benefits of eHealth applications for the effective organisation and delivery of healthcare. Figure 4.5 also recognises the value of the EHR and related applications for research, disease surveillance and health service planning, as well as the overlap with electronic knowledge repositories, which are critical to the development of effective decision support and eLearning.

**Figure 4.5 A conceptual map of eHealth**

[Described in terms of its applications]



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#### **4.4.1 CROSS-CUTTING ISSUES FOR EHEALTH**

In addition to defining and elucidating the applications of eHealth, Pagliari et al.'s review for NHS SDO identified a number of cross-cutting issues that reflect common themes within published research and commentary on the topic. These are:

- managing change (individual & organisational behaviour, public perception)
- integrating appropriate evaluation (tailoring to technology stage & research questions)
- optimising human-computer interaction (usability & accessibility)
- integrating data and systems (standards & interoperability; data quality & clinical coding)
- ethico-legal issues (eg data privacy and governance, digital health inequalities)
- quality improvement (clinical benefits, patient enablement, efficiency, cost, safety) and
- patient safety (reducing error and risks, preventing harm).

This review addressed all of these themes, with the exception of ethico-legal issues, for which the focus on systematic reviews of effectiveness is less suitable. Particular attention was paid to quality and safety, human and organisational issues affecting the technology adoption, socio-technical factors affecting the usability of technology, challenges for evaluation and maximising the communicative and integrative power of technologies and data.

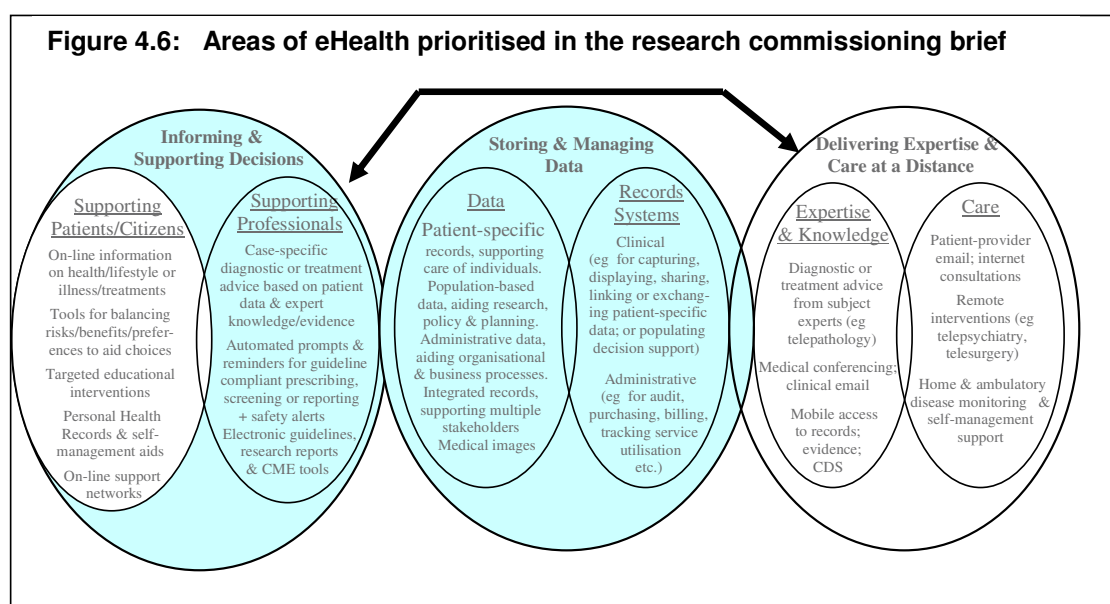
#### **4.4.2 NHS CONNECTING FOR HEALTH AND EHEALTH**

Our tracing of NHS Connecting for Health (NHS CFH; see Chapter 3)) reveals that it is a highly complex group of sub-programmes, only a fraction of which are represented within the headline deliverables typically cited. It has common strands with major quasi-independent initiatives, such as the National Knowledge Service and NHS Direct Online, while there is considerable internal complexity in the form of multiple design and specification programmes around IT architectures, standards and individual applications; supplier procurement and control mechanisms, and education and user engagement. Chapter 3 maps the key deliverables of NHS CFH and areas of synergy and overlap with other aspects of the National Programme for Information Technology (NPfIT). These elements are distributed throughout all three main eHealth applications domains, although the primary focus has been on delivering electronic applications that support NHS staff and organisations. A core component of NHS CFH is the



NHS Care Records Service (NHS CRS), whose primary objective is to deliver integrated EHR, which will support other applications such as appointment booking (Choose and Book) and the electronic transfer of prescriptions (ETP). The EHR is also central to the effective use of CDSSs, which NHS CFH and the National Knowledge Service are collaborating to develop. The National Knowledge Service and NHS Direct Online are engaged in knowledge delivery to professionals and patients, NHS Direct is using CDSS algorithms for triage and patient self-care support, while NHS Direct online is also one route by which patients can access HealthSpace for access to the Summary Care Record and the e-booking service. The transfer of clinical email and images supports the exchange of expertise and clinical care over geographic boundaries. The importance of internet-based data transfer and communications, as facilitated by New National Network (N3), also identifies these programmes with common definitions of eHealth. While the primary focus of NHS CFH has been professional and organisational interventions, a number of elements are consumer-oriented (most obviously HealthSpace). In addition, while telemedicine was originally outside the remit of the programme, areas such as remote disease monitoring and patient access to GP records are also being considered by the Programme.

Figure 4.6 shows the application domains at the centre of the larger eHealth map and is intended to illustrate the areas addressed by the commissioning brief, and the current project; which are mainly represented within the second, third and fourth ellipses from the left. Consumer health informatics and telemedicine and or telecare will be covered in an extension to this report.





## 4.5 INTEGRATING THE CONCEPTS OF QUALITY, SAFETY AND EHEALTH

As has already been described, the concepts of quality and safety are closely related, and arguments for the power of IT to improve healthcare quality and safety have been well made (although research evidence has yet to catch up with the vision). At the same time, there is also potential for technology to introduce new risks, which can be rooted in different aspects of the hardware, software or networks (eg reliability and usability), the users (including cognitive and psychological factors) or the teams and organisations in which they are used (eg safety culture).<sup>121</sup>

The links between technology, quality and safety are also reflected in the conclusions of the recent SDO eHealth review<sup>3</sup> which summarised the headline benefits as in box 4.3:

### Box 4.3 Headline benefits of eHealth, as discussed by SDO

#### Improving healthcare **quality** by:

- aiding evidence-based practice
- tailoring care to individuals, where IT enables more informed decision-making based on evidence and patient-specific data
- improving transparency and accountability of care processes & facilitating integrated and shared care
- reducing errors and increasing safety.

#### Improving healthcare **access** by

- helping to alleviate barriers to effective healthcare introduced by physical location or disability
- facilitating consumer empowerment for self-care & health decision-making.

#### Improving healthcare **cost-efficiency** by

- streamlining healthcare processes, reducing waiting times and waste
- improving diagnostic accuracy & treatment appropriateness.

Source: Pagliari et al. (2005)<sup>3</sup>

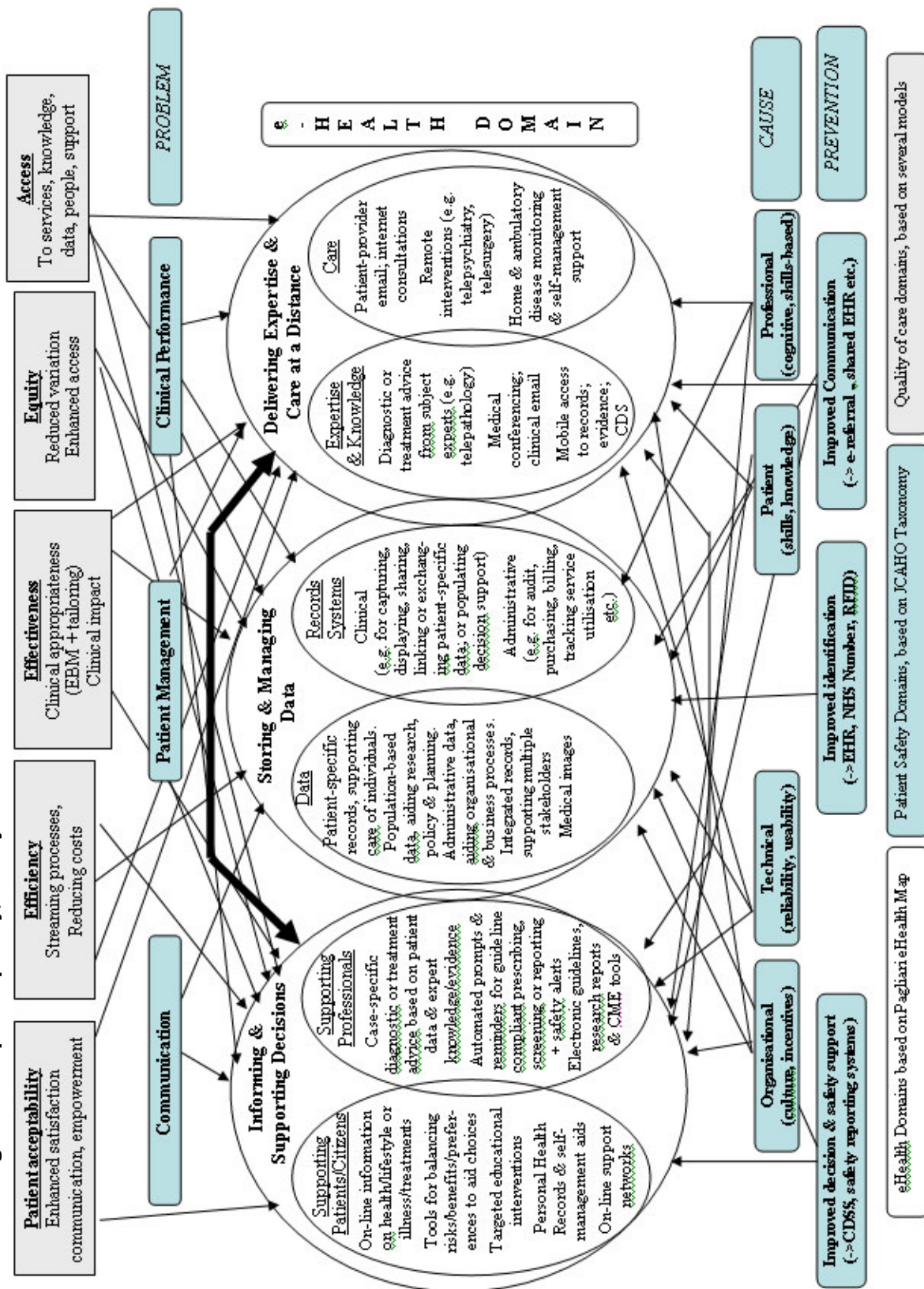
eHealth applications have the potential to improve the safety of patient care in many ways; for example, by ensuring that records are legible, less likely to be lost and more likely to reflect an accurate patient identity; by improving diagnostic accuracy, supporting evidence-based prescribing and flagging dangers through decision support; by aiding organisational learning through incident reporting systems, or by improving the capacity of patients to mitigate risks through identifying errors and maximising self-care.<sup>122</sup> At the same time, introducing new technology comes with risks attributable to the hardware or software itself or its misuse by healthcare personnel.<sup>123;124</sup> For this reason it is

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appropriate for this project to define the possible risks and safety benefits of eHealth applications and this requires an understanding of the frameworks by which patient safety has been traditionally understood and classified. Our efforts have been aided by multiple sources, including the comprehensive 2001 review of the safety and quality literature by the US Agency for Healthcare Research and Quality (AHRQ).<sup>91</sup>

Key elements of the safety and quality frameworks, discussed in this chapter, are triangulated with the core application domains from the eHealth map in Figure 4.7, illustrating the relevance of safety considerations to all aspects of technology design, development and deployment.

Figure 4.7: Integrated maps of quality, safety and eHealth



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#### **4.5.1 INTEGRATED JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS SAFETY CLASSIFICATION SCHEME AND eHEALTH APPLICATIONS**

##### **ACTION**

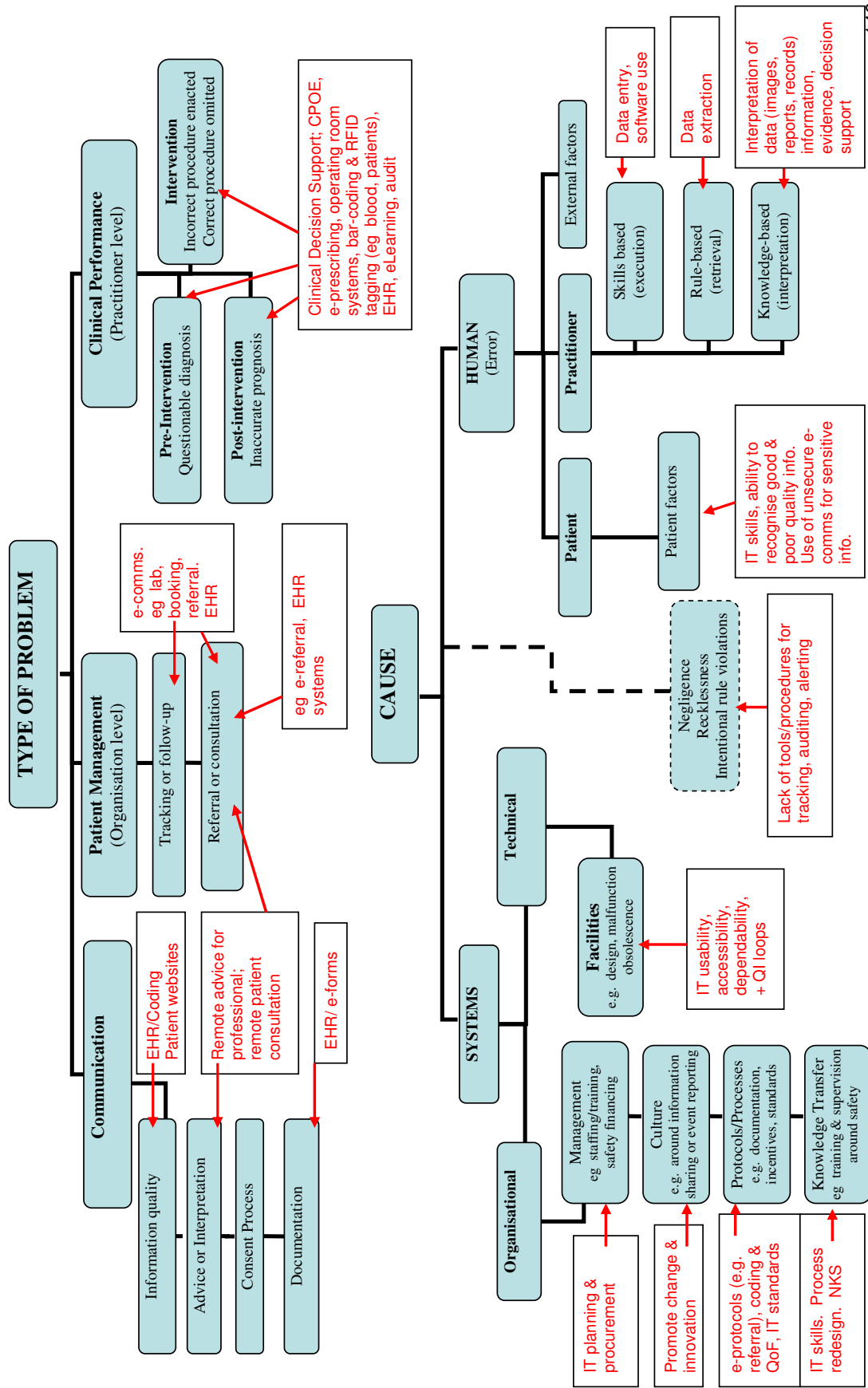
Below we further integrate earlier introduced (See section 4.4) conceptual maps and classification schemes of safety from JCAHO<sup>2</sup> and WHO<sup>1;102</sup> with a more detailed description of integration with those of eHealth. Figure 4.8 presents the core concepts within the JCAHO taxonomy, which have been annotated to illustrate issues for eHealth. (More elaborate organisational charts exist, but this level it is most easily triangulated with issues for eHealth).

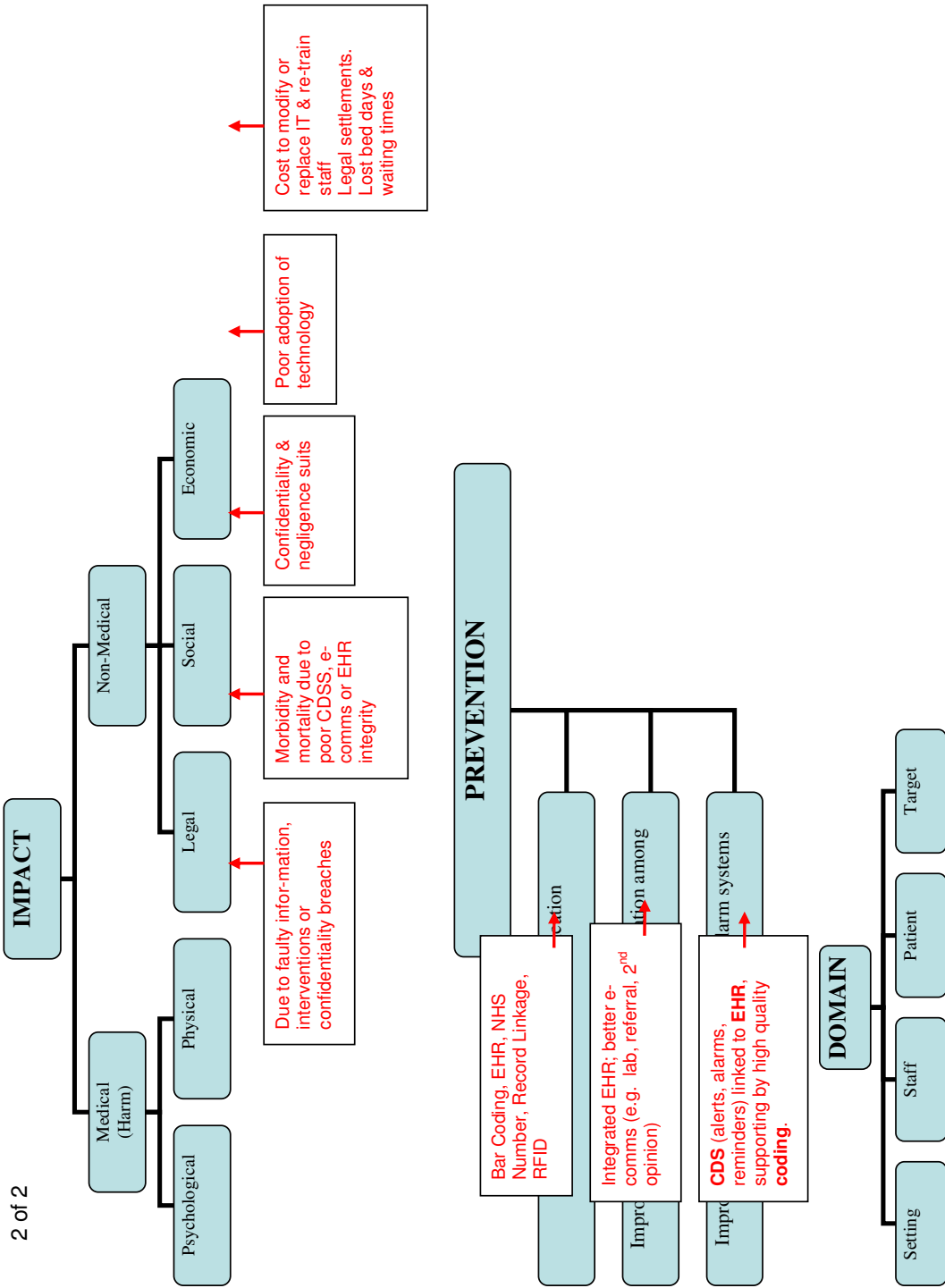
#### **4.5.2 DETAILED MAP OF THE IMPACT ON QUALITY AND SAFETY OF HEALTHCARE BY ePRESCRIBING**

According to Barber et al., errors related to medicines management are probably the most prevalent type of medical error in both primary and secondary care in the UK.<sup>125</sup> Of all types of medicines management errors—prescribing, dispensing, administration, monitoring, repeat prescribing<sup>126</sup>—prescribing errors are typically the most serious.<sup>125</sup> Thus from a combined conceptual map of quality, safety and eHealth here we present in detail how a specific application, namely ePrescribing can proactively and reactively improve quality and safety of prescribing.

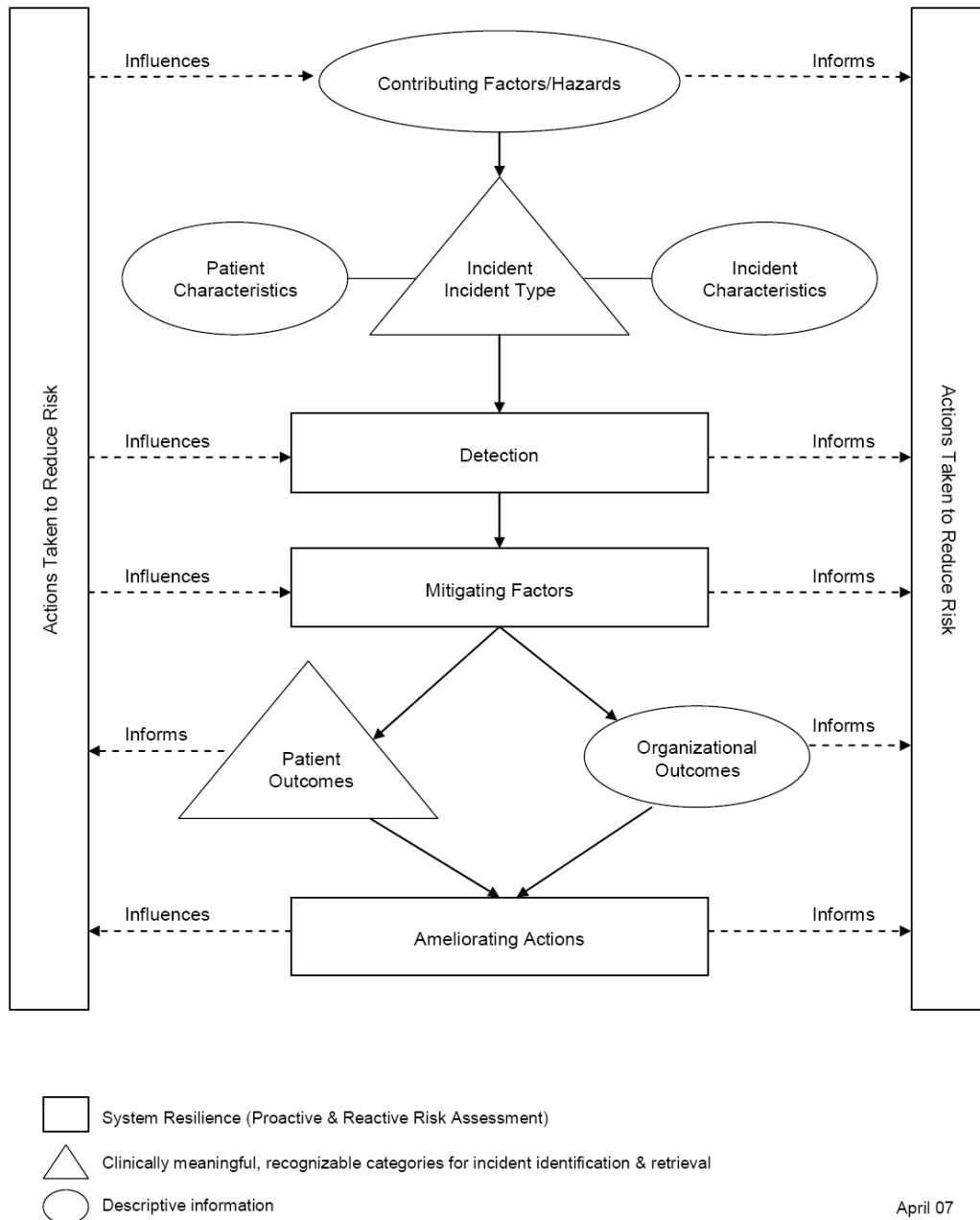
The International Classification for Patient Safety (ICPS) v.1.0. presents a comprehensive conceptual framework developed to be used in conjunction with other processes, systems and maps (See Fig 4.9). Based on Patient Safety and eHealth conceptual frameworks we present a list of problems related to medication incidents, contributing factors (staff and environment) and a detection process that may mitigate the process of prescribing, prevent or reduce likelihood of problems happening and recognise errors (see Table 4.1).

Figure 4.8: Core features of the JCAHO Patient Safety Taxonomy – Annotated to reflect sample eHealth solutions and issues





**Figure 4.9. to be read together with Table 4.1 Legend:** The solid lines enclose the 10 major classes of the ICPS and represent the semantic relationships between them. The dotted lines represent the flow of information. Incident type is medication incident and action taken to reduce risk is use of ePrescribing.



Source: WHO (2007)<sup>1</sup> Reprinted with permission from the National Patient Safety Agency.



**Table 4.1** Should be read together with Figure 4.9. It presents Problems leading to medication safety incidents, contributing prescriber, communication and environment factors, detection processes and finally theoretical modes of action of ePrescribing application that influence all the former.

Medication safety incidents*		Theoretical modes of action of ePrescribing as a pro-active and reactive application to improve quality and safety of prescribing
Wrong Patient	<b>Contributing prescriber factors</b> <b>Cognitive Factors</b> Perception/Understanding Knowledge-Based/Problem Solving Rule-Based Slip/Lapse Error/ Absentmindedness/ Forgetfulness Technical Error in Execution (Physical) Failure to Synthesise/Act on Available Information <b>Performance Factors</b> Distraction/Inattention Fatigue/Exhaustion <b>Behavior/Violation</b> Non-compliance Routine Violation Risky Behavior Reckless Behavior Problem with Substance Abuse/Use Sabotage/Criminal Act	1. Improved identification 2. Improved legibility 3. Automatic checks on previous response to the drug 4. Visual or audible alerts and warnings related to drug-drug interactions 5. Automatic checks for individual's characteristics (eg drug-allergies, comorbidities, weight, gender or ethnicity) that may influence the choice of drug, dose, strength of frequency, formulation or presentation, route or quantity 6. Automatic checks for results of clinical investigations (eg laboratory values of kidney function tests or blood pressure) that may influence the choice of drug, dose, strength of frequency, formulation or presentation, route or quantity 7. Automatic checks on previous response to the drug 8. Automatic checks on duplicate therapies 9. Automatic check on the amount of medication prescribed at last visit notifying about under and overuse of medication and reducing likelihood of under and overprescribing 10. Automatic barring of too high (dangerous) doses according to patient's characteristics (single, daily or life dose limits)
		(continued)

Medication safety incidents*		Theoretical modes of action of ePrescribing as a pro-active and reactive application to improve quality and safety of prescribing
Wrong Drug	<b>Communication Factors</b> Paper-Based Verbal	11. Advice regarding evidence-based alternative first-choice drug(s) from the same or similar class, drug dose, strength of frequency, formulation or presentation, route or quantity 12. Linking to algorithms emphasising (offering as a first choice when a drug is selected) cost-effective drug, dose, strength of frequency, formulation or presentation, route or quantity 13. Advice regarding the cost of medication and cheaper equivalent drug(s) from the same or similar class, dose, strength of frequency, formulation or presentation, route or quantity 14. Reminders about corollary orders 15. Access to information about previously prescribed medication (Anytime & Anywhere) 16. Reminders on drug guidelines 17. Faster Response to Physician's Clinical Orders 18. Reduced Patient Data Re-keying 19. Link to formulary—full information and knowledge-base about the medication prescribed 20. Instant provision of information about formulary-based drug coverage including on-formulary alternatives and co-pay information 21. Improved communication amongst prescribers and dispensers (eg call back queries, instant reporting that item is out of stock, alerts for unfilled, unrenewed prescriptions) 22. Automatic monitoring of orders and audit
Wrong Dose/ Strength of Frequency	<b>Contributing environment factors</b> Remote/Long Distance from Service	
Wrong Formulation or Presentation	<b>Detection process</b> Error recognition By Change in Patient's Status By System/ Environmental Change/Alarm By a Count/Audit/Review Proactive Risk Assessment	
Wrong Route		
Wrong Quantity		
Contraindication		
Omitted Medicine or Dose		
Adverse Drug Reaction		

Medication safety incidents*	Theoretical modes of action of ePrescribing as a pro-active and reactive application to improve quality and safety of prescribing
	<ul style="list-style-type: none"> <li>23. Shorter process turn-around time—transit time to dispensing site, time till first dose, prescription renewal or refill</li> <li>24. Paper Reduction</li> <li>25. Data are available for immediate analysis including post-marketing reporting, drug utilisation review, etc.</li> <li>26. Possibility of remote or long-distance prescribing</li> <li>27. Electronic access to checklists, protocols and or policies</li> </ul>
Adapted from: <i>The International Classification for Patient Safety v.1.0</i>	

#### 4.5.3 AN EXAMPLE OF A SCENARIO TO ILLUSTRATE THE POTENTIAL OF EHEALTH TO IMPROVE THE QUALITY AND SAFETY OF LABORATORY RESULTS REPORTING

As a further example, a detailed analysis of potential theoretical impact of eHealth on patient safety is presented in Table 4.2. This provides a scenario of eHealth's impact on the quality and safety of clinical processes using the example of laboratory results reporting.

**Table 4.2 Potential hazards in laboratory result reporting**

Action	Potential hazard	Possible solution
Doctor orders test (either by Computerised Provider Order Entry (CPOE) or paper form, or verbally tells patient to get x checked)	<ul style="list-style-type: none"> <li>• Unnecessary testing (eg previous recent tests not obvious on computer screen). Recent hospital OPD results not available to GP, no available online protocol to advise on appropriate testing)</li> <li>• May not enter correct patients details, eg wrong patient called up on computer scheme ( “similar name”)</li> <li>• Electronic ordering, incorrect test ordered or test left out, patient not informed to go for test, no follow up of uncompleted tests.</li> <li>• Patient misunderstands instruction</li> <li>• <b>Appropriate test does not get done</b></li> </ul>	<p>Shared patient records (primary and secondary care).</p> <p>Regular integration of results into GP system</p> <p>Clinician education to use patient date of birth for calling up records.</p> <p>Test request routinely recorded on computer and regularly audited against completion</p>
Nurse calls patient for test	<ul style="list-style-type: none"> <li>• Wrong patient presents (eg, mishears name, nurse does not check name)</li> <li>• “Similar name” problem as above</li> <li>• <b>Misidentified specimen sent to lab</b></li> </ul>	Clinician education, patient asked to check details on specimen label
Form completed sample bottles labelled	<ul style="list-style-type: none"> <li>• Wrong labels picked up and applied by accident</li> <li>• Wrong labels printed because of similar names</li> <li>• <b>Misidentified specimen sent to lab</b></li> </ul>	Clinician education, patient asked to check details on specimen label
Blood drawn	<ul style="list-style-type: none"> <li>• Wrong sample bottle used</li> <li>• Sample arrives late at lab and is old resulting in inaccurate analysis</li> <li>• <b>Unsuitable specimen</b></li> </ul>	<p>Easily available online advice.</p> <p>Computer alarm warning nurse that time for lat blood test is passed</p>
Samples and forms arrive at laboratory	<ul style="list-style-type: none"> <li>• Lost samples before reaching lab, clinician unaware that sample has not arrived.</li> <li>• <b>Lost specimen</b></li> <li>• Error at data entry level if form not bar-coded</li> <li>• <b>Misidentified sample analysed</b></li> </ul>	<p>Test request routinely recorded on computer and regularly audited against completion</p> <p>Bar-coding of all specimens</p>
Analysis performed. Result verified	<ul style="list-style-type: none"> <li>• Lab-based errors—eg calibration, poor storage of reagents, etc.</li> </ul>	

*(continued)*

**Table 4.2 Potential hazards in laboratory result reporting**

Action	Potential hazard	Possible solution
Posting of laboratory results—printed, emailed or web-based.	<ul style="list-style-type: none"> <li>Printed lab result goes missing</li> <li>email not noticed</li> <li>Mailbox full</li> <li><b>Wrong clinician/surgery gets results (delay)</b></li> <li><b>Confidentiality risk</b></li> </ul>	<p>Test request routinely recorded on computer and regularly audited against completion.</p> <p>Clinician education in mail box hygiene</p> <p>Patient asked to check for result</p>
Results pulled into practice computer system, scanned and entered manually, or entered automatically from web by software	<ul style="list-style-type: none"> <li>Results entered into wrong patient's records</li> <li><b>Result unavailable for intended patient</b></li> <li><b>Patient mistreated because of erroneous result</b></li> </ul>	<p>Administration education. Use of DOB/CHI for data entry.</p> <p>Test request routinely recorded on computer and regularly audited against completion.</p>
Results checked by clinician, on paper, scanned document or electronic entry	<ul style="list-style-type: none"> <li>Clinician does not read mail (eg on holiday no alternative provision made)</li> <li>Abnormal result not noticed, due to lack of knowledge, poor highlighting of abnormals, fatigue, information overload, multiple presentation of different lab results and set overlooked</li> <li><b>Abnormal result missed</b></li> </ul>	<p>Clinician/admin education. Regular check on mail boxes (especially holiday/illness) to ensure completion.</p> <p>Double checking of all "normal" results</p> <p>Presentation of tests individually on screen rather than layered</p>
Patient informed	<ul style="list-style-type: none"> <li>Patient does not call for result</li> <li>Patient is told some results normal, not aware that further potentially abnormal results are to follow</li> <li>Patient is told wrong result (misidentification, wrong record called up)</li> <li>Confidentiality risk, by phone, post or in person</li> <li><b>Patient does not get message</b> (phone/email/letter about abnormal result)</li> </ul>	<p>Test request routinely recorded on computer and regularly audited against completion. Patient informed is part of audit trail to be completed</p> <p>Clinician education on use of DOB/postcode/password before giving info</p>

*(continued)*

**Table 4.2 Potential hazards in laboratory result reporting**

Action	Potential hazard	Possible solution
Follow up of abnormal result	<ul style="list-style-type: none"> <li>• Patient does not understand significance of result and does not follow-up as intended</li> <li>• Patient does not attend follow-up of abnormal result, system not in place to detect this</li> <li>• Patient attends follow-up. One abnormal result noted by clinician but does not notice second abnormality</li> <li>• <b>Important result not followed up</b></li> </ul>	<p>Patient action required (eg send for) logged in computer. Regular audit to check attendance when sent for.</p> <p>All abnormal results highlighted in journal text</p>
Integration with computer alerting systems	<ul style="list-style-type: none"> <li>• Result scanned or added as free text, not in searchable form detectable by computer alerting system</li> <li>• Inappropriate drug prescribed despite biochemical, abnormality.</li> </ul>	Clinician/administration education

## 4.6 CONCLUSIONS

There is a clear relationship between the concepts of eHealth, quality, and safety. Each of these areas has suffered from variability in definitions, epistemologies and terminologies, which represent obstacles to the synthesis of existing research.

Effectiveness is a core construct of the quality concept, which also accommodates efficiency (and cost), access, equity and accessibility. Prevention of harm and identification of error and risks are at the centre of the safety concept, and human and organisational factors (including safety culture) are seen as important contributory factors. Networked data and communications are a pervasive theme within the eHealth concept, and EHRs a core application area. Tools for informing and supporting decisions and aiding clinical practice and patient care at a distance are also central eHealth domains. The multiple objectives of NHS CFH overlap with those of several other NHS technology programmes; notably the National Knowledge Service and NHS Direct Online. The primary focus of NHS CFH is the delivery of networks and tools for supporting healthcare professionals and organisations; however, elements of the Programme are consumer-oriented and there have been recent moves towards integrating remote healthcare within the scope of the programme. Nevertheless, the scope of this project's commissioning brief is firmly located within the former domain.

Evidence of effectiveness is crucial for motivating the adoption of new eHealth applications by clinicians and a primary objective of the review will be to synthesise available evidence on the outcomes of eHealth interventions and identify best-practice adoption and implementation strategies.

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## SECTION 3

# FINDINGS



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## DESCRIPTIVE OVERVIEW OF RESULTS

Our searches revealed a total of 46,349 potentially eligible articles of which 414 satisfied our pre-defined selection criteria (see Appendix 4 for details). Of these, 67 were systematic reviews details of which are summarised in Appendix 5. We also identified 284 trials (ie randomised controlled and controlled clinical trials), details of which are summarised in Appendix 6.

The chapters in this section (Chapters 5–14) draw in the main on evidence from the systematic reviews which have been assessed using the World Health Organization’s Health Educational Network and modified Critical Appraisal Skills Programme criteria (see Executive summary and Appendix 5), but we also, where necessary, draw on evidence from the trials identified and a broader body of technical, descriptive, qualitative and policy relevant work, all of which is referenced in individual chapters, to help contextualise our findings.

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## CHAPTER 5

### Health information exchange and interoperability

#### SUMMARY

- Effective and efficient sharing of clinical information is essential to the future development of modern healthcare systems, which are increasingly characterised by the involvement of many specialist healthcare providers, often working from different sites, contributing to the care of individual patients.
- The ideal in this respect is for professionals and also patients to have the ability simultaneously to access and seamlessly transfer, contribute to and integrate clinical data from disparate sources.
- Health information exchange and interoperability considerations aim to provide a shared platform and syntax by which different types of systems can exchange data seamlessly and enables clinicians and patients to access relevant sections of the electronic health record.
- The potential gains in relation to improving the quality, safety and overall efficiency of healthcare delivery are potentially enormous, as demonstrated by recent US- and UK-based economic analyses.
- Currently, however, most UK healthcare settings are characterised by relatively low levels of exchange and interoperability capability, this being particularly true of the hospital sector, where paper-based records are still the main means of recording and communicating clinical information.
- The National Programme for Information Technology has already begun greatly to increase the potential for health information exchange and interoperability, for example, through the new National Network for the NHS, the central Spine, encouragement of common operational standards such as Health Level Seven and co-operating with the Continua Health Alliance.
- The most important development in this respect will, however, be the deployment of the NHS Care Record Service, which will result in the creation of summary and detailed electronic health records that have the

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potential to be shared, to varying degrees, across healthcare settings and between providers.

- Although Connecting for Health's insistence that new eHealth applications must be Health Level Seven compliant—this referring to a voluntary, but nonetheless widely used standard for interoperability—is undoubtedly welcome, none of the headline National Programme for Information Technology's core applications will, however, achieve the optimum levels of health information exchange and interoperability, with the result that patient safety may continue to be compromised.
- Improving health information exchange and interoperability to the optimal level, so as to allow seamless transfer and access to data in all settings, whilst probably resulting in cost-savings in the longer run, will inevitably require considerable upfront investment in hardware and software capabilities.
- An important paradox to further developments in this area is that whilst increasing levels of interoperability are clearly desirable for many reasons, greater availability of data also inevitably increases the risk of threats to data security and inadvertent breaches of patient confidentiality.
- Key outstanding issues that face healthcare systems in realising the potential for seamless exchange of information include the need to develop and deploy standard coding structures across all care settings, eg using Systematized Nomenclature of Medicine-Clinical Terms, facilitate integration of the increasing amounts of patient-generated data (through HealthSpace, home sensors or telemetry devices, for example), and improve secure audited access to electronic health records to minimise the risks of breaching confidentiality.

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## 5.1 INTRODUCTION

Patients in the majority of economically developed countries now commonly receive their healthcare from a range of practitioners, many of whom work on different sites. For most people this will include health centres, pharmacy practices, dentists, opticians, a variety of hospitals and laboratory services, and occasionally ambulance services. Increasingly, sophisticated self-monitoring and guided self-care is also playing a role.

To a greater or lesser extent all these services and systems hold electronic records for patients (and with electronic self-monitoring the patients hold electronic information themselves). However, generally, such records are effectively held in silos with limited or no ability to interact with one another and little prospect for direct access by the patients and their clinicians to the bulk of these records.

This situation leads to wasted resource through duplication of tests and double entry and increases the risk of errors through delayed diagnosis, lost data and inaccurate data entry. Effective and efficient sharing of clinical information is therefore essential to the future development of modern healthcare systems.

This chapter aims to provide an overview of developing healthcare systems characterised by high levels of health information exchange and interoperability (HIEI) capability, the benefits that are likely to accrue from such developments and the possible risks associated with prompting system change along these lines. The chapter is not intended to be a detailed discussion of the technical infrastructures and ontologies which underpin HIEI (for which interested readers are referred to Coiera's useful introduction<sup>1</sup> or the more detailed review by Tanenbaum<sup>2</sup>), but rather to provide a basis for the key applications being introduced by NHS Connecting for Health's National Programme for Information Technology (NPfIT), which are considered in detail in subsequent chapters in this Section.

## 5.2 DEFINITION, DESCRIPTION AND SCOPE

### 5.2.1 DEFINITION

Health information exchange and interoperability refers to the ability to access, contribute to and integrate data from disparate sources. As defined by The National Alliance for Health Information Technology:<sup>3</sup>

'In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged.'

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### 5.2.2 DESCRIPTION

Health information exchange and interoperability opens the door to clinicians and patients being able to access necessary parts of the patient record. It does this by providing a shared platform and syntax by which different types of systems can exchange data seamlessly. However, the degree to which different systems can interact varies. Walker et al. provide a helpful conceptually driven analytic framework and taxonomy for HIEI, which is illustrated in Box 5.1.<sup>4</sup> This four level taxonomy reflects the amount of human involvement required, the sophistication of information technology (IT) and the level of standardisation needed for different degrees of information sharing capability between healthcare organisations.<sup>5</sup>

### 5.2.3 SCOPE

These considerations are clearly cross-cutting being of relevance to almost any eHealth application. Using this framework, it is clear that most systems in England will, despite the work of NHS CFH and the introduction of NPfIT, for the foreseeable future be operating at Levels 1, 2 or 3. For example:

- **Transfer of records between GPs:** despite the fact that UK primary care has a long history of using the electronic health record (EHR) in the UK, changing GPs has typically necessitated the printing out of the patients' EHR and the manual entry of a summary of this record into the new GPs system, this cumbersome process resulting in the loss of considerable amounts of data (Level 1). Currently most of the 9,000 practices in England deal with approximately 500 patient record transfers each year; inner-city and university practices will deal with far more. Re-entering data creates a huge administrative burden that raises the possibility of omitting important information and transcription errors. More recently, for most practices certain types of attachment (scanned files) can now be transferred, but these cannot be easily integrated with different GP software (Level 2). However, a new system, GP2GP, has recently been piloted by NHS CFH as part of NPfIT and is now being rolled out across England, which permits exchange of data between two of the major computer systems in the UK (In Practice Systems (InPS) and Egton Medical Information Systems (EMIS)). The exchange takes place remotely and automatically on completion of registration. This means that patients records, including, for example, full diabetes and blood pressure records, are available within hours of registration and that as a result many hours and in some cases days of repeat data entry are avoided (Level 3).

There are, however, some problems that still need to be ironed out, these including the fact that the differences between the systems necessitates data “cleansing” and furthermore re-organisation particularly when this involves transfer of data between computer systems. However, even when data transfer occurs between practices that use the same computers systems if they do not always organise their data in exactly the same way.

#### **Box 5.1 A conceptual analytic framework and taxonomy for health information exchange and interoperability**

- **Level 1:** Non-electronic data—no use of IT to share information (for example, ‘snail’ mail and this could also include meetings).
- **Level 2:** Machine-transportable data—transmission of non-standardised information via basic IT; information within the document cannot be electronically manipulated (for example, fax or personal computer [PC]–based exchange of scanned documents, pictures, or portable document format [PDF] files).
- **Level 3:** Machine-organisable data—transmission of structured messages containing non-standardised data; requires interfaces that can translate incoming data from the sending organisation’s vocabulary to the receiving organisation’s vocabulary; usually results in imperfect translations because of vocabularies’ incompatible levels of detail (for example, e-mail of free text, or PC-based exchange of files in incompatible/proprietary file formats, HL-7 messages, (see Glossary).
- **Level 4:** Machine-interpretable data—transmission of structured messages containing standardised and coded data; idealised state in which all systems exchange information using the same formats and vocabularies (for example, automated exchange of coded results from an external lab into a provider’s EHR automated exchange of a patient’s ‘problem list’).

*Adapted from: Walker et al. (2005)<sup>2</sup> Reproduced from Walker et al. (2005) with permission from Project HOPE.*

- **Choose and Book:** this system permits general practitioners and their patients to access hospital appointment systems and make appointments at times to suit them with the hospital of their choice (Level 3).<sup>6</sup>
- **NHS Care Record Service (NHS CRS):** currently under development and undergoing piloting, this will eventually replace the current mix of electronic and paper records held throughout the NHS allowing immediate access to some aspects of the patient’s record (the Summary Care Record (SCR)) from any part of the country and more detailed clinical, laboratory and radiology records (Detailed Care Record (DCR)) to local providers. This will in time allow the integration of decision support functionality for clinicians and patients (Levels 3–4 depending on which aspect of the NHS CRS is being considered; see Chapters 4 and 6 for further details).
- **ePrescribing and the Electronic Prescription Service (EPS):** for most

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patients, prescriptions are generated by computer in their practice printed on paper and taken to pharmacies where the same information is entered into the pharmacy computing system to print labels and maintain a database of their dispensing activity. The paper prescriptions are then sent on to the pricing bureau to be again computer-entered for payment (Level 1). The Electronic Prescription Service being implemented through the Electronic Transmission of Prescriptions (ETP) programme allows for the transmission of prescriptions from GPs and other prescribers directly to pharmacies thus automatically populating their databases for dispensing. Prescriptions are also sent electronically to the Prescription Pricing Authority, the organisation that reimburses dispensers, ie community pharmacies for the medication they have supplied to patients. The system provides a robust audit trail of prescribing activity reduces administrative effort and may reduce errors of transcription. Such ePrescribing systems have the potential to decrease delay in order completion, reduce errors related to handwriting or transcription, allow order entry on or off-site, error checking for duplicate or incorrect doses, and facilitate inventory and posting of charges (Level 3; see Chapter 10).<sup>7,8</sup>

- **Picture Archiving and Communications System (PACS):** until recently radiological images were printed on film and held in hospital records departments. If patients were seen in outpatient departments or wards other locations, eg for a specialist assessment, images had to physically transported with many not arriving in time, if at all, and resulting in repeat investigations or delay in diagnosis. PACS, pioneered by NHS CFH in England allows access to digital centrally stored images within and between hospitals and eventually will permit full interoperability and compatibility with other NPfIT services. It permits, for example, an accident and emergency department to access specialist opinion in another trust and images will, it is planned, also be accessible in some primary care settings. In due course, PACS will be integrated with the NHS CRS removing the cumbersome barrier between images and other aspects of the patient record (Level 3–4).
- **Laboratory results:** while laboratory data are digitally recorded and stored, results are often printed out on paper and sent to those ordering the tests. In many cases these results are scanned and entered into an electronic record; the most relevant data are often manually entered into, for example, the GP patient records (Level 1). Recent developments have provided access to all patients' laboratory results across several hospitals



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and practices (SCI store in Scotland)<sup>9</sup> (Level 2) and for many practices in other parts of the UK results may be downloaded, for example via Pathlinks,<sup>10</sup> directly into practice computer systems with occasional need for modification (Level 3).

## 5.3 THEORETICAL BENEFITS AND RISKS

### 5.3.1 BENEFITS

The examples in the preceding section illustrate the types of benefits that more integrated computer systems can yield. Walker et al., in a review of the potential of HIEI to improve health services in the US,<sup>11</sup> succinctly summarised these (see Box 5.2).

Most of the benefits the authors describe also apply to the UK NHS. In summary, HIEI should save resources through the reduction of administration by ending double- and in some cases triple-entry, preventing duplication of investigation, facilitating more targeted investigation and improving access to records for front-line staff. This improved access to more comprehensive records should also help obviate the problems associated with access to the current fragmented records, which can for example, reduce the risks of errors that commonly occur when people move across healthcare transition boundaries, eg being discharged from hospital back to primary care.

Walker et al. estimated the projected financial benefits in the US based on the impact on laboratory services alone at \$31.8 billion. In their analysis of aspects of interoperability for which they were able to allocate:<sup>12</sup>

‘... dollar values, net savings from national implementation of fully standardised interoperability between providers and five other types of organisations [they] estimate that this could yield \$77.8 billion annually, or approximately 5% of the projected \$1.661 trillion spent on US healthcare in 2003.’

Although a detailed analysis to quantify the patient safety benefits expected from the Programme have not been conducted by NHS CFH, it believes, based on a limited preliminary economic analysis, that this could be worth several billions over in the next 10 years. This estimate includes: ‘£2.5 billion as the human value of preventable fatalities from medication errors arising from inadequate information about patients and medicines; a large proportion of the £500 million spent each year on treating patients who are harmed by medication errors and adverse reactions; a reduction in the payments by NHS Trusts each year (approximately £430 million each year) for settlements made on clinical negligence claims.’<sup>13</sup>

### Box 5.2 The benefits of health information exchange and interoperability

- **Interoperability between both freestanding and hospital-based outpatient clinicians:** this would enable computer-assisted reduction of redundant tests, and it would reduce delays and costs associated with paper-based ordering and reporting of results. In addition, provider-laboratory connectivity would give clinicians better access to patients' longitudinal test results, eliminate errors associated with reporting results orally, optimise ordering patterns by making information on test costs readily available to clinicians, and make testing more convenient for patient.
- **Connectivity between external radiology centres:** this would reduce redundant tests and would save time and costs associated with paper- and film-based processes. Interoperability here could also improve ordering by giving radiologists access to relevant clinical information, thereby enabling them to recommend optimal testing; improve patient safety by alerting both the provider and the radiologist to test contraindications; facilitate coordination of care and help prevent errors of omission by enabling automated reminders when follow-up studies are indicated; and lessen adverse environmental impacts by reducing the use of chemicals and paper in film processing.
- **Out-patient providers and pharmacies:** interoperability between out-patient providers and pharmacies would reduce the number of medication-related phone calls for both clinicians and pharmacists. It would also improve clinical care by facilitating the formation of complete medication lists, thereby reducing duplicate therapy, drug interactions and other adverse drug events, and medication abuse. It could also enable automated refill alerts, offer clinicians easy access to information about whether patients fill prescriptions, and complete insurance forms required for some medications. In addition, it could help identify affected patients in the event of drug recalls, uncover new side effects, and improve formulary management.
- **Provider-provider connectivity:** has the potential to save time associated with handling chart requests and referrals. Connectivity would reduce fragmentation of care from scattered records and improve referral processes.
- **Provider connectivity to the US public health system:** this would make reporting of vital statistics and cases of certain diseases more efficient and complete. However, the most important impact of public health interoperability would almost certainly derive from earlier recognition of emerging disease outbreaks and bio-surveillance, as it becomes easier to identify warning signs and trends by aggregating data from many sources. Since robust quantitative evidence about the value of HIE in earlier recognition of disease and bio-surveillance does not yet exist, we did not project value from these sources<sup>14</sup>.
- **Provider-payer transactions:** these enjoy a relatively high degree of standardisation, largely because of *Health Insurance Portability and Accountability Act*. Some transactions are highly automated but others are not, particularly in smaller organisations.

*Taken from Walker et al. (2005)<sup>2</sup> Reproduced from Walker et al. (2005) with permission from Project HOPE.*

Halmaka et al. suggest that new clinical models, self-care and decision support tools, application and communications software, and even re-designed care practices will emerge within this new integrated environment.<sup>15</sup> They also point out that research and new approaches to prevention and management can be strengthened and the results more rapidly put into practice.<sup>16</sup> As a result,

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there is the potential to facilitate delivery of high quality care, possibly at less expensive, primarily through ensuring that the right knowledge is brought to the right person at the right time. They argue that such technological advances should enable healthcare providers to:<sup>17</sup>

‘...put patients and families at the centre of the healthcare system, supported and surrounded by an information environment that they can use (or allow others to use) to make decisions, monitor health, provide feedback, and support strategic analytic functions that produce measurable improvements in health.’

In discussing the potential impact on patient safety, Kaelber and Bates estimated that developments in HIEI should enable up to 18 per cent of the patient safety errors and as many as 70 per cent of adverse drug events to be eliminated if the right information about the right patient was available at the right time.<sup>18</sup> Improved potential for continuity of care is another important potential benefit of such developments.<sup>19</sup>

The two reviews by Blick (1997 & 2001) are important.<sup>20;21</sup> In the first, (1997) Blick described and gave examples of an expert laboratory computer system that could be designed to handle both predictable and unpredictable data events and suggested that the major motivation for laboratory computerisation and automation should be to improve the total quality and predictability of the laboratory service. In his subsequent review, (2001) Blick looked at HIEI and point-of-care (as known as critical care testing). He concluded that true quality in the clinical laboratory cannot be achieved by focusing primarily on errors in the analytical process. In order to improve the HIEI, laboratories should concentrate on trying to eliminate events that are obvious errors, ie lost specimens, poor specimen or test inquiry and tracking, slow turn-around time, lost reports, and billing errors. Laboratory computer systems ideally need to address all such issues, these including:<sup>22</sup>

- expert systems and coded comments expert systems and the test order
- reflex test order and cancelling results return issues
- clinician inquiry
- laboratory sections requiring expert computer support
- types of expert “actions” being used
- requirements of an expert system
- features of newer expert systems.

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### 5.3.2 RISKS

#### *Movement across geographical boundaries*

The automatic transmission of data relies heavily on adequate identification of patients.<sup>23</sup> In England, patients will in due course have a unique NHS Number (a unique Community Health Index number already exists in Scotland).<sup>24</sup> Therefore, even within the UK, translation algorithms may be required when patients move between different countries. This has also been identified as a major issue in countries that do not have unique identifiers.<sup>25;26</sup>

#### *Transcription errors*

While HIEI reduces the frequency with which data are keyed in and is hence likely to reduce error, the potential to key in the wrong information into the wrong file still exists. When transcription errors occur in systems interacting at Level 1 or Level 2, the necessary human interaction means that at least some check on data is occurring. Obvious errors that a machine may not detect (eg a pregnancy test result wrongly attributed to a 65 year old woman, or the contraceptive pill being prescribed to a man) may go unnoticed unless plausibility checks are incorporated into higher level systems.

#### *Privacy and security*

Security is a major concern. Any system which makes it easier for clinicians and patients to access their data inevitably make it easier for unauthorised individuals to gain access. Similarly, the more people that have access to a patient's record the more risk there is that, whether by accident or design, confidential information will leak. This particular concern has been at the centre of the controversy surrounding NHS CFH's attempts to create a central SCR for every patient.<sup>27</sup> One way around this is to provide levels of access to different providers, for example, drug history and allergy history to pharmacists. However, pharmacists who increasingly are on the frontline of giving advice to patients are seeking fuller access to such records, but this is not popular with patients.<sup>28</sup>

This debate is not confined to the UK. Halmaka et al. point out that consumers and patients in the US are fearful of uses of their personal health information by anyone other than their doctor, noting that:<sup>29</sup>

‘The public is legitimately concerned: Institutions may repair mistakes in financial transactions through economic adjustments, but privacy breaches involving health information can be both extremely hurtful and nearly impossible to undo. Without widespread trust in health information exchange, patients might not tolerate

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increased electronic information sharing among providers, payers, researchers, or others.’

Casual access by clinical staff to unauthorised material is a long recognised challenge.<sup>30</sup> Audit trails and personal logons which can identify unauthorised entry are another option, but in the fast paced environment of hospital wards, GP surgeries and pharmacies it is easy for machines to remain logged on and unauthorised access to occur. While such breaches were always possible, HIEI potentially increases the harm of such breaches.

Secure protocols for transmission of information are essential with a range of organisations signed up to this. N3, the dedicated NHS broadband network, goes some way to providing security from potential breaches from outside the NHS.<sup>31</sup> However, further development of security and access is necessary to minimise the risks of breaching confidentiality whilst at the same time ensuring ready access to those who legitimately require it.

### *System failure*

The risk that failure in one component has a major effect on the functioning of the whole system increases exponentially as systems become more integrated. A practice which keeps a local record will not, for example, be affected by a failure in communication with a central server. Therefore, the HIEI system as a whole, and all its components, must be reliable and be able to assure a uniform, satisfactory level of service quality in addition to running being securely and regularly backed up, so that organisations can rely on the overall system availability. It must provide for real-time access to information, particularly for urgent care specialties such as emergency medicine and intensive care.<sup>32</sup>

### *Considerations relating to Implementation*

As previously mentioned, most UK healthcare settings are characterised by relatively low levels of HIEI; this is particularly true of the hospital sector. Similar problems exist in the US and solutions have tended to evolve locally, but this can create subsequent problems with reluctance to yield ownership of a well known local system to become part of a larger more integrated system with thus no clear ways for HIEI capabilities to easily expand beyond these initial projects.<sup>33</sup> Likewise some vendors who rely on interoperability of their products as a means of generating revenue are likely to see the use of a common platform as a threat. There are parallels here with general practice computing in the UK.

Improving HIEI to the desired level is likely to generate revenue savings in

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the long-run. This will, however, require considerable up-front investment in hardware and software capabilities with early adopters paying the most. There is considerable debate in other countries about to what extent the development of EHR should proceed before agreed systems of HIEI are developed<sup>34</sup> with early adopters of such records fearful that a subsequent standards agreement will leave them stranded with obsolete systems. However, experts in the US strongly advocate the integrated approach, berating the potentially wasted energy in developing local systems.<sup>35</sup>

## 5.4 EMPIRICALLY DEMONSTRATED BENEFITS AND RISKS

We identified two systematic reviews (SRs)<sup>36;37</sup> of variable quality (see Appendix 5). In total, these SRs assessed 92 studies, of which 10 were randomised controlled trials (RCTs), nine were controlled trials, 16 were before-and-after studies and the remaining consisted of other studies (surveys, experimental laboratory and interrupted time series designs). We also identified five reports or overviews<sup>38–42</sup> and three further studies not discussed in the SRs (a prospective study,<sup>43</sup> mixed methods<sup>44</sup> and a before-and-after study).<sup>45</sup> Below we discuss the key findings from these studies.

Empirical studies of the impact of HIEI per se on both economic and quality outcomes are rare. There are, however, complex intervention studies in which HIEI plays a role. For example, Georgiou et al. reviewed current evidence of the impact of computerised provider order entry (CPOE) on hospital pathology services.<sup>46</sup> Nineteen studies were identified which reported 10 areas of impact assessment and 39 indicators used to measure the impact of CPOE on different stages of the pathology test ordering and reporting process. Several studies suggested that CPOE systems are beneficial for clinical and laboratory work processes in particular reduction in test volume, redundant tests and test costs, but they found no evidence of impact on adverse events or safety. Few data are available regarding the impact of CPOE on patient outcomes.<sup>47</sup> They cautioned that the more rigorous RCTs in these studies were limited by being sharply focused on specific wards and units and displayed a technical novelty side to their investigation. It was unclear in many cases where other factors may have influenced the results, as little information was presented about consideration or adjustment for patient case mix, clinician knowledge and experience, or other potential confounders. In addition, many of the studies presented in this review were over five years old; four of them being over a decade old.<sup>48</sup> They concluded that these data are limited, and further research is needed.

The Santa Barbara County Care Exchange (SBCCE) demonstrated how a



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patient's clinical information can be readily accessed by any authorised person, including the patient.<sup>49</sup> In this pilot experimental health information exchange study, Brailer et al. noted that for clinicians, the improvement in quality and service was more important than the direct financial benefits. The authors perceived the costs of missing clinical data and unnecessary duplicated tests as harming their practice and their patients. They also perceived these problems as currently very large and therefore any solution in turn having the potential to yield very large benefits.<sup>50</sup>

One way patient safety might be improved through the improved access to records that HIEI delivers is the checking of the accuracy of records by patients themselves. A survey of patients in relation to patient accessible EHRs found that 69 per cent of patients expressed a willingness to look for errors in their medical record and 63 per cent would track their test results.<sup>51</sup>

In a systematic review of communication between hospitals and family practices Kripalani et al. found that deficit in communication and information transfer at hospital discharge are common, these needlessly jeopardising patient care.<sup>52</sup> They concluded that interventions such as computer-generated summaries and standardised formats may facilitate more timely transfer of important patient information to primary care physicians and consistently make discharge summaries more available for follow-up. Studies were mainly observational but one RCT by van Walraven et al. reported that generation of the discharge summary from a hospital database resulted in a higher percentage of summaries completed at four weeks compared to dictated summaries.<sup>53</sup> The database-generated summaries also were more likely to include many of the items judged important by primary care clinicians, including the main discharge diagnosis (100 per cent vs 65 per cent;  $p < 0.001$ ), pertinent physical findings (99 per cent vs 87 per cent;  $p < 0.001$ ), radiology test results (47 per cent vs 39 per cent;  $p = 0.08$ ), laboratory test results (30 per cent vs 17 per cent;  $p = 0.01$ ), discharge medications (100 per cent vs 93 per cent;  $p < 0.01$ ), medical follow-up (99 per cent vs 95 per cent;  $p = 0.57$ ), and test results pending at discharge (41 per cent vs 9 per cent;  $p < 0.001$ ). Dictated summaries were significantly more likely to include social history (37 per cent vs 6 per cent) and information about consultations (47 per cent vs 19 per cent;  $p < 0.001$  for each).<sup>54</sup>

The study by Brailer et al. in Santa Barbara that implemented a regional HIEI, (including hospitals, public health facilities, pharmacies, laboratories and imaging centres) revealed that the net financial benefit to the community was more than \$1 million per year, this being over-and-above the fully laden cost of deployment and operation of regional data sharing.<sup>55;56</sup> The authors believed



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this to be a conservative estimate as it did not take into account any financial benefits from clinical efficiency changes nor any service or quality benefits.<sup>57</sup> They concluded that there is therefore at face value a moderate return on investment on HIEI, but draw attention to two important considerations:<sup>58</sup>

‘First is that the financial returns are completely related to lowering the volume of manual data handling. This benefit is related to clinician adoption and use. Hence, in HIE, as in every other clinical IT in health care, the key variable is clinician adoption. The workflow simplification in clinician offices induced by HIE creates a strong and unique adoption factor that may spill over to other information tools destined for the clinician’s office. The other consideration is that the overall magnitude of returns is relatively low.’

By considering the breakdown of returns by constituent in the US, Brailer et al. argued that each organisation should bear some cost for implementing and operating data sharing.<sup>59</sup> These costs include all of the internal costs for data integration and implementing data sharing as well as an allocated share of the central infrastructure costs.<sup>60</sup> Each organisation was found to gain from participation in the regional network as a result of having a single place for clinicians to get the relevant data for their patients. Their study thus found overall that every organisation had positive overall returns from regional data sharing.<sup>61</sup>

### *Risks*

Some studies appear to have shown a reduction in patient safety with increased use of eHealth applications. These studies did not, however, focus specifically on HIEI but rather on ePrescribing in relation to electronic medical record systems.<sup>62</sup> One study appeared to show an unanticipated increase in paediatric mortality following the introduction of a commercial ePrescribing system. Multivariate analysis revealed that CPOE remained independently associated with increased odds of mortality (odds ratio: 3.28; 95 per cent confidence interval: 1.94–5.55) after adjustment for other mortality covariables. Additional time was needed to enter orders through CPOE as compared with written form, keeping doctors and nurses away from critically ill children and entering computer data. Before CPOE implementation, antibiotics and vasoactive drugs were administered according to national guideline-recommended timelines. Yet, after CPOE implementation, fewer than half of the patients received critical antibiotics and vasoactive infusions within those timelines. The other was a qualitative study in which clinicians gave examples of how (due to system failure) ePrescribing occasionally resulted in delay in prescribing.<sup>63</sup> Other

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studies have shown no increased risk to patients however (see Chapter 10 for a fuller description of ePrescribing).

## **5.5 IMPLICATIONS FOR POLICY, PRACTICE AND RESEARCH**

### **5.5.1 POLICY**

There are several features of UK practice which are positive for increased HIEI although important challenges remain. There is, for example, strong central government support for increasing interoperability with a recent House of Commons report emphasising the need to press on with this policy.<sup>64</sup> The central procurement of major IT by NHS CFH will allow much greater enforcement of standards nationally in relation to interoperability compared to previously haphazard IT commissioning with numerous systems. All patients in England will soon have a unique identifier, which may then be used to link all their records. NPfIT has furthermore greatly increased the potential for HIEI by investment in N3,<sup>31</sup> and will encourage this further through the deployment of the SCR and DCR, which can and will be shared to varying degrees across healthcare settings.

The adoption of Health Level Seven (HL7)—which is a volunteer organisation that ‘. . .provides a framework (and standards) for the exchange, integration, sharing and retrieval of electronic health information through defining standards, guidelines and methodologies’<sup>65</sup>—by NHS CFH is also an important development.<sup>66–68</sup> The HL7 version 3 messages and clinical document architecture are used by the NHS to facilitate the transfer of information.<sup>8</sup> Importantly, this standard is being adopted internationally, in Australia by the National EHealth Transition Authority for example.<sup>69</sup> However, alternative systems such as OpenEHR<sup>70</sup> also have strong support and are gaining ground in many European countries.

While ensuring complex computable semantic interoperability will continue to pose significant problems to healthcare IT<sup>71</sup> security and confidentiality also remain a challenge and further developments need to be encouraged to reassure both clinical staff and the public that information, widely available to many different groups within the NHS, will remain secure.

### **5.5.2 PRACTICE**

Up to £90 million has been made available to support systems integration to enable any suppliers in the NHS to test the integration of their software with the proposed Spine.<sup>72</sup>

One of the key challenges that face healthcare systems in realising the potential

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for seamless exchange of information is the development and deployment of standard coding structures across all care settings. Currently, in the UK, different codes are used by hospitals and different primary care computing providers. However, NHS CFH, with strong central backing, has adopted the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) system.<sup>73;74</sup> This is a common computerised language that will be used by all computers in the NHS to facilitate communications between different healthcare professionals. It is a joint development between the NHS and the College of American Pathologists to create an agreed terminology and is likely to be widely adopted internationally. It has greater depth and coverage of healthcare than other versions of clinical terms such as Read codes and will facilitate the exchange of healthcare and clinical knowledge by clinicians, researchers and patients worldwide.<sup>73;75</sup>

One of the real opportunities for the future of healthcare, but an important challenge to integrated care, is the growth of patient-generated data from telemetric devices. The Continua Health Alliance is attempting to standardise protocols and improve interoperability of such devices and NHS CFH is an important member of this consortium.<sup>76</sup>

It is clear that the current policy of encouraging HIEI through the rigorous setting of standards, through contractual arrangements, for software and hardware intended to link with the SCR has been shown to be effective, particularly in primary care computing systems (eg GP2GP) and such arrangements should continue. This development and the sign-up to the Continua Health Alliance are important. The creation of a national authority to oversee this, along the lines of the Australian National EHealth Transition Authority,<sup>69</sup> could, however, greatly facilitate the move towards greater interoperability and should be considered by NHS CFH.

Part of the reasons underpinning the success of GP2GP has been the close liaison with general practice representative bodies such as the British Medical Association's General Practitioners Committee and the Royal College of General Practitioners on the GP2GP Project Board, this dating back to the outset of the project. Such liaisons in general practice and other parts of the NHS are important in facilitating the introduction of innovations such as HIEI (see Chapters 15 and 16).

Staff training is of central importance, particularly when introducing new ways of working such as GP2GP. Ideally, there should be a dedicated team of trainers that work with practices, as well as a dedicated helpline for GP2GP, as shown in the Bury Primary Care Trust case study.<sup>68</sup> GP2GP still needs to be rolled out to other practice systems to obtain universal coverage across England.

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### 5.5.3 RESEARCH

While there is little applied research assessing the effectiveness of developments in this area, there is general expert agreement and some evidence from pilot projects that the introduction of HIEI will benefit patients and in the long term reduce costs to health services through decrease in duplication of effort, reduction of error and more timely diagnosis and management. Most UK healthcare settings, however, are currently characterised by low levels of HIEI, particularly in hospital practice.

It is clear that further research to identify both the benefits and costs of HIEI and the barriers (eg concerns regarding confidentiality and commercial interests) and facilitators to its implementation are required. Both qualitative and quantitative approaches to investigate these issues would be appropriate, ideally conducted, in the UK within the context of the national roll-out of the NHS CRS. Events such as errors are currently poorly recorded, but numbers of laboratory and radiology investigations are well recorded and may be relatively easily studied using before-and-after studies, while qualitative approaches to explore barrier issues with purchaser, vendors and users of the systems would also be helpful. Research on how patient-generated data can easily be incorporated into the EHR and how these are then synthesised and made use of is also necessary.

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## CHAPTER 6

### Electronic health records

#### SUMMARY

- The electronic health record is a complex construct encompassing digitised healthcare records and the information systems into which these are embedded.
- Multiple terms have been used to describe different types of electronic health record and there is no single agreed taxonomy.
- Electronic health records lie at the heart of eHealth implementation plans around the world, and are a core feature of NHS Connecting for Health's National Programme for Information Technology. The long-term vision is for a fully integrated, longitudinal, patient record, supported by universal data and interoperability standards and high level communication and decision support technologies; this is, however, some way from being realised.
- Electronic health records have the potential to improve the accuracy of healthcare documentation and information transfer; electronic health records that integrate decision support may also improve clinical decision-making, enhance health promotion activities, and reduce medical errors.
- However, despite the many theoretical benefits of electronic health record systems, previous studies have yielded mixed evidence of their effectiveness and long-term economic appraisals are generally lacking.
- Empirical evidence demonstrates that clinicians perceive the electronic health record favourably.
- The benefits of electronic health records appear to depend greatly on the quality of the implementation process, and extent to which decision support is integrated
- The quality of data recorded in electronic health records varies widely, due to a range of socio-technical factors surrounding individual users and variations in the mechanisms and practice of data coding. Standardised and widely accepted measures of data quality in electronic health records are lacking but the introduction of the Systematized Nomenclature of



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Medicine-Clinical Terms has potential to improve the consistency of clinical coding across the NHS.

- Many of the practical benefits of electronic health records in improving quality of care, patient safety and public health may arise from the secondary use of data for health monitoring, planning and research. However, this gives rise to multiple ethical and technical challenges and relatively little is still known about public attitudes to secondary uses of such data.

## 6.1 INTRODUCTION

The implementation of electronic health records (EHRs) is a core objective of national and organisational eHealth strategies worldwide, including that of NHS Connecting for Health's (NHS CFH) National Programme for Information Technology (NPfIT).<sup>1</sup> This reflects a growing recognition of the potential benefits of EHRs for healthcare quality and efficiency, as well as its central importance for the delivery of eHealth systems and services, as illustrated in the conceptual maps in Chapter 4.

This chapter reviews the development of the EHR, considers the theoretical benefits and risks associated with their introduction and uses this background to review the empirical evidence investigating their impact on quality, safety and organisational efficiency. The literature on personal health records will be considered in a follow-up to this report.

## 6.2 DEFINITION, DESCRIPTION AND SCOPE

The EHR is a complex construct encompassing different types of digitised medical and healthcare records and the information systems into which these are embedded. Multiple terms have been used to describe different aspects of the EHR and it has been difficult to achieve universal consensus on a single taxonomy.

The EHR has been defined in terms of data, eg '...an individual patient's medical record in digital format';<sup>2</sup> databases, eg '...a repository of information regarding the health of a subject of care, in computer processable form';<sup>3</sup> and systems, eg '...a computerised patient information system'<sup>4</sup>—although more comprehensive definitions recognise all of these components. Box 6.1 illustrates prominent US and UK policy definitions, which are broadly compatible. These emphasise the role of the EHR as the integrator of patient information across time and between providers, although, to an extent, this objective still represents a vision rather than reality.

### Box 6.1. US and UK Government definitions of the electronic health record

**Electronic health record:** a longitudinal collection of patient-centric, healthcare information, available across providers, care settings, and time. It is a central component of an integrated health information system. [Source: US Institute of Standards & Technology. <http://www.itl.nist.gov/div897/docs/EHR.html>]

Electronic health record: the concept of a longitudinal record of a patient's health and healthcare to combine information from primary healthcare with periodic care from other institutions [Source: UK Department of Health. <http://www.dh.gov.uk/Home/fs/en>]

*Source: Pagliari et al. (2005)<sup>5</sup>*

Box 6.2 illustrates a range of related terms that have been used to describe EHR.

### Box 6.2 Examples of terms used to describe types of electronic health record

- **electronic medical record (EMR), electronic patient record (EPR) computerised medical record (CMR), computer-based medical record (CBMR), digital medical record (sometimes reserved for web-based records):** Broadly equivalent terms used to describe digitally stored patient records, including those created on computer or transcribed or scanned from paper records. Usually refers to information from single providers (eg a GP practice, a diabetes clinic, a hospital), but often used interchangeably with EHR.
- **integrated care record (ICR):** A record that contains information from multiple providers of the patient's care. Varies in how the information is integrated (eg centralised data storage versus linkage to federated data stores), how much information is integrated (detailed or summary), and the scope and providers of the information (eg an integrated diabetes care record vs a more generic shared care record.)
- **longitudinal health record (LHR):** Occasionally used to describe the EHR.
- **continuity of care record (CCR):** An evolving standard for a core (summary) electronic record that can be accessed by and added to by multiple health professionals caring for a patient, so as to support integrated and current care.
- **interoperable electronic health record (IEHR):** One term for complex EHR that can interface with a range of records systems, databases and tools for decision-making and communication.
- **personal health record (PHR):** Sometimes referred to as electronic patient carried medical records (PMR), these refer to records that are accessible by the patient themselves. These vary in locus of control (patient or provider as controller of data), medium (eg smart card, PC, web) and extent of integration with provider-held EHR systems.

At the heart of the EHR are individual patient records; often referred to as electronic patient records (EPRs). These vary on multiple dimensions, including level of detail (from summary to detailed care records), data source (single- or multiple-provider) and timeframe (eg episodic or longitudinal). As well as patient histories and details of recent care (which may include natural

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language and diagnostic codes), these records may incorporate digital images and scanned documents. The broader EHR also includes non-medical data relevant to healthcare administration and or planning.

Increasingly, EHR are incorporated within complex systems that integrate a range of other functions for supporting communication, decision-making and task management, in addition to documentation (eg order entry, clinical decision support, clinical messaging, results reporting, scheduling, referrals). In some countries functions for billing patients or insurers are a key part of EHR systems. Although this is not the case in the NHS, relevant functionality may need to be incorporated to meet the needs of Practice Based Commissioning and Payment by Results.

In an attempt to differentiate the EHR from the EPR, previous Department of Health reports<sup>6</sup> have defined the EPR as a record of a patient's contacts with one healthcare provider, such as a general practice, and an EHR as a record of their overall health and healthcare, which combines information stored in EPRs held by different healthcare providers, such as general practices, community services, and hospitals. However, many reports and studies do not make this distinction.

The long-term vision for a fully integrated (cross-sectoral), longitudinal, (“cradle to grave”) patient record, supported by universal data and interoperability standards and high-level communication and decision support technologies is shared by the UK Department of Health,<sup>7</sup> in common with international agencies such as the US Institute of Medicine, although this is still some way from being realised.<sup>8</sup> In the UK, single-provider EPRs are still the most common format (general practice, clinic, hospital). However, the advent of the NHS Care Records Service (NHS CRS) promises increasingly greater integration and the imminent roll-out of the Summary Care Record (SCR), which may be accessed by multiple stakeholders caring for the patient (and by the patient themselves), represents a significant step forward (see Chapters 3 and 14).

Nevertheless, EHR are well embedded in some parts of the NHS, particularly in general practice. Most general practices in the UK are now computerised to some extent, with many practices now “paperless” or “paper-lite”. Such systems are available from many vendors and there is some variation in functionality between them; however, all primary care systems generally cover seven broad areas (see Box 6.3).

In addition to general practice computing systems, detailed clinical information may also be held in specialist clinical databases and disease registers based in secondary and tertiary care, with more basic information being held

in hospital patient administration systems. These records have historically been maintained separately, due to the absence of a single, reliable, definitive means of recording and sharing up to date patient demographic information.<sup>9</sup> This situation is set to change with the implementation of the NHS Number—a unique patient identifier which will be applied to all healthcare transactions in order to facilitate data linkage and thus integrated care records.

**Box 6.3 Classes of data captured within electronic health record systems in UK primary care**

- administrative and demographic information, such as name, age, date of birth, NHS number, address and telephone number
- clinical and diagnostic information in the form of Read coded data
- results of laboratory and radiological investigations; and measurements such as height, weight, Body Mass Index (BMI), and blood pressure
- information on prevention of disease and screening, such as immunisations, cervical screening, smoking status and alcohol intake
- prescriptions issued using the EHR system
- free text entered during consultations
- image files of documents scanned after being received from external agencies such as hospitals and social services.

The NHS CRS envisages a patient-centred record, designed to improve access by health and social care professionals where and when they are needed, provided they have legitimate relationships, as well as giving individuals secure access to their own health record via the Internet.<sup>10</sup> This is set within a more complex architecture of centralised (summary) and localised (detailed) care records, as described in detail in Chapter 3. The NHS CRS will be supported by the high speed New National Network for the NHS (N3), the National Data Spine and the Personal Demographics Service;<sup>9</sup> the Secondary Uses Service will provide controlled access to aggregated data for management, research and other non-clinical purposes.<sup>9</sup>

As already noted, EHR lie at the heart of IT implementation plans in healthcare systems around the world and Box 6.4 summarises three examples considered in the recent *House of Commons Report on Electronic Patient Records* (Box 6.4).<sup>9</sup>

#### Box 6.4: Examples of other countries embarking on important electronic health record projects

- **Canada:** A Private Lifetime Record for each citizen is being created and is being co-ordinated by Canada Health Infoway that aims to create an electronic record for 50% of Canadian citizens by the end of 2009.
- **France:** A Dossier Médicale Personnel was passed in June 2004, which will include a collection of health information to be viewed online. Patients will have their own access and will legally own their record.
- **United States:** Several integrated electronic records systems already exist and in 2004, President Bush established that electronic health records would be available for “most” US citizens by 2014.

*Source: House of Commons Report (2007)<sup>9</sup>*

## 6.2 THEORETICAL BENEFITS AND RISKS

### 6.2.1 BENEFITS

The substantial international investment in EHRs and related eHealth applications is predicated on the assumption of the development of accurate and readily accessible electronic patient records will improve the quality, safety and efficiency of healthcare (Table 6.1).

The fundamental premise is that clinicians require comprehensive and accurate data on patients at the point-of-care if they are to provide high quality health services. Electronic health records can aid this objective by dispensing with the need to use difficult to access, and often illegible, paper-based records. The improved record keeping, legibility and access afforded by EHRs can help to avoid the inconvenience of lost records, data recapture and re-entry and mitigate the risk of recording and prescribing errors, thus improving the appropriateness and safety of patient management. By facilitating the secure exchange and sharing of patient information, an EHR can support shared and continuous care both within single healthcare episodes (eg hospital admission and supported discharge) and over time (as in the management of long-term illnesses). An EHR with integrated decision support can help providers improve the quality of clinical decision-making, guideline compliance, aid preventive care and reduce utilisation of services and costs of care.<sup>11–13</sup> (See also Chapters 8 and 10).

Electronic health records can also aid patients more directly, by making information about their health much more readily accessible, thus allowing them to become more active in the provision of their own healthcare and the improvement of their health.<sup>14</sup>

In addition to supporting healthcare delivery, electronic databases derived

from an EHR have many secondary uses; for example they can improve the administration, management and quality control of healthcare through facilitating clinical audit and the monitoring of service use; contribute to public health by identifying health inequalities and trends; support patient safety through pharmacovigilance and other risk monitoring; and aid research into the impacts of new healthcare interventions and the scientific study of disease aetiology and drug effects (see also Chapter 8).<sup>15;16</sup>

**Table 6.1: Key theoretical benefits of electronic health records**

Attribute	Benefit
Immediate and universal access to the patient record	Increased efficiency (eg reduced time spent pulling charts, and duplicate history-taking etc). Increased quality (better information at the point-of-care)
Easier and quicker navigation through the patient record	More efficient point of care assessment and data abstraction
Increased legibility and comprehensiveness, through computer-aided history taking systems and better formatting (eg templates)	Better quality information to aid clinical decision-making and shared care; fewer errors in patient management (eg mis-prescribing)
Secure record keeping	No lost records, fewer unnecessary waits or missed appointments, aiding informed patient care. Patient satisfaction.
Standardisation of care among providers within the organisation	Through better recording and sharing of information and linkage to CDSS
Reduction of paperwork, documentation errors, filing activities	Removes duplication, reduces processing time, decreases personnel costs
Coding efficiency and efficacy	Improved data quality
Alerts for medication errors, drug interactions, patient allergies	Safer patient care
Ability to electronically transmit information to other providers (assessments, history, treatments ordered, prescriptions, etc.)	Fewer delays, more efficient and integrated patient care. Enhanced patient satisfaction.
Availability of clinical data for use in quality, risk, utilisation, analyses	Better monitoring of quality and efficiency
Availability of non-clinical data	Easier management of costs, performance and workflow
Availability of data for research	With downstream benefits for patient care
<i>Adapted from: Healthcare Information and Management Systems Society (2007)<sup>17</sup></i>	



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### 6.2.2 RISKS

It is, however, important to recognise that the introduction of an EHR may also have unintended consequences. As illustrated in Chapter 4, the EHR and other eHealth applications have potential to introduce error and risk at many levels, including the user (via inappropriate system operation and interpretation of outputs), the computer (via poor interface design or usability leading to missed readings or alerts), the underlying knowledge-bases (eg faulty decision support algorithms) and the infrastructure (eg poor system reliability leading to missed alerts or information exchange).

One of the major sources of risk is related to the quality of the data held within an EHR. As previously indicated, EHRs lie at the heart of eHealth systems, with related functionality such as ePrescribing, decision support, and computerised order entry, utilising the data in the EHR. The accuracy of the data stored in the EHR is thus a key factor in ensuring that an EHR will be used effectively. There are currently large variations in the accuracy and completeness of information recorded in EHRs by clinicians. For example, in the UK, disease prevalence and specialist referral rates, based on information derived from an EHR, vary widely between general practices. The scale of the variation is so large that a significant proportion of the variation is likely to be due to differences in the accuracy of the data recorded.<sup>18</sup> A second issue with data quality arises with the information stored in 'legacy' paper records. Unless this information is summarised and entered into EHRs, the EHR will not give an accurate and complete record of a patient's medical history (see Chapter 7 on computer history taking systems).

Patients' access to their EHR has the potential to mitigate some of these risks by enabling individuals to identify errors in their record. Access to the SCR via HealthSpace is planned in early adopter sites (see Chapter 14) and access to the GP record has been provided in some UK practices.

Electronic health records often incorporate computerised decision support systems that can potentially reduce errors of omission and commission at the point of care and which can be a critical safety advantage. Siderov noted that although the AHRQ has endorsed several IT interventions that promote patient safety (such as error tracking and alerts about the timing of tests), the AHRQ's *20 tips to help prevent medical errors* fails to mention the use of the EHR.<sup>19;20</sup>

Siderov observed that inpatient medication errors occur at a rate of 142 per 1,000 patient days.<sup>19;21</sup> Both EHR-based decision support and ePrescribing have the potential to decrease these errors and reduce costs.<sup>19</sup> Also, rapid retrieval of medication lists is a beneficial attribute of these systems. However, ePrescribing



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and the EHR are not synonymous and ePrescribing can be implemented without the use of an EHR.<sup>19</sup>

Electronic health records may also have unintended influences on softer variables, such as aspects of the clinical consultation. For example, based on an ethnographic study, Ventres et al. demonstrated that using an EHR in the consulting room influences both cognitive and social dimensions of the clinical encounter.<sup>22</sup>

### **6.3 EMPIRICALLY DEMONSTRATED BENEFITS AND RISKS**

Although the case for an EHR is in many ways persuasive, robust evidence of their benefits is more elusive. A recent overview of the field concluded that most EHR policies are based on attitudes regarding the optimistic value of the EHR instead of the available observed evidence and that few assessments of the impact of an EHR on clinical work have been reported in the literature.<sup>23</sup>

We identified seven systematic reviews (SRs) that address the associations between EHR and healthcare quality and safety (see Appendix 5). The seven SRs dealt with the quality of care,<sup>24;25</sup> the impact of the EHR on the efficiency of the use of the time of clinicians and nurses;<sup>26</sup> measures of data quality within an EHR in primary care<sup>27</sup> and the quality of morbidity coding in general practice.<sup>28</sup> These are summarised in Table 6.1. The reviews were conducted around the EHR and clinical care (eg delivering evidence-based healthcare,<sup>23;29</sup> patient safety,<sup>30</sup> outcome analysis of healthcare<sup>31</sup> and management and analysis of EHR data),<sup>32</sup> clinical conditions (eg diabetes),<sup>33</sup> as well as cost-effectiveness.<sup>19</sup> Hence, as with literature on other areas of eHealth such as CDSS, the EHR literature encompasses a broad range of uses. It is important to recognise that, keeping with the complexity of the EHR as a topic, existing SRs and the empirical studies which they analyse, vary in scope. For example, some concern digital patient records in single organisations, whilst other concern multi-functional EHR applications or large organisational implementations.

**Table 6.2: Evidence from systematic reviews on electronic health records**

Author	Definition	Aim	No. studies	Key results	Conclusion
AHRQ report, Shekelle et al. <sup>13</sup>	EHR	To systematically review evidence on the effect of HIT on quality, efficiency, and costs of healthcare	257	EHR is more frequently examined in the outpatient setting; after implementation of the EHR, there was a relative decrease of 9% for total office visits; there is an absence in the literature of key data on the financial context of capitation believed to be an important factor in defining the business case for EHR use	The benefits of IT appear to depend greatly on the quality of the implementation and the level and type of decision-support technology. One potential benefit of EHR systems is a reduction in morbidity through improved patient safety
Clamp and Keen	EHR	To summarise literature about the value of EHR	70	Positive evidence of process change associated with EHR; evidence that EHR can increase time costs, particularly for clinicians; In many papers the evidence was not decisive; no compelling evidence that EHR reduce the incidence of adverse drug events, or that the introduction of EHR increases or decreases consultation time.	The positive effects of EHR in some specific clinical settings are clear, but there are many areas where the understanding of costs and effects is limited
Delpierre et al. <sup>25</sup>	CBPRS	To analyse the impact of EHR on medical practice, quality of care, and user and patient satisfaction	26	Use of a EHR was perceived favourably by clinicians; a positive impact of EHR on preventive care was found; evaluations found that positive experiences were as frequent as experiences showing no benefit; no study analysing the impact of EHR on patient outcomes reported any benefit	EHR increased user and patient satisfaction, which might lead to significant improvements in medical care practices. However, the studies on the impact of EHR on patient outcomes and quality of care were not conclusive. Alternative approaches considering social, cultural, and organisational factors may be needed to evaluate the usefulness of EHR

Table 6.2: Evidence from systematic reviews on electronic health records continued

Author	Definition	Aim	No. studies	Key results	Conclusion
Hogan and Wagner <sup>87</sup>	CPR	To review the published evidence on data accuracy in EHR	20	Studies reported highly variable levels of accuracy; variability arose from differences in study design, in types of data studied, and in the type of EHRs; differences confound interpretation in the literature	This review showed that the understanding of data accuracy in EHR does not correspond with its importance. Description and accuracy in EHR must be measured, and ways to improve it must be investigated
Jordan et al. <sup>28</sup>	EPR	To assess the completeness and correctness of morbidity coding in computerized general practice records in the UK	24	Variation in the methodology and quality of studies, and problems in generalisability; A consistent finding was that quality of recording varied between morbidities.	Completeness and correctness of data entry may rely on the enthusiasm of individual practices and of general practitioners. Hence, variations in the accuracy of EHR will be present among general practices. Like Thiru et al., they noted the lack of well defined data quality standards and the need to correct this if better measurement of data quality in primary care EHR was to be established
<i>(continued)</i>					

Table 6.2: Evidence from systematic reviews on electronic health records continued

Author	Definition	Aim	No. studies	Key results	Conclusion
Poissant et al. <sup>26</sup>	EHR	To examine the impact of EHRs on documentation time of physicians and nurses and to identify factors that may explain efficiency differences across studies	23	The use of bedside terminals and central station desktops saved nurses, respectively, 24.5% and 23.5% of their overall time spent documenting during a shift; Studies that conducted their evaluation process relatively soon after implementation of the EHR tended to demonstrate a reduction in documentation time in comparison to the increases observed with those that had a longer time period between implementation and the evaluation process	This review highlighted that a goal of decreased documentation time in an EHR project is not likely to be realised. It also identified how the selection of bedside or central station desktop EHRs may influence documentation time for the two main user groups, physicians and nurses
Thiru et al. <sup>27</sup>	EPR	To systematically review measures of data quality in EHR in primary care	52 studies (primarily descriptive surveys)	Variability in methods prevented meta-analysis of results Prescribing data were generally of better quality than diagnostic or lifestyle data	The lack of standardised methods for assessment of quality of data in electronic patient records makes it difficult to compare results between studies. Studies should present data quality measures with clear numerators, denominators, and confidence intervals. Ambiguous terms such as "accuracy" should be avoided unless precisely defined.

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### 6.3.1 IMPACTS OF ELECTRONIC HEALTH RECORDS

As part of their wider systematic review on the impacts of healthcare IT on healthcare quality for Agency of Health Related Quality (AHRQ), Chaudhry et al.<sup>24;34</sup> examined and synthesised the available research evidence on the impact of EHR on quality of care in outpatient settings. From their database of 257 articles, they identified 96 studies that related to EHR and met their inclusion criteria of evidence on eHealth and the ‘...quality, safety, efficiency and costs of health care’. The authors found a number of studies on laboratory investigations of documentation, or the entry of orders, and how they impacted upon point-of-care alerts and reminders embedded within an EHR applications.<sup>11;35–41</sup> It was also found that the EHR, when properly implemented altered clinicians’ ordering behaviours, promoted efficient resource utilisation and avoided repetition of diagnostic testing (see also Chapter 8).<sup>42–45</sup>

A number of identified studies demonstrated positive effect of an EHR on provider productivity,<sup>46–48</sup> and patient safety.<sup>47</sup> For example, one study of a hospital-based EHR system incorporating ADE detection and reporting capability, demonstrated improved detection of ADEs and increased patient safety (see also Chapter 8).<sup>49</sup>

The randomised controlled trial (RCT) by Tierney et al.<sup>13;50</sup> demonstrated the positive effects on ‘...resource utilisation, provider productivity, and care efficiency an EHR’ when combined with integrated ePrescribing.<sup>11–13</sup> Subsequently, EHRs with integrated decision support improved the quality of documentation, clinical decision-making and guideline compliance, thus reducing the costs of service provision.<sup>13</sup> The AHRQ report drew attention to the self evident point that the benefits of IT were dependent on the type of decision support technology and the quality of implementation.<sup>23;51</sup>

In their recent narrative synthesis of the evidence, Clamp and Keen adopted a broad definition of the EHR. Drawing on systematic reviews by Poissant et al.<sup>25</sup> and Delpierre et al.,<sup>23</sup> they identified five methods commonly used to evaluate EHRs: experimental designs; economic evaluations; surveys; narrative observational methods; and predictive modelling of cost-savings. Their analysis also revealed that existing studies have examined four main effects of the EHR, namely direct patient outcomes, clinician or administrator work patterns, and the time costs of undertaking specific tasks (eg entering data into patient records), and costs and cost-savings.<sup>26</sup>

Clamp and Keen found the evidence-base on the impact of the EHR to be disappointing, partly because of the small number of high quality papers and partly because of the poor design of existing studies. None of the published

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studies provided adequate contextual information to allow complete evaluation of the evidence presented. They noted that study designs often reflected researchers' assumptions that it is possible and desirable to capture the costs and effects of an EHR by studying it in a single setting, whereas an EHR occurs within complex networks and impacts may not be detectable at the point of intervention.<sup>52</sup> The papers they identified tended to support two theories of change: that the EHR can have a direct impact on clinician behaviour; and that it can influence communication patterns and the quality of communications (see also Chapter 5 on health information exchange and interoperability). Only one paper by Laerum et al. compared different EHR systems with one another.<sup>23</sup> There were no studies which actually sought to capture all of the costs and benefits associated with an EHR at the level of a process or within a single hospital setting. Clamp and Keen did not find any studies that showed other possible mechanisms by which EHR use influenced behaviour at the micro level or any effect on patient outcomes. Moreover, they found no technically reliable evidence on the cost changes associated with EHR use. Also, they did not find any studies on the "macro" effects; such as effects on economies of scope and scale, even though there is comparable evidence from other contexts.<sup>26</sup>

Clamp and Keen also identified a range of unintended effects of EHRs, as described in the review by Poissant et al.<sup>23</sup> and several other papers, including increases in time costs for clinicians, clinician dissatisfaction, and poor use of available functionality. They also found no strong evidence that EHRs reduce the incidence of ADEs, or that the introduction of EHR changes consultation times. However, in many papers, the evidence was not decisive.<sup>26</sup>

Poissant et al.<sup>26;53–60</sup> reviewed evidence of the impact of the EHR on the efficiency of time use by clinicians and nurses. Outcomes assessed included differences in processing time arising from computer and paper-based documentation, direct patient care time,<sup>50;55;57;61</sup> user satisfaction,<sup>53;57;62</sup> accuracy of information,<sup>54;57;63–66</sup> completeness of data entered<sup>50;58;67;68</sup> and overall impact on workflow.<sup>26</sup> Out of 63 papers assessed, 40 failed to meet the minimum requirements for review with the most common reason being unavailable or limited information on methodology. The 23 papers that met the inclusion criteria included five RCTs, six post-test control studies and 12 one-group pre-test post-test designs. A large number of these studies (58 per cent) used a 'time and motion methodology' to collect their data as opposed to 'work sampling' (33 per cent) or 'self-report or survey methods' (8 per cent).<sup>50;69–74</sup>

The authors conclude that there are time savings for nurses, but not doctors; possibly due to differences in the types of information the two groups record;

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and this pattern does not change with increased use. In addition, retrieval time for doctors was also found to increase. However, improvements in technology make it difficult to compare systems developed 20 years or more ago with those developed more recently. These results illustrate that time savings are not always guaranteed and it may be premature to use this promise as a means of encouraging EHR implementation. More research, using rigorous methods, is required to conclusively demonstrate the impact of an EHR on time efficiency.<sup>26</sup> Poissant et al. also concluded that those studies that carried out their evaluation process straight after the implementation of an EHR system showed a decline in time taken for documentation whereas increases were found for those that had a longer time period between their evaluation and their implementation. They point out that this:<sup>25</sup>

‘. . . may represent a ‘Hawthorn effect’, with a change in a system (in this case, the introduction of an EHR) leading to improvements in efficiency that then decrease over time as the intervention becomes more established and is no longer an innovative intervention.’

A systematic review of EHR use and quality of care by Delpierre et al.<sup>61;75–82</sup> found 26 articles, (corresponding to 25 studies). Several study designs were used: 9 were RCTs,<sup>83–92</sup> 11 were before-and-after studies,<sup>52;65;93</sup> 3 were cross-sectional studies<sup>94;95</sup> and two were based on qualitative interviews.<sup>25</sup> They found mixed results from these studies, but that studies demonstrating the impact on preventive care to be positive (as shown by other SRs). Inconsistent evidence was found in the advancement in medical practice and the adoption of clinical practice guidelines. They also found six studies that did not show any benefit of EHRs on patient outcomes.<sup>19</sup>

Siderov<sup>19;96</sup> reviewed the evidence on the costs and limitations of EHRs and discussed the case for the EHR (Box 6.8). He notes that EHR promise to transform the efficiency, quality and patient acceptability of medical practice through enhancing patient-centeredness, shared decision-making, group visits, open access, outcome responsibility, chronic care, and other disease management. However, he cautions that simply adding such interventions to current paper-based record systems may not address the problems of poor efficiency, inappropriately high costs, inconsistent quality of care, and the risk of malpractice.



### Box 6.5: Positive aspects of EHR

- **Worker productivity gains:** The evidence for this is unclear. Where Poissant et al.<sup>28</sup> showed EHR increased documentation time among clinicians by approximately 17%, Garrido et al.<sup>97</sup> demonstrated that EHR implementation at Kaiser Permanente resulted in a 5–9% decrease in office visits replaced by telephone contacts. If the EHR consistently reduced labour costs in the US, the lower staffing ratios should enable insurers to reduce their fee schedules among EHR-enabled providers. Although there is little evidence that this is occurring among the 17% of practices (in the US) possessing an EHR.
- **Billing optimisation (in the US):** Where increased billings are a likely outcome and that EHR enhancements could increase healthcare costs without any corresponding increase in quality.
- **Medical mistake avoidance:** As Siderov<sup>19</sup> points out:

‘EHR advocates point to “decision support” that reduces errors of omission and commission at the point of care as a critical safety advantage.’

But the available evidence is mixed.

- **The cost of quality:** cost savings associated with the EHR’s quality-based interventions vary and occupy time lines extending beyond one year. Accordingly, if the EHR leads to increases in such interventions, more lives saved will come at a heavy price.
- **Malpractice reduction**
- **Storage of data:** medical records are notoriously vulnerable to damage or disappearance. For instance, the destruction by Hurricane Katrina’s on the Gulf Coast clinician office practices is as an example of the need for electronic medical information storage.<sup>22</sup> However, as pointed out by Siderov, Hurricane Katrina’s cost was not factored into any of the previous savings estimates. Furthermore, the history remains a time-honoured and reimbursable feature of every clinician-patient encounter.
- **Impact on outcomes:** in addition to the EHR’s individual impact, the technology should also facilitate aggregate outcome studies. Patient registries could presumably be tapped for population-based, real-world research; quality improvement studies; or cost effectiveness analyses.

*Reproduced from Siderov (2006) with permission from Project HOPE.<sup>19</sup>*

Siderov concluded that EHR-based clinical decision support had no effect on adherence to primary care guidelines for asthma or angina management; leads to ‘variable’ and ‘limited’ adherence to diabetes and coronary artery disease reminders; had no effect on evidence-based interventions for heart disease and heart failure; caused no change in the care of patients with depression; led to ‘unwieldy’ tracking and monitoring of preventive health and chronic illness; and had no impact on diabetic control.<sup>19</sup> Siderov gives a number of possible explanations for the lack of consistency in research findings. For example, excessive testing may have less to do with inaccessible data than with defensive medicine, ease, or fear of uncertainty—all factors that EHR use is unlikely to influence.<sup>97</sup>

One stand-alone study, not included in any of the SRs in Table 1 was a recent cross-sectional study by Linder et al. that assessed the association between EHR

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use, as implemented, and the quality of ambulatory care as delineated by 17 quality indicators. Worryingly, for 14 of the 17 quality indicators, there was no significant difference in performance between visits with vs without EHR use and for one quality indicator, EHR use resulted in significantly worse quality: statin prescribing to patients with hypercholesterolemia (33 per cent vs 47 per cent;  $p < 0.01$ ). The authors concluded that as implemented, EHRs were not associated with better quality ambulatory care.<sup>98</sup>

### **6.3.2 FACTORS AFFECTING THE SUCCESSFUL ADOPTION OF ELECTRONIC HEALTH RECORDS**

Realising the potential efficiency and quality gains of EHRs is dependent on their effective implementation, which presents a host of technical and non-technical challenges with clinician resistance to change being particularly influential.

A literature review by Anderson investigated the perceived benefits and barriers to use of healthcare information technology by primary care clinicians in Europe, the US, Canada, Australia, and New Zealand.<sup>98</sup> Primary care clinicians perceived benefits from the use of IT in their practices, but also cited major barriers to implementation. These included the capital cost of investment in IT (this may be less of an issue in the UK where the capital costs are met by the NHS rather than by the clinician); lack of data standards that permit effective, accurate and timely exchange of electronic clinical data between healthcare providers; concerns about patient privacy; and legal barriers to the use of electronic records. Recommendations for overcoming these barriers include the use of subsidies to encourage the use of IT and the use of performance incentives by payers and government (both of which have been introduced in the UK). Barriers to use could also be reduced by the certification and standardisation of applications and systems to permit exchange of electronic clinical data exchange; removal of legal barriers; and greater security of the medical data stored in EHRs.<sup>19;49</sup>

Drawing on the results of his literature review, Siderov highlighted a number of human and organisational factors likely to influence the potential effectiveness of the EHR. For example, clinicians may fail to engage with systems due to resentment over the loss of professional autonomy or limited tolerance for on-screen prompts;<sup>19;99</sup> the EHR may also impede addressing other immediate patient needs in a time-limited office visit.<sup>19</sup> Perverse incentives are also likely to have an influence; for example, in healthcare systems where clinical tests are an important source of revenue, some laboratory or radiology departments may resist EHR-based interventions that reduce test ordering.<sup>100</sup>

The Chameleon Project<sup>100</sup> used ethnographic studies of EHR implementations, interviews with stakeholders and workshops to examine fundamental assumptions surrounding the EHR, and explore the fit with existing and emerging practices, technologies and regulatory requirements. The authors concluded that the main challenges to successfully delivering an EHR system on time are standardisation, improved quality and appropriate information and integrating but not disrupting ‘. . . systems of work, work practices and legacy technologies.’<sup>101</sup> The authors also identified important issues that must be seriously considered as NHS programmes continue (Box 6.6).

Concerns over information security and confidentiality are prominent amongst reasons for poor engagement with the EHR, as has been evidenced by the strong reaction from the British Medical Association and others to NHS CFH. Win assessed whether current information security technologies are adequate for EHRs concluding that they urgently require improvement and that further study regarding information security of the EHR is warranted.<sup>101</sup> Since EHRs contain sensitive patient information, this can impact on a patient’s health and even their life.<sup>101</sup> Win suggested that different authorisation mechanisms incorporating cryptographic techniques might possibly enhance the information security of an EHR and that the security of an EHR should be studied to ensure patient safety through providing secure EHRs to healthcare providers, consumers, primary and secondary users of EHRs (see also safety map Chapter 4).<sup>101</sup> Win concluded that when implementing information security, private and public interests should be addressed to achieve maximum usage of the EHR.<sup>101</sup> Also, the current information security technologies are not adequate and still require improvement for the security of the EHR.<sup>100</sup>

#### Box 6.6: Important issues that must be considered for the EHR systems and NHS programmes

- **Procurement:** the NHS has misjudged the scale of the undertaking EHR. The changing government and NHS policies has made procurement difficult, and has made it difficult to assess the appropriate systems
- **Coding:** medical and administrative coding requires full technical integration and standardisation
- **Consideration of the purchase of systems:** improved management of stakeholder and local user, although managing this successfully is challenging
- **Criteria for assessing the appropriateness and reliability of EHR systems:** currently too narrow, there is a need to systematically concentrate on the reliability of the design of these systems and develop different testing methods
- **‘Top down’ and ‘bottom up’ approaches to delivering the EHR:** select methods and technologies to try and avoid the consequences of each approach

Source: Simmonds et al. (2006)<sup>100</sup>

Another area that warrants attention is the possible effects of EHR use on the doctor-patient consultation. Ventres et al. found that the introduction of an EHR into practice influences multiple cognitive and social dimensions of the clinical encounter and identified numerous factors that shape how EHRs are perceived and used in medical practice today.<sup>22</sup> However, this study was conducted in only four primary care offices and hence might not represent the full breadth of behaviours and attitudes towards the use of EHRs.<sup>22</sup> Further attention to questions raised by Ventres et al. (Box 6.7) could facilitate integration of the EHR into medical practice and foster use of the EHR to enhance therapeutic relationships.<sup>22</sup>

#### Box 6.7: Example questions for implementation of electronic health records

- Can EHR software be designed to facilitate communication between clinicians and patients?
- What resources are available to help clinicians best integrate this technology into their style of patient care as they transition to the use of the EHR?
- Are there examples of best practices—standard procedures or phrases—that clinicians can use to assist patients as they are introduced to the EHR?
- When and how should medical educators introduce the EHR to students and residents, especially given the current emphasis on training patient-centred interviewing skills? What responsibilities do vendors or health care systems have to train clinicians about the relational aspects of the EHR?

*Adapted from Ventres et al. (2006)<sup>27</sup> Reproduced with permission from Physicians, patients, and the electronic health record: an ethnographic analysis from the March/April 2006 issue of Annals of Family Medicine. Copyright © 2006 American Academy of Family Physicians. All Rights Reserved.*

#### 6.3.3 DATA QUALITY

Two SRs have assessed data quality in primary care; an additional review relates in the main to quality of EHR-generated data in hospital care. Thiru et al. examined data quality measures used in primary care EHR. They identified 52 studies that examined data quality (31 from the UK).<sup>27</sup> Quality of data was measured in different ways, most commonly with comparisons of rates derived from the EHR with an external standard. Data validity was examined using a range of terms (eg completeness, correctness, accuracy, consistency, and appropriateness); these terms were often undefined in many studies. The most commonly used measure of validity was sensitivity (completeness of recording); the proportion of total cases of a disease or events such as prescriptions that were recorded by the EHR system. Prescriptions had the highest rate of recording (sensitivity), probably because prescribing is a core function of many EHR

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systems and is used even in circumstances when EHRs are not used for other functions such as morbidity recording. The recording of diseases varied, with completeness generally highest for diseases with clear diagnostic criteria. Lifestyle and socio-economic data had lower rates of recording than prescription or diagnostic data. Positive predictive value was generally high for all recorded elements (ie if a data element was recorded in the EHR, it was usually correct with false positive recording of data elements a rare event). One of the main conclusions from the study was that there were no agreed reference standards for reporting data quality and that this limited comparisons of data quality across sites and systems.<sup>28</sup>

Jordan et al. carried out a SR to assess the completeness and correctness of morbidity coding in computerised general practice records in the UK using four criteria: (1) the completeness of consultation recording (are all consultations recorded?); (2) the correctness of consultation recording (ie are the morbidity codes recorded in a consultation correct?); (3) the completeness of the morbidity register (are patients with a disease included on the morbidity register derived from the EHR system?); and (4) the correctness of a morbidity register (ie does the morbidity register have any false positives?).<sup>28</sup> They identified 24 studies that had examined morbidity coding. Recording of consultations was generally high (typically greater than 90 per cent), but assigning a morbidity code during each consultation was more variable (66–99 per cent complete). Coronary heart disease was the most commonly assessed disease register in previous studies and completeness of recording was generally moderate (typically around 70 per cent). Positive predictive value of coronary heart disease registers was generally high (typically around 83–100 per cent). Other diseases that were examined in the 24 studies (such as asthma and epilepsy) showed similar patterns of completeness of recording and positive predictive value of recorded diagnoses but rates were generally lower than for coronary heart disease. They concluded that completeness and correctness of data entry may rely on the enthusiasm of individual practices and of general practitioners. Hence, variations in the accuracy of the EHR will be present among general practices. Like Thiru et al., they also noted the lack of well defined data quality standards and the need to correct this if better measurement of data quality in primary care EHRs was to be established.<sup>102</sup>

Hogan and Wagner identified 20 articles that reported the results of 26 studies of accuracy in 19 unique EHRs (which in their study they termed computer-based patient records or CPRs).<sup>87</sup> As their study was published in 1997 and was confined to articles published by February 1996, it is likely to be less relevant to

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current practice than the more recent papers by Thiru et al. (2003)<sup>29</sup> and Jordan et al. (2004).<sup>30</sup> Many of the studies they examined were also hospital-based and carried out in the US, in contrast to the two reviews above, which were primary care-based. Despite these differences, they drew similar conclusions to the other two reviews and noted the wide variability in the accuracy of EHRs and the lack of standard measures of data accuracy.

### **6.3.5 EVIDENCE FOR COST-EFFECTIVENESS AND EFFICIENCY**

The AHRQ report found that while the EHR undoubtedly improves efficiency and healthcare quality its implementation requires considerable capital investment and organisational restructuring. Healthcare organisations in the process of adopting EHRs are attempting to reduce their implementation costs by learning from the examples of other healthcare providers which have adopted an EHR.<sup>102</sup>

The evidence of economic costs and benefits of an EHR system from the AHRQ report is demonstrated in their interactive evidence database (available online at <http://healthit.ahrq.gov/tools/rand>) that provides a structured abstract for each of the nine identified studies examining the costs and benefits of the EHR. They estimated an annual savings of \$3,700,000 (in 1996 dollars) from ‘. . . reduced medical record room and support staff, elimination of clinical forms, and automatic collection of billing data.’<sup>13</sup>

Five cost-benefit studies on the implementation of an EHR system showed consistent results; there are, however, several important caveats (see Box 6.9). In conclusion, the authors did find empirical evidence that demonstrated the ‘. . . positive economic value of an EHR system and the component parts of EHR.’<sup>102</sup> However, they concluded that ‘. . . proper alignment of the healthcare financing system, strong leadership, effective implementation strategies’ were important to successfully implement the EHR system.<sup>23;51</sup>

Clamp and Keen urge caution when interpreting cost analysis studies.<sup>103</sup> In their 2005 report, they found limited solid economic evidence on EHR systems. Even the studies that they stated were better quality and had presented cost data, did not include health economists. There was no technically sound evidence about cost changes associated with the EHR, apart from the paper by Bryan et al. on Picture Archiving and Communication Systems (PACS).<sup>104</sup> There was no evidence on ‘network effects’. They stated that there is good evidence that modern electronic networks have measurable positive economic effects in other contexts. However, no study has been carried out in a healthcare setting. Most papers failed to include all reasonable costs, irrespective of whether they would



tend to increase or decrease overall costs. Most papers made linear projections of cost-savings in future years, typically up to five years ahead. However, there was often no basis for these projections.

#### Box 6.8: Important caveats outlined by Agency of Health Related Quality report

- All studies are predictive analyses that are based on many analytical assumptions and limited empirical data. Hence, the strength of evidence is often weak.
- In all studies, the EHR system was assumed to have multiple functionalities and the functional capability of the EHR system is critical to the benefit that may occur from using it.
- The organisations that were the subjects of four studies were all large. The literature review did not identify cost benefit studies for EHR implementation in small organisations.
- The costs of implementing an EHR system may be underestimated. Only one of the five cost benefit analyses included the cost of the implementation process, and found that this cost was 1.5 times the cost of the EHR system.
- Implementing an EHR system requires extensive changes in the organisational processes, individual behaviours, and the interactions between the two. These resulting costs are often omitted or not reported from studies but can be substantial.
- The financial benefits depend on the financing system. As shown in the sensitivity analysis of one study,<sup>13</sup> the benefit estimates are most sensitive to the assumption of the proportion of capitated patients. Realising all quantifiable benefits of EHR implementation would require changes to the current healthcare financing system.
- Both the cost and the benefit of attaining interoperability among EHR systems are directly proportional to the level of data exchange achieved. For example, although the cost of achieving machine-organisable or machine-interpretable interoperability is greatest, it offers the most potential for increased efficiency, improved healthcare utilisation, and reduced costs.

*Adapted from: AHRQ (2006)<sup>13</sup>*

Clamp and Keen did not find any studies which captured the costs and effects of the EHR ‘in the round’.<sup>51</sup> They recommend that in order to provide correct cost analysis information, studies should gather evidence about the impact of an EHR at several points along a care pathway, such that the sum of the costs and effects at the different points would provide a reasonable proxy of the total impact of an EHR on a service.<sup>51</sup> They also advocate including an observational component, so it is clear which programme theories lead to change and which do not. These studies would need to collect evidence that directly tests the different theories of change proposed for EHRs.<sup>23;51</sup>

Clamp and Keen claim that it would also be possible to study the macro effects of EHR use.<sup>23;51</sup> The above approaches could then be used to determine which of the various programme theories reported in the literature is accurate, and



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to determine what works, in what circumstances, and the underlying reasons for this.<sup>105</sup>

Other cost benefit studies, not picked up by the above reviews have shown the costs to unit, practice or hospital to be important when considering EHR systems. For instance, in small offices in the US, EHRs offer hope of improving income through pay-for-performance and reduction of dictation and staffing costs. However, as an Association of Departments of Family Medicine survey has shown, most family medicine units incur the costs of implementation without the benefits of the associated savings.<sup>105</sup> This is not the case in the UK, where the costs of implementing EHRs in general practice is largely being met by the NHS. In UK primary care, EHR use can also help general practices achieve targets in the Quality and Outcomes Framework and this may incentivize practices to use EHRs, particularly for morbidity recording and recording of process and intermediate clinical outcome measures.<sup>106</sup>

Randolph and Ogawa tracked the cost of implementing a computerised patient record across three intensive care units at a large paediatric hospital.<sup>106</sup> They found the total phase 1 implementation cost was estimated to be about \$3 million dollars, but the actual cost was about \$1 million (35 per cent) greater than anticipated. A significant proportion of the extra costs were for the personnel required to implement the EHR system.<sup>106</sup>

## **6.4 IMPLICATIONS FOR POLICY, PRACTICE AND RESEARCH**

Although the establishment of EHR systems is a key priority for NHS CFH, the prior assessments of the benefits of EHR systems have been of very variable quality and have shown limited benefits in areas such as increased efficiency of the use of clinical time, patient safety, and quality of care. This may reflect the “piecemeal” way in which such systems have been introduced, rather than being introduced as part of an overarching strategy as envisaged by NPfIT. The economic appraisal of EHR systems has also been weak. Clinician attitudes can also have a major impact on the benefits that accrue from the use of an EHR and clinician engagement is therefore a key factor in successful implementation.

The introduction of EHR systems offers many potential benefits for the NHS, including a reduction in clinical errors and improved patient safety. EHR systems can also make information about their health and use of health services much more readily accessible by patients, thus allowing them to become more involved in the provision of their own healthcare. Furthermore, in addition to their primary function of patient management, information derived from an

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EHR can be used for a range of other purposes, including clinical audit, quality improvement, public health monitoring and research.

Many of the benefits of EHRs in improving quality may come from these secondary uses of the data held in EHRs, which allow measurement of healthcare quality for pay for performance and quality improvement programmes, as well as for the monitoring of inequalities and public health. The impact and economic value of these uses is difficult to quantify and new methods may be required to establish the effects.

Both the primary and secondary uses of EHRs assume that the data they hold is a complete and accurate record of a patient's health status and use of healthcare. The two SRs that have examined data quality in primary care systems both found considerable variation in quality, using a range of data quality definitions. Recent reviews of the quality of data in EHRs used in hospital settings are lacking, but data quality studies have found many errors in the data recorded in hospital Patient Administration Systems that form the basis of England's Hospital Episode Statistics system.

One key area for further work is the development and evaluation of data quality standards for use in EHRs, and the evaluation of methods for improving data quality. Accurate, complete data is an essential prerequisite for effective EHR use and this should therefore be seen as a priority for NHS CFH. A second key area is the economic evaluation of EHRs and their impact of healthcare provision. In particular, longer-term studies are needed to determine if the early benefits are maintained once the initial enthusiasm has worn off. A third key area is understanding what aspects of EHRs appeal to clinicians and why some aspects of the use of EHRs (for example, Choose and Book, the on-line booking system) are so unpopular with clinicians. Other important areas include minimising duplicate data entry (eg between hospital and general practice records) and developing methods for incorporating information on patients' experiences of healthcare and patient reported outcomes into EHRs.

Further exploration of the impact of EHRs on the clinical encounter and the patient experience is also warranted.

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## CHAPTER 7

### Computer history taking systems

#### SUMMARY

- Most computer history taking systems are designed for use by healthcare professionals, often as templates incorporated into the electronic health record, although some elicit information directly from the patient, as in the case of pre-consultation interviews.
- Computer history taking systems that elicit data directly from patients can be used in a variety of clinical settings and have proven particularly useful in obtaining potentially sensitive information, such as in relation to alcohol consumption, sexual health and psychiatric illnesses (eg suicidal thoughts).
- Computer-based questionnaires can prove useful for gathering important background data prior to the consultation, which, may then allow more time for focusing on key aspects of the health problems during the actual consultation.
- Speech software and speech completed response computer history taking systems allow adaptability for those with special needs, such as those who are illiterate, patients that do not speak English and those that have a hearing impediment.
- Compared with pen and paper methods, computer history taking systems can result in substantial time savings in the consultation, these being most likely to occur in contexts in which structured histories are routinely taken. These systems can also save money by reducing administrative costs.
- There is good evidence that data collected electronically using computer history taking systems are more accurate and contain fewer errors than data captured manually with traditional pen and paper techniques; such data are also more legible.
- The current generation of computers is, however, not adept at detecting non-verbal behaviour; since a computer does not sense a patient's mood, these must not be seen as a substitute to, but rather an adjunct to the clinical encounter.

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- There have been no comparative studies that have formally assessed the effectiveness and cost-effectiveness of different computer history taking systems.
  - It is important for NHS Connecting for Health to consider the efficiency opportunities to be had from incorporating both professional and patient completed computer history taking system functionality into future iterations of its electronic health record, but only in contexts in which history taking is typically highly structured and is not reliant on clinical intuition. This will, however, need to be done within a clear evaluative context.

## 7.1 INTRODUCTION

Computer history taking systems (CHTS) have been discussed for many years, but are seldom used in routine clinical practice. Rapidly increasing familiarity, experience and confidence in using computers by members of the general public, albeit in other contexts, together with the increasing use of electronic health records (EHRs) does, however, make the greater use of CHTS in which professionals use templates as part of the EHR an increasing possibility. Also of relevance is the increasing potential for patients directly to complete aspects of their history, prior to or post the consultation, either whilst on-site in their general practice or hospital, for example, or remotely. This is especially true in England as NHS Connecting for Health's (NHS CFH) National Programme for Information Technology (NPfIT) has as its central development the creation of a longitudinal EHR, which also aims to allow patients and carers direct access to this record through HealthSpace.<sup>1</sup> Similar possibilities also exist in other parts of the world as, for example, with 'RelayHealth'<sup>2</sup> and 'PatientSite'<sup>3</sup> in the US. In this chapter, we review evidence on electronic tools to facilitate the taking of the patient history, both by professionals and also directly from patients.

## 7.2 DEFINITION, DESCRIPTION AND SCOPE FOR USE

### 7.2.1 DEFINITION

The medical history of a patient is the information obtained by a clinician or other healthcare professional by asking the patient or their carer specific questions related to their condition. A history taking system (eg computer programme) is a tool that aids clinicians in gathering data from patients to inform a diagnosis or treatment plan,<sup>4</sup> or can even be used as a form of quality control.<sup>5,6</sup> It is an added functionality, most commonly operating in the form of an electronic template. Patients can also enter their own personal details into

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a CHTS so the information can be used by the clinician or health professional whether during or as an adjunct to a consultation.

### 7.2.2 DESCRIPTION

Computer history taking systems can draw on a range of eHealth technologies with varying degrees of functionality. Table 7.1 illustrates different means of collecting a patient history via a CHTS and the types of collection methods involved. In practice, however, CHTS are most likely to involve generating data on the patient history using one or more of the following approaches:

- **computer-facilitated professional-generated history:** whereby a semi-structured clinical history is collected by a clinician who enters results into the computer system and is guided by a system with conditional branching of questions according to previous responses
- **computer-based patient questionnaire:** whereby a standardised questionnaire is administered electronically and all participants are posed the same questions
- **computer-facilitated patient-generated history:** where a structured clinical history is collected electronically from the patient in a system with conditional branching of questions according to responses.

Data generated by CHTS can link with other eHealth applications such as computerised decision support systems (CDSSs); these will, however, not be considered further here as such added functionality to support various aspects of clinical decision-making is reviewed in subsequent chapters (see Chapters 8–11).

### 7.2.3 SCOPE FOR USE

There are two main approaches to using these tools to facilitate history taking, namely either aiding healthcare professionals or eliciting information directly from patients:

- **Health professional:** Where health professionals input patient details into computers, typically via templates; this can include: entry to fixed templates; systems that actively guide the clinician to complete relevant data fields; and those which suggest questions based on answers to previous questions. This latter form is in effect a form of CDSSs, which could ultimately lead to probable diagnoses (see Chapter 8 for more details on CDSSs). Examples of healthcare professionals using CHTS technology include:
  - **NHS Direct:** Nurses type patient responses to questions generated by

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the computer and the software programmes then direct them to further appropriate questions and ultimately a diagnosis and or immediate management plan.<sup>5</sup>

- ❑ **Emergency services:** This is a similar system to that described above; for example, when a patient calls 999, the telephone staff ask a specific set of questions that they input into the computer and this information guides staff towards a course of action.<sup>7</sup>
- ❑ **General practice systems:** Where healthcare professionals record aspects of the patient's history into a computerised template, which forms part of the patient record.<sup>8-12</sup>

Table 7.1: Possible different computer history taking systems aided approaches for taking the patient history

Means of obtaining a patient history		Types of collection methods				
		Computer-facilitated professional-generated history			Computer-based patient completed questionnaire	
		NHS Direct	Emergency services	General Practice systems		
(1) Information collection						
Computer questionnaire	Standardised questionnaire administered electronically—all participants posed the same questions					✓
Computer clinical history	Structured clinical history collected electronically in a system with conditional branching of questions according to responses		✓			✓
Computer guided history	Semi-structured clinical history collected by clinician, entering results into, and guided by a system with conditional branching of questions according to responses	✓	✓	✓		✓
(2) Decision-making						
Diagnostic system	Automatic system using algorithm / weights to give diagnosis independently of clinician					✓
Probabilistic advice system	Interactive system advising clinician of most probable diagnosis /action	✓			✓	
Question prompt system	Interactive system advising clinician of additional information requirements		✓			
(3) Management support						
Protocol reminder system	Computerised display of information relevant to diagnosis or management triggered by clinician entry		✓			
Protocol conformance system	Computerised pathway for information, inviting, or requiring completion		✓			

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- **Patients:** When the computer prompts the patient to input relevant information themselves, for example, with a computer-based pre-consultation interview or when inputting information into a health diary (also known as patient reported outcomes (PROs)). Examples of these include:
    - **Pre-consultation questionnaire in general practice:** Similar to general practice systems described above, but instead, the patient answers questions about their history and inputs this information into the computer themselves.<sup>8;9;12–14</sup>
    - **Pre-consultation questionnaire in psychiatry:** Whereby the system enables patients to complete the history either on a computer in the waiting room or at home.<sup>15;16</sup> This has, for example, been shown to help professionals to rapidly appraise psychiatric referrals and prioritise services.<sup>1</sup>
    - **EHR:** Where the patient types their own history into sections of their EHR and, as mentioned above, this could potentially link with HealthSpace<sup>17–20</sup> and other similar patient-held records. Although this has not yet been fully developed, there is great potential for patients to utilise resources of this kind.

Although an increasing number of approaches can be used to generate and record data using CHTS (see Table 7.1), we focus in this chapter on the most commonly employed techniques in the literature, concentrating on personal computers (PCs),<sup>18;20–22</sup> and personal digital assistants (PDAs),<sup>21–24</sup> comparing these with the more traditional approaches based on pen and paper (P&P).<sup>8;9;12</sup>

Whilst most CHTS are designed for use by healthcare professionals, some elicit information directly from patients, as in the case of pre-consultation interviews.<sup>18;20–22</sup> Histories may be entered into computers using standard desktop or laptop computers and or PDAs.<sup>21</sup> A PDA is a small hand-held computer, often now with a touch-sensitive screen. Paper-based questionnaires can, for example, be converted to electronic PDA versions, which respondents can then complete using the touch screen functionality. Patient responses can then either be held locally or conveyed to a database on a central server, possibly via home hubs and, in the future, Bluetooth technology, and the data are thus potentially ready for analysis in a matter of seconds.<sup>21;22</sup> PDAs can also be used in the form of electronic diaries<sup>21</sup> to gather PRO data, where the patient inputs their own information, for example, on a daily, weekly or monthly basis.<sup>25</sup>



## 7.3 THEORETICAL BENEFITS AND RISKS

### 7.3.1 BENEFITS

Computerised history taking systems can be used in a variety of clinical settings and have the potential to benefit both professionals and patients.

#### *Saving professionals time on documentation*

Clinicians have limited time in consultations such that, in a traditional face-to-face clinical encounter, it is often impossible to obtain a complete or, in some cases, even relevant medical history.<sup>26;27</sup> Box 7.1 illustrates some salient features regarding the limitations associated with current approaches to taking the patient history in a consultation.

The studies by Tang et al. (1995 & 1996) evaluated ambulatory practices and found that clinicians spent 20 per cent of their day writing.<sup>28</sup> Also, in an Ohio family practice, dictation and charting outside of examination rooms occupied 56 minutes of an eight-hour working day,<sup>29</sup> and an antenatal clinic where two-thirds of the working day was spent recording information.<sup>30;31</sup> These studies demonstrate the potential importance of CHTS as a time-saving device for clinicians, particularly if these devices can also sift and present relevant data in an easily accessible format.

#### **Box 7.1: Observations around history taking and patient consultations**

- Clinicians often discourage the voicing of concerns, expectations and requests for information. For instance, during the standard interview, a clinician will interrupt a patient in less than 24 seconds after the patient begins talking.<sup>8</sup>
- Confusing medical terminology – medical terminology used by the clinician is misunderstood by patients.<sup>32</sup>
- Important information is missed, for example, studies show that 50% of psychosocial and psychiatric problems are missed<sup>33</sup> and that 54% of patient problems and 45% of patient concerns are neither elicited by the clinician nor disclosed by the patient.<sup>8</sup>
- Patient and clinician do not agree on the presenting complaint 50% of the time.<sup>8</sup>
- Clinicians control the duration of the interview.<sup>8</sup>
- Time is limited, and it is impossible to obtain complete medical histories regularly from all interviewees during a traditional interview.<sup>26;27</sup>
- Clinicians can spend a lot of their time writing patient notes, for instance, Tang et al. (1995 & 1996) evaluated ambulatory practices and found that clinicians spent 20% of their day writing.<sup>8</sup>

*Adapted with permission from Bachman (2003)<sup>9</sup>*

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### *Increased patient engagement and involvement*

The main potential benefit of CHTS for the patient is that it may allow them to spend more time with their clinician in the consultation actually discussing their health problem. For example, the overview by Bachman drew particular attention to the earlier work by Mayne et al.<sup>34</sup> that documented the effectiveness of patient-computer interviewing, whilst also counteracting the suggestion that a computer programme is impersonal:<sup>8</sup>

‘It is claimed that the time the clinician spends with his patient in obtaining the medical history is the basis for establishing the harmony and rapport needed for successful interaction. This may not necessarily be the most efficient way to develop a successful clinician-patient relationship; in effect, this claim derives from an oversimplified view of this relationship.. . .Therefore, until there is evidence to the contrary, it seems reasonable to suppose that the time spent with a patient discussing the meaning of data pertinent to his problem, which have been collected prior to the interview, would provide an equally satisfactory basis for establishing the desired rapport.’

One noteworthy point that Dale and Hagen mention, is how protocol compliance is likely to be higher if patients believe that investigators take an interest in them and give an impression that they care for them. This may well be an example of performance bias and the sheer novelty of the PDA method may inadvertently lead to altered behaviour in both researchers and respondents alike, resulting in possible bias.

### *Collection of more comprehensive and valid information*

Patient questionnaires—in particular computer-based questionnaires—can be used as a helpful checklist; when these CHTS checklists are used more comprehensive assessments are often made. The length of time associated with documenting information was noted almost four decades ago and was one of the reasons that Mayne et al.<sup>8</sup> initiated their research into the scope for patient interviews being aided by computers, coming to the conclusion that patient-computer interviewing was a positive experience for both the clinician and the patient. As Bachman points out:<sup>8</sup>

‘Their (Mayne et al.) well controlled, documented study and conclusions have been confirmed. The strengths and weaknesses of patient-computer interviewing are established. The computer provides structure, allows a patient to provide information to the clinician, and outlines the framework for an interview. A further strength of the patient computer interview is that it acts as a checklist.’

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The overview by Bachman illustrated that the number of questions a clinician needs to remember in an interview are many, and omitting an important question can have considerable implications. They point out that since the Mayne et al. article was published, numerous studies have confirmed their conclusions. Therefore, in terms of the strengths of a patient-computer interview, Bachman listed a number of important points when considering CHTS (Box 7.2). Importantly, computer interviewing may be more effective for obtaining certain personal information that people often find difficult to discuss face-to-face.

Patient completed CHTS may offer several advantages over more traditional approaches to obtaining the history, such as:<sup>8</sup>

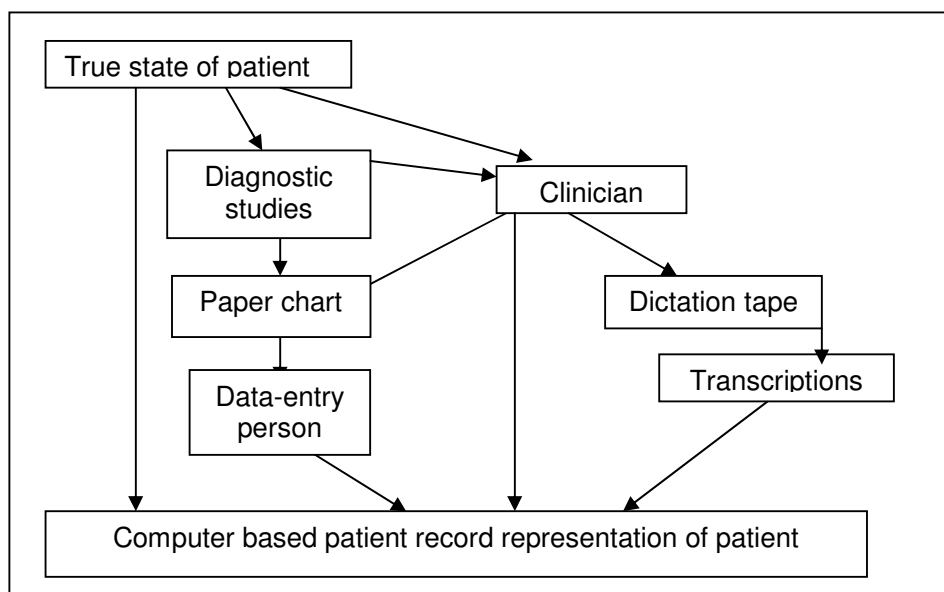
- patients can complete them at their own pace at home and can consult others if they have questions
- questionnaires can serve as prompts to remind patients of things they may have forgotten
- such questionnaires are an inexpensive means of generating a thorough account of the patient's history
- they bypass potential professional biases in obtaining and recording the history, and they can also overcome transcription errors, particularly if several tiers of staff are involved in recording the patient history (see Figure 7.1)
- data obtained from pre-consultation questionnaires can provide a helpful context for the subsequent clinical interview.<sup>21</sup>

### Box 7.2: Important points to consider with CHTS

- Patient-computer interviews are structured and provide more historical data.
- Computer interviews can be done at the patient's pace and are satisfying for patients.
- Computers may obtain more sensitive information.
- Patients are better prepared for the medical interview after being interviewed by a computer.
- Interviewing by computer provides legible summaries and can be manipulated by an EHR, or the results can be entered directly into an EHR.
- Computers calculate well and can analyse questions and produce scales that are easily interpreted by clinicians. Computerised rating scales have been reviewed.
- Patients seldom stop a computer programme; therefore, typically all questions presented are answered.
- Computers allow efficient interviewing of potential contributors to the history.
- Computers can provide questions in different languages, provide multi-media forms for patients who cannot read, and allow patients who are deaf to read or enter information in alternative ways. Considerable deficiencies have been shown when non-English speakers were interviewed with an interpreter.
- Research and audit are easier with computer-generated histories. If a computer is used for history taking, it is easier to set up electronic systems for data retrieval.

*Adapted with permission from: Bachman (2003)<sup>9</sup>*

**Figure 7.1: The variety of mechanisms by which historical facts, observations, and measurements flow into a computer based patient record, errors can be introduced at any step.**



*Reprinted from Hogan and Wagner (1997) with permission from Elsevier Limited.<sup>58</sup>*

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Some reports have highlighted that the PDA is a potentially improved method with which to collect PRO data when compared to P&P techniques.<sup>35</sup> For example, Kerkenbush et al. highlighted that PDAs may help address some of the limitations associated with paper-based diaries, such as: ‘non-compliance; fabrication of data; poor data quality; and missing, out-of-range, illegible entries and entries that cannot be coded’.<sup>35</sup> Also, the processing of data in paper diaries can be time-consuming and expensive, important points to consider when clinicians are trying to establish treatment options for patients.<sup>35</sup>

Although falsification or suspicions of falsification of data have been found with the P&P method, in contrast, the date or time stamp feature of PDAs should allow better detection of falsified data.<sup>35</sup> An important benefit, pointed out by Kerkenbush et al. is that ‘...data collected using PDA technology can be shared electronically not only between patient and provider, but also between multiple providers’.<sup>35</sup>

#### *Facilitate delivery of care to those with special needs*

There are various potential benefits of CHTS in the care for people with particular needs. For example, computers can allow questions to be asked in a number of different languages for those who are not conversant in English. They can also provide multi-media forms for patients who cannot read and write through making computers voice questions and digitally record spoken responses.<sup>9</sup>

Parkin notes that, in the context of child psychology and psychiatry, despite clinical resistance to using a computer-based interview as a CHTS questionnaire, these tools can prove very useful:<sup>9</sup>

‘[We] have seen children make remarkable and sometimes unexpected observations and changes in their lives when using computers to describe personal issues in a structured way.’

In trying to explain the reasons underpinning this observation they pointed out that there are two aspects of the use of computers that may affect this process: firstly, the control that the children have over the interview; and secondly, the fact that they should not fear the instant and possibly prejudicial response of a ‘fellow human’.<sup>37</sup> Some studies report that ‘young people find computerised questionnaires equally or more acceptable than the clinical interview or written questionnaire’.<sup>9,38</sup> In one study, parents originally assumed that an interview using a computer was not as ‘friendly and personal’, but became more optimistic after the interview was completed.<sup>9</sup> ‘No other studies have described patients withdrawing on the grounds of computerised assessments being impersonal’.<sup>9</sup>

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### 7.3.2 RISKS

#### *Confidentiality*

In terms of CHTS, it is very important that the confidentiality of patients and their relatives is secure.<sup>9</sup> Given the risks of breaching confidentiality, there must therefore be a clear justification for using the proposed patient-generated data and steps must be taken to avoid any unwarranted intrusions.<sup>9</sup> The design of a questionnaire should be such that it collects essential information but it is not overly-intrusive. The proposed questionnaire needs to be explained to the patient (or person giving consent on the patient's behalf) this includes any potential risks and benefits. It is ethical responsibility on those designing the questionnaire and on those overseeing them to meet these important procedures.<sup>8</sup>

#### *Irrelevant questioning*

CHTS may have problems in that not every question can be meaningfully answered in a questionnaire; such issues are likely to be particularly relevant when using general questionnaires which may include questions irrelevant to individual patient concerns and needs. Similarly, such fixed questionnaires can be difficult to modify when a question needs to be added in an attempt to obtain further pertinent information. Other important points include that there may be too many questions asked (this reflecting the fact that they are not tailored) and that such an impersonal approach is a deviation from the standard history taking practice and may therefore be disconcerting for both patients and professionals.

#### *Failure to record non-verbal communication*

Downsides to CHTS include the fact that computers are on the whole currently unable to detect non-verbal behaviour since a computer cannot sense a patient's mood that might easily be picked up in a consultation (see Box 7.3).<sup>12</sup> Another related concern is that computers may '...depersonalize the doctor-patient relationship,'<sup>12</sup> although as Lilford et al. point out this has not actually been demonstrated in the clinical setting.<sup>19</sup>

### Box 7.3 Weaknesses of CHTS

- Computers are not adept at detecting non-verbal behaviour since a computer does not sense a patient's mood.
- In some cases, patients can make inadvertent errors during a computer interview because they misunderstand, forget, become careless, or lie. These tend to be false positive and can be clarified with traditional interviewing.
- Computers can be damaged and require supervision, which has been a problem in certain populations such as jail inmates.
- Computers are not for everyone. Computers are generally viewed favourably by patients but a minority of patients do not want to use computers to enter their history.
- Computer programmes are often viewed as impersonal.
- Computers require space.
- Patient-computer interviewing provides false positive information to clinicians.
- Computer software has not been readily available to clinicians. Computer-patient studies run out of funding, the inventor moves on, or the study is difficult to replicate.

*Adapted with permission from Bachman (2003)<sup>9</sup>*

#### *Technical problems and frustration with the system*

Kho et al. point out in their systematic review (SR) on PDA use by medical trainees that while most medical trainees who use handhelds for patient history taking appear comfortable and generally satisfied with them, certain barriers still exist, such as:<sup>19</sup>

- lack of technical experience
- a preference for P&P
- difficulty handling the small device
- concerns about data loss and security.

The authors describe that initial training and ongoing technical support are important factors to consider, particularly for clinicians who lack familiarity with the devices.<sup>12</sup> Liford et al. also noted repeatedly that the success of a CHTS may depend on both the CHTS and the healthcare setting.<sup>12;39;40</sup> They point out that if the patient history taking procedure is 'more structured' and 'disciplined', the recording of a patient's history may be greatly improved, but that these same benefits are potentially much more difficult to realise in contexts where more intuitive and less structured histories are routinely taken.<sup>41</sup> Thus, what may work in some clinical settings (such as an infertility, antenatal or allergy clinic) may not work as well in other areas where patients more typically present with undifferentiated problems (such as general practice or a general medical or gynaecology clinic, for example).<sup>18–22;42;43</sup> This is because in the latter context, it is very difficult to develop appropriately branching questionnaires



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and furthermore positive responses being generated to very many questions may make it difficult to actually focus on the essence of the problem.

## 7.4 EMPIRICALLY DEMONSTRATED BENEFITS AND RISKS

We identified seven SRs that covered some aspect of CHTS which were of varying quality (see Appendix 5 for details).<sup>8;9</sup> that covered some aspect of CHTS which were of varying quality (see Appendix 5 for details). In total, these SRs assessed 140 studies, of which, 23 were randomised controlled trials (RCTs), 90 were surveys, and the remainder consisted of other studies (eg before-and-after, and crossover studies). We also identified two overviews.<sup>44</sup>

### *Saving professionals' time*

A study comparing PDA use by patients for documenting acute pain assessment time and completeness and comparing this to P&P showed that PDA usage decreased the overall consultation time (such as chart review, assessment and documentation) by 22 per cent.<sup>43</sup> But, as Poissant et al. point out, although over 90 patient encounters were considered in this study, it was a single clinician study so the results may not be generalisable to other settings.<sup>43</sup> Further, Poissant et al. demonstrated that the use of central station desktops for CHTS is slightly less time-consuming (with a weighted average reduction of 8 per cent) for clinicians, when compared to bedside or point-of-care computer systems.<sup>21</sup>

Dale and Hagen point out that PDA use for CHTS benefit healthcare professionals as there is a 'reduction in the data management and processing time'.<sup>21,45–49</sup> However, barriers still exist as all five (out of a total of nine) of the studies in this SR that reported data concerning feasibility of collecting data using PDAs identified persistent 'technical difficulties with the PDA technology'.<sup>47–49</sup> 'Power problems' and 'PDA malfunction' were the most universal problems. As a result of these problems and other difficulties, data were reported as lost in three of these studies.<sup>37;50</sup>

### *Benefits for patients*

CHTS can be used in a variety of clinical settings and have been proven particularly useful in obtaining additional potentially sensitive information, for example, relating to alcohol consumption,<sup>38;51–53</sup> psychiatric care,<sup>54</sup> sexual health<sup>55;56</sup> and gynaecological issues.<sup>20</sup> This method has proved useful as an alternative to P&P methods when recording the patient history and has also been shown to improve documentation and patient care.<sup>45;46</sup>

There is good evidence, as demonstrated by two RCTs that patients prefer

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to record aspects of their history using PDA technology when compared with recording using P&P.<sup>45;46;49;57</sup> Further, if patients use a PDA for CHTS, they are less likely to falsify data when compared with those generated by P&P, as demonstrated, for example, by four RCTs.<sup>58</sup>

#### *More valid and comprehensive information collected*

The accuracy of the history data entered directly by clinicians versus data entry personnel in the same version of the EHR at the same time was assessed by Wagner and Hogan.<sup>59</sup> They found that in one study, no significant difference in the accuracy of history data entered directly by clinicians versus data entered from encounter forms by licensed nurses' aides was found, but this study lacked statistical power to demonstrate small differences.<sup>60</sup> In contrast, a study by Kuhn et al. measured history data accuracy in a new version of their EHR and used direct clinician entry of data into structured, electronic forms comparing it to the accuracy of an earlier version of the EHR based on clinician's dictation of unstructured reports.<sup>60</sup> They found a significant improvement in patient history accuracy with direct clinician entry; however, this result is confounded by a potential checklist effect of the structured form introduced in the new version of the EHR and by the use of a historical control.<sup>60</sup>

Computer history taking systems have been suggested as being particularly useful for specialist areas of work that involve a good deal of routine questioning, such as antenatal care, infertility and pregnancy terminations.<sup>56;61</sup> These CHTS have been shown to gather more significant and appropriate information,<sup>62</sup> although the gains over and above using other paper-based structured approaches at obtaining such data appear marginal.<sup>41</sup> Also, as Bingham et al. discovered in their study of obtaining gynaecological histories that CHTS may not be the more appropriate approach when dealing with undifferentiated disease.<sup>42</sup>

#### *Completeness of data*

Montgomery et al.<sup>63</sup> draw attention to an RCT in which patient medical histories were recorded on either paper or computer records and found that recording of 15 key items was significantly improved in computer records.<sup>64</sup> The percentage of patients with no record of these 15 key symptoms in the computer group ranged from 0–2 per cent and in the P&P group from 16–81 per cent; all differences were significant at  $p < 0.001$ . Similar results were found for family history of hypertension and smoking, significantly fewer patients in the P&P group had this recorded in their paper records ( $p < 0.01$ ).<sup>21</sup>

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### *Data quality*

The PDA is an improved method with which to collect PRO data when compared to P&P.<sup>35</sup> Kerkenbush et al. found increased compliance with data entry<sup>35;65</sup> and noted that invivodata™ (a company exploring electronic diary technology) showed that patients responded in a well timed way to 93 per cent of all the electronic data gathering prompts, this being noted in over two dozen RCTs.<sup>66</sup> Also, Kamarack et al. found 99 per cent compliance with assessments that needed to be completed every 45 minutes during waking hours over a six-day period.<sup>19</sup>

Kho et al. highlight several issues raised about documenting clinical experience via a handheld computer, such as

‘. . . inaccurate data entry, the potential to lose data, patient privacy, incomplete trainee participation, technical difficulties with software installation, and the need to provide additional training and support for users unfamiliar with the technology’.<sup>21</sup>

Dale and Hogen caution that ‘software and design validation are important elements for a successful PDA data collection setup’.<sup>9</sup>

Included studies in the SR by Parkin<sup>51;67–69</sup> demonstrated that the quality of data obtained by computer-based assessments is as high as that from clinical interview or written questionnaires.<sup>9,20</sup> CHTS enable clinicians to focus more on patient care as they save clinicians time in the accessing, retrieving and recording of data.<sup>18</sup> However, there is a lack of evidence on the use of CHTS by other healthcare professionals, this to a large extent reflecting that this is an under-studied group.<sup>8;70</sup>

Bachman showed in a study of 134 primary care clinicians that they asked only 59 per cent of essential history items in an ambulatory setting and concluded that other approaches need to be considered to ensure that complete and accurate information is available for diagnostic and treatment plans.<sup>8</sup> Also, data retrieved from computer-based questionnaires completed by patients has been shown to be reliable and the process has been found to be acceptable to patients.<sup>20</sup> Preferably, clinical outcomes should be measured as Wu and Strauss found no primary or secondary outcomes evaluating changes in reviewing information, ordering by clinicians or improvement in patient care.<sup>22</sup>

Data accuracy is an important consideration. For instance, Wu and Strauss found that ‘documentation comprehensiveness’ was significantly better in the PDA group and found that more diagnoses were entered using the PDA (364 vs 150,  $p < 0.0001$ ).<sup>20</sup> Lane et al. found in two studies that data gathered

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electronically were ‘more accurate and included less errors than data collected manually with P&P’.<sup>22</sup> In one study, the P&P approach of data collection resulted in a seven per cent error frequency, compared with a significantly lower three per cent error frequency acquired by patients using computers.<sup>18</sup> In addition, a survey of 250 family clinicians in the US found that a high percentage of clinicians (85 per cent) stated that they would consider carrying a handheld computer.<sup>48;49;71</sup>

Three articles included within the SR by Dale and Hagen reported on data accuracy and all three demonstrated fewer errors in the PDA data records than in the paper diaries.<sup>21,48;71</sup> Two of the studies reported that the PDA data sets were 100 per cent correctly completed.<sup>21,48;71</sup> In contrast, two studies report that 50 per cent and 80 per cent, respectively, of the P&P data were inaccurate and contained errors.<sup>21,58</sup> Hogan pointed out that hardly any reasons for error in CHTS data have been found, this possibly reflecting researchers directing most of their attention to data entry.<sup>58</sup>

Adult psychiatric patients have been found to input information to a computer that they may not share with healthcare professionals<sup>54</sup> such as reporting higher daily alcohol intake<sup>72</sup> and suicidal ideation.<sup>9</sup> This is likely to be because patients favour the perceived confidentiality, less judgemental attitudes and reduced time pressures.<sup>9;73</sup> Interestingly, Parkin has also noted that acutely ill adult patients were more aware of themselves and reported feeling better after they completed a computerised questionnaire.<sup>9,54</sup> However, as Erdman et al. caution, computer-assisted interviews may be impersonal and not the best mode of action when patients are experiencing psychological distress.<sup>72</sup>

### *Secondary uses of data*

Research and audit opportunities are greatly enhanced with electronic data such as those that are produced by CHTS.<sup>8</sup> For instance, it is simpler to set up ‘electronic systems for data retrieval’ when a computer is used for history taking and can be directly put into an EHR with a coded form such as Systemised Nomenclature of Medicine Clinical Terms (SNOMED-CT—see Chapter 5).<sup>8</sup> Importantly, this approach should allow researchers to have more standardised patient histories, which is important for ‘assessing the effectiveness of interventions’.<sup>8</sup>

### *Cost-effectiveness of computer history taking systems*

No studies have formally assessed the cost-effectiveness of CHTS. Dale and Hogen found that although studies stated that the electronic collection of PRO data is a ‘time-saving measure with certain aspects of cost benefit to it’, none of

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the reports examined the total amount of time and the costs in generating patient data using computer-aided techniques when compared to the more traditional techniques, taking into account all the time needed for PDA preparation, training and support.<sup>21</sup>

## **7.5 IMPLICATIONS FOR POLICY, PRACTICE AND RESEARCH**

### **7.5.1 POLICY**

Barriers still exist to CHTS, such as a preference for P&P, concerns about data loss and security as well as difficulty handling small devices such as PDAs.<sup>9</sup>

The displacement of professionals coupled with the loss of empathy built up in a traditional clinical interview are two specific issues that have been highlighted as concerns by professionals.<sup>9</sup> One further worry that has been expressed is that people who do not have the training or skills are extensively using and interpreting automated tests.<sup>9</sup> These concerns may, however, be based on a misunderstanding of the function of computers in clinical practice. As Parkin states:<sup>74</sup>

‘ . . . [computers] should not replace professionals but should be seen as a tool. Like a surgeon’s scalpel, they may wreak damage in unskilled hands. Such tools should be administered only by professionals qualified to do so and who have an understanding of the specific test being used, including its limitations.’

Currently, systems and technologies introduced by NHS CFH as part of NPfIT are not concerned with patient-generated data through CHTS. Rather, the focus for this Programme is on the EHR, which is reviewed in Chapter 6.<sup>74</sup> Based on the strong potential in some context, and in relation to some empirically demonstrated benefits, consideration needs to be given to incorporating professional templates into future iterations of the Detailed Care Record for use in specialities or contexts where history taking routines are well characterised and not particularly dependant on clinical intuition. Consideration also needs to be given to incorporating patient completed diaries, through HealthSpace, thereby allowing information on key complaints and self-generated data (for example, blood pressure or peak expiratory flow) to be made available to clinicians before the actual consultation.

In hospitals, patient notes are often hand-written and difficult to read and this can lead to incomplete, inaccurate or missing data in the care record and can be the cause of medical errors. An initial scoping paper prepared by the Care Records Development Board Ethics Advisory Group outlined the dimensions of data quality to be included in the National Care Record.<sup>74</sup> Both clinician and

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patient completed CHTS data are potentially important additional functionalities of the EHR as together they can help improve data quality through: data entry forms with data validation checks; encoding of data; legibility; easier access to past records; attribution of entries; easier availability; and facilitating patient checks of their own data.

Salford Royal Hospitals NHS Trust, for example, introduced its EHR pilot scheme in 1999.<sup>75</sup> The CHTS data that were input into the EHR enabled healthcare professionals to access and update records at the point-of-care and at the bedside using wireless devices. The system grew to encompass the following: the electronic ordering of investigations; referrals and electronic discharge summaries including the prescribing of drugs. Wherever possible, paper records have been removed to avoid ambiguity and to ensure that data is secure and accurate.

NHS CFH advocates the use of remote and wireless technology in order to avoid the need to transcribe information from paper to an electronic record. The progressive change in focus from hospital care to community-based care will mean that staff are more mobile and will therefore need to access and input data at the point-of-care. An example of this is an innovative project in Huddersfield using PDAs to improve the care of children and families.<sup>77</sup> This project has been piloted by health visitors using Palm Pilots to develop a universal needs assessment for pregnant women who are supported by social services. The information gathered is then shared with a multi-agency team who can decide on and allocate personnel to the patient.

Another example of using mobile technology for computerised history taking can be seen in the South Yorkshire Ambulance Service's use of on-board laptops.<sup>77</sup> The laptops, known as "tough-books" are used in place of traditional paper records to record details of emergency incidents and the treatment given to the patient. Touch screen technology allows the details to be input easily and quickly. Each patient record is then transmitted to a central data centre where they can be accessed by personnel at other ambulance stations, Doncaster A&E, and ambulance headquarters. This has resulted in more standardised records with better data quality and has also led to faster treatment for patients as receiving staff at the hospital are able to locate patient notes for the arrival of the ambulance.<sup>78</sup>

One further example of CHTS is Historian which is an automated psychiatric history taking system on the Internet, based in the North East London Mental Health Trust and was a joint winner of the 'Most innovative eHealth product' at the EHealth Innovation Awards 2005.<sup>79</sup> Devised by Dr Jason Taylor, this is a



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programme for patients referred to mental health services that enables histories to be taken in more than 15 languages, including many that are common among ethnic minorities and offers English output to the assessing professional. The system enables patients to complete the history at home and helps professionals to appraise psychiatric referrals rapidly and prioritise services.<sup>19</sup>

Tablet PCs, which are larger and combine the features of a notepad, laptop computer and touch sensitivity, may be a viable alternative for those who find PDAs and pocket PCs difficult to use. Although Tablet PCs have not been adopted widely and were seldom mentioned in the studies reviewed, members of our team are currently involved in a study evaluating the effectiveness of this approach to obtain patient-generated histories.

#### **7.4.2 PRACTICE**

Several studies reviewed in the article by Bachman used programmes that are now obsolete. Consequently, ‘criteria were developed to evaluate off-the-shelf software that a clinician can use today’.<sup>8</sup> The criteria include a programme that:<sup>8</sup>

‘. . . has been supported for at least the past 10 years, has a Web presence, uses branching questions, is designed for patient entry, has had published evaluations of its performance, and has complexity beyond a mental health tool or health risk appraisal.’

Two products that met these criteria in the US in 2003<sup>80</sup> were Instant Medical History<sup>81</sup> and HealthQuiz<sup>1</sup> (the latter is now redundant). In the UK, although it is still in its infancy, there is the potential to develop Healthspace<sup>82</sup> into a CHTS. There is considerable potential to use the Internet to obtain such data as demonstrated, for example, by the availability of the Patient Health Questionnaire (PHQ-9) for eliciting information on mental health disorders.<sup>83</sup>

#### **7.4.3 RESEARCH**

As Parker notes, computers have not yet been used to their full potential in clinical practice.<sup>9</sup> For example, little use has been made of tailored, or adaptive questionnaires, which entails sophisticated programming that ensures the selection of ‘test items’ appropriate to the individual questionnaire.<sup>9,84</sup> The difficulties around ‘tailored questionnaires’ means that they are not frequently used in written questionnaires and interviews.<sup>9</sup> However:<sup>9</sup>

‘. . . computers can calculate more precisely the necessity of each question as it arises and can detect inconsistencies and return to previous questions in order to



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clarify them further. This results in fewer no responses and inconsistencies and may reduce testing time by up to 50 per cent.'

Parker also highlights that 'speech recognition software' has also been used in 'personality testing'<sup>87</sup> and the 'screening of depressive symptoms',<sup>88</sup> and is likely to be used in 'most tests and interventions currently available'. Another factor to consider is determining in how hard keys are pressed or the response times, because this provides 'clinically important information'.<sup>9</sup> There is also the potential to develop questionnaires and interventions using 'virtual environments' in various areas of medicine, this can be used to support patients and clinicians by building up their skills.<sup>9</sup> Other technologies such as '...voice-activated software, graphics, measuring response time, tailored questionnaires, and virtual environments' are important areas for development.<sup>9</sup> Outcome studies, using clinically relevant endpoints are, however, needed to assess the effect of such technologies.<sup>9,18;20-22</sup>

With PDAs, more rigorous evaluations are required in larger samples, and multiple populations in order to study the impact of 'demographics and subpopulation characteristics such as age, gender, educational level'.<sup>21</sup> Also, the design of a good CHTS interface needs to be further investigated such as visual, ergonomic aspects, screen layout and ease of use (see Chapter 12).<sup>21</sup> And research on the impact of 'training, support, and other auxiliary measures' would provide an insight into how the quality of the data sets collected can be improved.<sup>21</sup>

Comprehensive cost-effectiveness analyses are needed in order to assess the financial rationale for choosing one CHTS over another.<sup>22</sup> Differences between the handheld and P&P instruments in data entry, in data handling and transfer times, were infrequently evaluated in studies, yet, 'theoretically handheld computers offer enormous temporal and financial benefits that deserve further exploration in clinical research'.<sup>22</sup>

As shown by Lane et al., there is evidence that handheld computer devices are an effective CHTS for data collection in the healthcare setting and in health-related research.<sup>22</sup> When compared to P&P methods of data recording the handheld computers appear to be the preference of most patients as they are quicker. However, although the accuracy of the data collected may be greater with handheld computers, in some studies the definitions of accuracy varied between studies. Therefore, future studies in this area would benefit from an improved standardised definition of accuracy to 'allow for inter-study comparisons'.<sup>22</sup> Additional information such as assessing the reliability of different methods

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of data collection would also be useful in assessing the value of collecting data using handheld computer technology in the healthcare setting.<sup>58</sup>

As Hogan and Wagner demonstrated in 1997, it is clear that errors may be introduced at several points throughout the history taking process (see Figure 7.1) so it may not be sufficient to implement a single intervention to improve data accuracy.<sup>58</sup> Moreover, even after successful interventions, accuracy may not be maintained over time. Medical processes are ‘complex and ever changing’, and data error, as well as procedural changes may occur due to the high turnover of personnel.<sup>19;43;58</sup> Hence, there is a pressing need for ‘evaluations on regular monitoring, analysis of errors, and interventions designed to improve accuracy, analogous to techniques in continuous quality improvement’.<sup>58</sup> Greater involvement of patients in recording their history through CHTS also opens the door to increased opportunities for patients to check aspects of their history and proactively identify any errors.

A number of authors have stressed the limitations of randomised trials in assessing the role of CHTS, indicating that questions such as how and why computer systems are used and explanations of various phenomena are best answered by studies based on qualitative, technical, psychological and other methods.<sup>43</sup> There is the need to develop integrated qualitative and quantitative approaches. Consideration therefore needs to be given to RCTs with embedded qualitative approaches so as to be able to answer questions of effectiveness and why the CHTS do or do not work (see Chapter 16).

Finally, an important evaluative consideration to bear in mind, highlighted by Poissant et al. is that the ‘major technology improvements that have occurred over the years make systems developed years ago incomparable with those developed more recently’.<sup>43,89–91</sup> Thus, for example, whilst much of the data on patient-generated data comes from studies of PDA technology, much of the PDA functionality has now been incorporated into mobile phones, with the possibility that PDAs may become redundant in the not too distant future. More rounded appreciations of the impact of these technologies than has often hitherto been conducted would allow an assessment of the extent to which findings from PDA studies are generalisable to, for example, mobile phones and or Internet-based approaches for generating these data.

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## CHAPTER 8

### Computerised decision support systems

#### SUMMARY

- There are strong theoretical reasons for believing that improved access to relevant clinical information for healthcare professionals, at the point of care, can translate into improvements in healthcare quality and patient safety.
- Computerised decision support systems are defined as software applications that use patient data, a repository of clinical information (knowledge-base) and an inference mechanism to generate patient specific output. These applications are highly variable in sophistication and the extent to which they can integrate with other clinical information systems.
- These applications have the potential to improve clinical decision-making by providing practitioners with patient specific and evidence-based support, in real-time, and by providing individually tailored feedback.
- Although numerous evaluations of these applications have taken place, very little consistent and generalisable evidence exists on their ability to improve practitioner performance and patient outcomes; evidence is often limited to particular conditions (eg diabetes and hypertension) or an aspect of clinical care (eg preventative care).
- The use of computerised reminders for preventative care has been empirically demonstrated to be of the most benefit. However, trials have not yet assessed patient outcomes; this to a large extent reflects the prohibitive size and or duration of study needed to demonstrate an effect on clinical outcome measures.
- These applications are largely unregulated in the US and UK, as they fall outside the remit of the Federal Drug Administration and Medicine and Healthcare Products Regulatory Agency, respectively.
- Without formal quality and safety assurances in relation to these applications, the potential risks to patient safety need to be seriously considered as they may in certain situations paradoxically introduce new errors.
- As evidence of benefit is clearest and risk of harm is lowest in relation to

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support for preventative healthcare, NHS Connecting for Health should consider introducing a range of computerised health promotion tools into primary care and, in the context of the roll-out of the electronic health record, also into secondary care.

- Arriving at one overarching message regarding the effectiveness and safety of these applications is naïve and should be abandoned. Rather, research should focus on understanding the contexts in which these applications are most likely to prove effective and this should be a priority consideration for NHS Connecting for Health as it introduces new eHealth applications with built in decision support functionality.

## **8.1 INTRODUCTION**

Computerised (or clinical) decision support systems (CDSSs) are software applications that integrate patient data (input) with a knowledge-base and an inference mechanism to produce patient specific output in the form of care recommendations, assessments, alerts and reminders to actively support practitioners in clinical decision-making.<sup>1-3</sup> These systems can take a number of forms such as, for example, the more advanced professional completed computer-aided history taking systems which, as discussed in the previous chapter, make use of previous responses or image interpretation systems of the type considered in the following chapter. It should be noted that whilst patient or consumer directed CDSSs exist, they will not be considered as these fall outside the scope of this report; we do hope, however, to review the literature on these increasingly important patient-orientated eHealth applications in planned future work.

## **8.2 DEFINITION, DESCRIPTION AND SCOPE FOR USE**

### **8.2.1 DEFINITION**

There is no universally agreed definition of CDSS, this in part at least reflecting the continuing evolution of the scope and application for these artificial intelligence computerised clinical support systems.<sup>4</sup> Wyatt and Spiegelhalter's definition of CDSS as '...active knowledge systems which use two or more items of patient data to generate case-specific advice'<sup>5</sup> is widely used, but as this definition currently stands it excludes simple memory aids to clinicians (such as the more basic computer history taking systems discussed in the previous chapter). It further also excludes the more novel patient support tools (sometimes known as decision support systems), systems that make clinical decisions on population level data and systems that provide additional

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information to a clinician (such as prognosis) at the point of care without explicitly supporting the decision-making process. There is thus, as with most other eHealth applications need for greater clarity in what exactly is being referred to when using the term CDSS. In the context of this chapter, we will be focusing on studies investigating computerised systems that draw on specific patient data to support the professional management of individual patients.

### 8.2.2 DESCRIPTION OF USE

Computerised decision support systems vary in design and function.<sup>6</sup> Applications can be used by any healthcare professional involved in the provision of healthcare. They can be stand-alone or integrated within or interfaced with other clinical information systems. Engagement with a CDSS can be active or passive meaning that end-users can actively choose to engage with a CDSS or this support can be automatically provided whilst entering information into the electronic health record, ordering tests, prescribing (see Chapter 10), or undertaking other clinical information system related activities. Patient data can be input by digital entry, queried from other clinical information systems or transmitted from medical devices.

Patient data (input) are compared against a knowledge-base (the collection of clinical knowledge) and made sense of by an inference mechanism (the logic). The knowledge-base can be procured commercially or developed in-house. The inference mechanism can be highly variable in sophistication ranging from simple ‘yes’ ‘no’ and ‘if’ ‘then’ statements to Bayesian prediction techniques and or fuzzy logic. The output can also take a number of forms and can be delivered to a number of destinations occurring at any time before or during interaction (synchronously) or post-interaction (asynchronously).

The Australian National Electronic Decision Support Taskforce has adopted the following helpful classification system to describe CDSSs:<sup>7</sup>

- **Type One:** Provides categorised information that requires further processing and analysis by users before a decision can be made
- **Type Two:** Presents the clinician with trends of patients’ changing clinical status and alerts clinicians to out-of-range assessment results and intervention strategies. Clinicians are prompted to review information related to the alerts before arriving at a clinical decision
- **Type Three:** Uses deductive inference mechanisms to operate on a specific knowledge-base to automatically generate diagnostic or care recommendations based on changing patient clinical condition with the knowledge-base and inference mechanism stored in the application

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- **Type Four:** Uses more complex knowledge management and inference mechanism such as case management reasoning, neural networks, or statistical discrimination analysis to perform outcome or prognostic predictions. Such applications possess self-learning capabilities and use fuzzy set formalism and similarity measures or confidence level computation as mechanisms to deal intelligently and accurately with uncertainty.

Other ways of conceptualising CDSSs have been proposed by various authors. For example, Perreault and Metzger categorise CDSSs as: providing access to information; guiding choice; knowledge-based prompting; and understanding clinical practice.<sup>8</sup> Broverman differentiates between applications that are: passive versus active; aggregate versus individual patient-based; concurrent versus retrospective; integrated with the patient database versus stand-alone; and applications that are proprietary versus standards-based encoding.<sup>9</sup> Finally, Sim et al. make the distinction between applications that are evidence-adaptive in which the clinical knowledge-base of the CDSS is derived from and continually reflects the most up-to-date evidence from the research literature and practice-based sources and those that do not.<sup>10</sup>

### 8.2.3 SCOPE FOR USE

A widely known contributing factor to the deficits in the quality of healthcare today is the growing complexity of clinical knowledge and the difficulties associated with managing vast amounts of information.<sup>11</sup> The general premise underlying the use of CDSSs is that they support clinicians in making more informed (better) decisions. As such, knowledge-bases can supplement the gaps in clinician's knowledge and inference mechanisms can aid in the interpretation of patient data to improve clinical decision-making. By improving clinical decision-making, CDSSs have the potential to impact on the quality—the effectiveness, efficiency and economics—and perhaps most importantly, the safety of healthcare.

CDSSs can be used for a variety of clinical activities such as preventive care, diagnostics, therapeutics, comprehensive disease management, image recognition and interpretation and prognostics. Theoretically, CDSSs can be used for any speciality of clinical care and in any setting where the requisite knowledge-base and technological infrastructure exists.

Additionally, CDSSs can support research studies by identifying patients who may fit a certain description and assisting in management of such individuals in accordance with research protocols. CDSSs can also provide assistance with

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quality assurance activities such as tracking orders and referrals with no results, need for follow-up and need for preventive services, supporting clinical coding and documentation, procedures authorisation and referrals management.<sup>8</sup> The plasticity of this application suggests a diverse range of opportunities for impact on the quality and safety of healthcare.

## 8.3 THEORETICAL BENEFITS AND RISKS

### 8.3.1 BENEFITS

#### *Healthcare quality*

Quality healthcare encompasses a multitude of dimensions.<sup>11</sup> As discussed in Chapter 4, the domain targeted by the use of CDSSs is improved decision and safety support, ie supporting the clinical decisions made by healthcare professionals. CDSSs have the potential to improve the quality of clinical decision-making by providing cost-conscious, evidence-based and patient specific support. The delivery of healthcare can be standardised to a certain degree depending on the extent that clinicians consider the output such as making clinical decisions that adhere to best-practice guidelines. This aspect of CDSSs could impact most beneficially on outlier clinicians practicing below an acceptable standard of care.<sup>12</sup> CDSSs can also provide clinicians with individually tailored educational opportunities by providing feedback to improve future clinical decision-making.<sup>7,13</sup> as well as facilitating quality assurance and epidemiological research and monitoring. CDSSs can also provide ready access to a substantial evidence-base thereby ameliorating the need to search disparate sources of information in order to locate findings. Providing evidence-based information at the right time and place to clinicians is one of the key strategies to encourage the provision of healthcare that judiciously balances cost with effectiveness.<sup>14</sup>

#### *Patient outcomes*

By improving the quality of practitioner performance, it is reasonable to infer that patient outcomes should subsequently be improved, indirectly improving patient safety by decreasing the risk of preventable adverse events. It is also reasonable to infer that improved practitioner performance should also directly improve patient safety by decreasing the risk of iatrogenesis.

### 8.3.2 RISKS

The use of such expert applications rather than impact beneficially on the quality and safety of healthcare can actually result in a detrimental effect. Unfortunately,

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these negative outcomes tend to go relatively unstudied, this perhaps reflecting the optimism of the technophiles who develop and often also evaluate these eHealth applications.

#### *Healthcare quality*

Oversights on the behalf of system designers and developers or implementation strategists might lead to diminished healthcare quality. Such risks include:

- a worsening in clinical capability due reliance on a CDSS resulting in a “deskilling” effect<sup>15</sup>
- a worsening professional experience in delivering care, for example, increased clinician workload which, in turn, results in dissatisfaction<sup>16;17</sup>
- changes to clinician-patient relationship such as a loss of patient respect for clinical skills or dissatisfaction with the nature of the clinician-patient interaction<sup>17</sup>
- changes in onus of responsibility with implications for litigation of, for example, the individual clinician, organisation procuring the software or software developer,<sup>18</sup> which is particularly important as there is apparently no case law to establish the relevant precedents in the US, Europe or elsewhere.<sup>18</sup>

#### *Patient safety*

CDSSs are largely unregulated in the US and UK due to their being excluded from the remit of the Federal Drug Administration (FDA) and Medicine and Healthcare Products Regulatory Agency (MHRA) respectively.<sup>19;20</sup> In their paper, *Clinical Decision Support Systems: A Discussion of Quality, Safety and Legal Liability issues*, Fox and Thomson, in the context of acknowledging this regulative deficit, discuss four primary approaches to quality and safety for CDSS applications:<sup>18</sup>

- use of rigorous software engineering to ensure the reliability of the platform
- systematic quality control for the clinical content of an application and its associated scientific evidence-base
- explicit hazard management during operation of the system
- comprehensive documentation to permit quality and safety reviews by end-users, technology licensors, etc.

However, the authors posit that even CDSS software development supported by internationally accepted standards, is insufficient as ‘...no current standard can guarantee the safety of a complex technology such as clinical software; the



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most that one can practically achieve is to commit reasonable effort to attaining acceptable quality and safety.’<sup>18</sup>

Without formal quality and safety assurances in relation to CDSS software applications, the potential risks to patient safety need to be seriously considered as although the use of a CDSS is intended to reduce the burden from some types of medical errors by improving clinical decision-making and alerting or warning end-users to certain types of situations, applications might also introduce new errors. For instance, an incomplete or inaccurate knowledge-base or invalid inference mechanism might lead to:<sup>16;21–24</sup>

- incorrect output generated by CDSSs → incorrect therapeutics, tests or images ordered and administered → e-iatrogenesis.

Fox and Thomson suggest that methods for quality control of clinical knowledge-bases might include:<sup>18</sup>

- automated analysis to find internal inconsistencies, gaps, redundancies, ambiguities, etc (eg based on syntax-directed verification techniques).
- peer review by competent individuals; the review may include static assessment of content (eg reading the knowledge-base) and dynamic assessment (eg testing the application against standard cases)
- all content should be available in a legible form for review, both in static form (eg as text) and dynamic form (eg as explanations of any decision or recommendation)
- provision should be made for end-users to report queries and problems to the application developers as easily as possible.

The authors offer some important pointers on issues to consider in attempting to ensure that the clinical knowledge-base of a CDSS is of high quality noting that:<sup>18</sup>

‘Clinical knowledge is subject to frequent change and research often shows that past clinical practices are ineffective, or even hazardous. Furthermore, knowledge quality will often be a professional judgement, either of an individual or group of experts, and efficacy and safety aspects are not necessarily always based on objective scientific evidence. Even when there is evidence, it may be limited, open to different interpretations and subject to change as scientific knowledge advances.’

And that:

‘...developers of decision support systems should seek to achieve at least the level of quality assurance that is associated with more traditional knowledge sources (such as clinical journals and reference texts) augmented with methods that are appropriate for the new types of knowledge technology.’



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But that:

‘. . . a computer-based representation of clinical knowledge cannot in principle be proved to be clinically complete or objectively correct; it can only attempt to capture the current state of professional and scientific opinion.’

Nevertheless, they argue:

‘Current techniques make it possible to verify formally that the clinical knowledge used in a CDSS satisfies certain technical requirements like consistency and completeness, at least partially by automatic means.’

Apart from risks to patient safety arising from inaccuracies in the knowledge-base or inference mechanism, risks to patient safety by use of a CDSS could occur at any point in the use of applications due to errors made by the end-user either due to incompetence or poor usability, for example:

- incorrect patient selected if integrated with a clinical information system  
→ inappropriate output generated → inappropriate clinical decision made  
→ e-iatrogenesis

It is entirely possible that end-users may have inadvertently selected the wrong patient for a variety of reasons continuing to work the system using the wrong patient data.

- incorrect or incomplete patient data inputted → incorrect output generated → incorrect clinical decision made → e-iatrogenesis

Hogan and Wagner conducted a review of the accuracy of patient data in EHRs and found that included studies reported highly variable levels of accuracy.<sup>25</sup> The authors posited that the variability seen is due to differences in study design, in types of data studied and in the EHRs themselves, and that these differences confound the interpretation of this literature echoed by two other similar reviews.<sup>25–27</sup> The risks to patient safety stemming from inaccurate patient data, although inherently important and one that can be targeted for intervention are often overlooked in evaluations of CDSSs.

## **8.4 EMPIRICALLY DEMONSTRATED BENEFITS AND RISKS**

We found numerous systematic reviews (SRs) conducted with regards to CDSSs (see Appendix 5 for details of these reviews).<sup>1;2;17;28–37</sup> Reviews specifically focusing on the use of CDSSs for prescribing are discussed in the chapter on ePrescribing (Chapter 10). For the sake of brevity, we do not detail reviews on the use of CDSS for image interpretation. We do, however, undertake a detailed case study of the use of CDSS for image interpretation for the purposed of

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screening mammography in the following chapter, which illustrates the most pertinent issues.

The reviews that do focus on CDSSs have been conducted in a variety of ways (systematic or otherwise) looking at particular conditions (eg computer-aided diagnosis of melanoma),<sup>30</sup> different settings (eg neonatal care)<sup>28</sup> or aspects of clinical care (eg reminders for preventative care).<sup>29</sup> However, as CDSSs vary greatly in context of use (end-users, setting, problem), sophistication, knowledge and data sources, nature of decision support offered, mode of delivery and workflow impact, reviewing the literature on CDSSs is far from straight-forward.<sup>6</sup> To generalise from these reviews proves even more difficult as reports and indeed even evaluations of individual studies rarely provide the necessary information to contextualise findings.

The reviews tend to be methodology driven and largely ignore the range of issues that pertain to eHealth evaluations in general and to-date no such review—systematic or otherwise—has been conducted in a manner that demonstrates sufficient sensitivity to the issues surrounding the evaluation of eHealth applications (see Chapters 2 and 15 for a fuller discussion of this important point). Of particular relevance is the important point made by Wears and Berg, who argue that:<sup>40</sup>

‘CDSSs come in many different forms, have a myriad of aims, and can be implemented in many ways, so it is fair to ask if these systems can really be approached as a single intervention.’

For those interested in how best to navigate evaluations of CDSS, we suggest the *Users’ Guides to the Medical Literature: XVIII. How to Use an Article Evaluating the Clinical Impact of a Computer-Based Clinical Decision Support System* as an excellent starting point.<sup>41</sup>

#### **8.4.1 BENEFIT**

Nonetheless, as the most comprehensive secondary evaluation to date in this field, the SR by Garg et al. published in 2005 is a natural place to look for evidence on the impact of CDSSs on the quality of care.<sup>1</sup> Where possible we indicate how the findings of this review differ from those reported elsewhere. This SR was an update of the systematic review by Hunt et al.,<sup>2</sup> which in turn, was an update of the SR by Johnston et al.<sup>34</sup> The Garg review assessed the methodological quality of 100 controlled trials—randomised and non-randomised—comparing the effect of care with a CDSS to care provided without a CDSS on practitioner performance and patient outcomes. A noteworthy limitation of Garg et al.’s review

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is the failure to distinguish between the evidence obtained from randomised and non-randomised controlled trials. Improvement was defined as a positive effect for at least 50 per cent of outcomes measured. Outcomes were categorised into practitioner performance and patient outcomes and studies were grouped by activity of care into: preventative care; diagnosis; disease management; and organisational efficiency.<sup>1</sup> Again, Garg et al. included studies on prescribing and those results are considered in the discussion on ePrescribing (Chapter 10).

The 100 trials had the following characteristics: 92 per cent enrolled clinicians as primary users, 48 per cent enrolled healthcare practitioners in training (interns and residents) as users, 34 per cent described pilot testing with users prior to implementation, 42 per cent described user instructional training at the time of implementation, 76 per cent took place in academic centres, and 33 per cent were inpatient-based. In 47 per cent of studies, the CDSS was part of an EHR or computerised provider order entry (CPOE) system. Most of these were early generation applications lacking the full functionality of current applications. In 15 per cent of studies, the CDSS had a graphical user interface. Feedback from the CDSS occurred at the time of patient care in 88 per cent of studies; in 60 per cent the user was automatically prompted to use the system (versus the user actively initiating the system); and in 91 per cent the CDSS suggested new orders (versus critiquing existing orders). Expert clinician opinion or clinical practice guidelines usually formed the knowledge-base for the CDSS. The process of data entry into the CDSS was clear in 80 per cent of trials, some of which used more than one method. Existing personnel most often entered data (attending or training clinician, 38 per cent; other healthcare staff (eg nurses or clerks), 29 per cent), although many trials used staff paid by research funds (21 per cent) or automated data capture from an EHR (30 per cent). The method of delivering computer recommendations to the clinician was clear in 81 per cent of trials. Most CDSSs directly provided the recommendation on a computer screen viewed by the practitioner (41 per cent of all trials) or generated printed reports that were placed in clinical charts by healthcare staff (29 per cent) or by staff paid by research funds (16 per cent).<sup>1;35;38;39</sup>

### *Practitioner performance*

There were 21 trials evaluating the impact of reminder applications on practitioner performance.<sup>40–60</sup> CDSSs were found to be beneficial in 16 (76 per cent) of these trials.<sup>61–76</sup>

Performance outcomes were usually rates of screening, counselling, vaccination, testing, medication use, or the identification of at-risk behaviours. Successful use

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of CDSSs was typically demonstrated for cancer screening (six of seven trials; 86 per cent),<sup>77–82</sup> vaccinations (two of three trials; 67 per cent)<sup>83;84</sup> and multiple preventative care interventions including cancer screening, vaccinations and cardiovascular disease prevention (8 of 11 trials; 73 per cent).<sup>85–92</sup> This finding is consistent with the meta-analysis conducted by Austin et al. whose results indicated that for cervical cancer screening and tetanus immunisations, clinician reminders are an effective information intervention and can improve compliance for these two preventive healthcare procedures;<sup>93</sup> and the meta-analysis by Shea et al. which found that computer reminders improved preventive practices compared with the control condition for vaccinations (adjusted odds ratio [OR] 3.09; 95 per cent confidence interval [CI] 2.39–4.00), breast cancer screening (OR 1.88; 95 per cent CI 1.44–2.45), colorectal cancer screening (OR 2.25; 95 per cent CI 1.74–2.91), and cardiovascular risk reduction (OR 2.01; 95 per cent CI 1.55–2.61) but not cervical cancer screening (OR 1.15; 95 per cent CI 0.89–1.49) or other preventive care (OR 1.02; 95 per cent CI 0.79–1.32)—for all six classes of preventive practices combined the adjusted OR was 1.77 (95 per cent CI 1.38–2.27).<sup>29</sup>

All 10 trials evaluating diagnostic applications measured practitioner performance and the CDSS was found to be beneficial in four (40 per cent) of these studies.<sup>94–103</sup> Two of the four (50 per cent) successful CDSSs were diagnostic applications for cardiac ischemia in the emergency department and these decreased the rate of unnecessary hospital or coronary care admissions by 15 per cent ( $p < 0.05$ ).<sup>104;105</sup> The third study to demonstrate benefit increased mood disorder screening in a post-traumatic stress disorder clinic by 25 per cent ( $p < 0.01$ ).<sup>106</sup> The fourth improved the time to diagnosis of acute bowel obstruction (one hour when computer was used vs 16 hours when diagnosis was made with contrast radiography;  $p < 0.001$ ).<sup>97</sup>

There were 31 trials of CDSSs for active health conditions.<sup>107–136</sup> These CDSSs improved practitioner performance in trials evaluating this outcome. For diabetes care, practitioner performance was usually judged by rates of retinal, foot, urine protein, blood pressure and cholesterol examinations; five (71 per cent) of these seven trials reported improvements.<sup>137–141</sup>

A number of other reviews, systematic or otherwise, have been conducted on the general use of computers in diabetes care.<sup>142–148</sup> Significantly improved guideline compliance was reported in six of eight computerised prompting studies were reported by Balas et al. in a systematic review of randomised controlled trials (RCTs).<sup>142</sup> For cardiovascular disease management and prevention, performance was judged by blood pressure and cholesterol assessment, identification of

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smoking and use of cardio-protective medications; 5 (38 per cent) of these 13 trials reported improvements.<sup>149–153</sup> Similarly, Shea et al. found that the use of computer-based clinical reminder applications significantly improved cardiovascular risk reduction (OR 2.01; 95 per cent CI 1.55–2.61).<sup>29</sup> A SR of RCTs on the use of computers in the management of hypertension, an important risk factor for cardiovascular disease, reported that ‘. . .it seems that computers have a favourable effect on the uptake and follow up of patients in hypertension management.’<sup>154</sup> However, the effect of computers on clinicians knowledge, recording of information, and blood pressure control in patients is less conclusive.<sup>154</sup>

Other CDSSs varied in purpose, providing recommendations for urinary incontinence, human immunodeficiency virus infection management, functional assessment and management of acute respiratory distress syndrome; six of these nine trials (67 per cent) reported improvements.<sup>131;155–159</sup>

### *Patient outcomes*

Unsurprisingly, most trials of computer-assisted reminders for preventative care have not assessed patient outcomes as for most preventative care interventions the numbers and or time needed to demonstrate an effect on patient outcomes is often prohibitive. However, one trial did assess clinical endpoints, but failed to demonstrate an improvement in the primary analysis; post hoc sub-group analyses, however, demonstrated a significant reduction in winter hospitalisation and emergency department visits in patients’ eligible for pneumococcal or influenza vaccination.<sup>160</sup>

Of the five trials of diagnostic applications assessing patient outcomes, none have reported an improvement in clinical endpoints and this finding is consistent with the findings of the SR conducted by Nies et al.<sup>35</sup>

Of the 27 trials for disease management assessing patient outcomes, 5 (18 per cent) demonstrated improvements. One CDSS improved blood pressure control (70 per cent of patients had controlled blood pressure with CDSSs use vs 52 per cent with routine care;  $p < 0.05$ ).<sup>161</sup> A second CDSS reduced urinary incontinence in nursing home residents over a 10-week period (23 per cent incontinent with CDSSs vs 69 per cent with routine care;  $p < 0.01$ ).<sup>131</sup> A third CDSS improved scores of barotrauma ( $p < 0.001$ ) and organ dysfunction ( $p = 0.04$ ) in mechanically ventilated patients with acute respiratory distress syndrome.<sup>128</sup> One participating centre in this trial provided data demonstrating lower tidal volumes ( $p = 0.03$ ) and a reduction in exposure to high plateau pressures in the group receiving CDSS-guided mechanical ventilation ( $p < 0.001$ ).<sup>162</sup> A fourth

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CDSS reduced patient-reported asthma exacerbations (8 per cent vs 17 per cent; odds ratio, OR=0.43; 95 per cent CI 0.21–0.85), emergency nebuliser use (1 per cent vs 5 per cent; OR=0.13; 95 per cent CI 0.01–0.91), and the need for additional consultations for asthma management (22 per cent vs 34 per cent; OR=0.59; 95 per cent CI 0.37–0.95) over six months.<sup>163</sup> A fifth CDSS reduced hospital length of stay ( $p=0.02$ ) for patients with a variety of general clinical diagnoses.<sup>164</sup>

In post hoc secondary or sub-group analyses, some trials have described statistically significant improvements in patient outcomes of disease-specific emergency department visits,<sup>165</sup> hospital length of stay,<sup>166–169</sup> body weight,<sup>170–172</sup> diastolic blood pressure,<sup>173–175</sup> serum lipids,<sup>176;177</sup> and a reduced estimated risk of future cardiovascular events.<sup>178</sup>

#### **8.4.2 RISKS**

Evaluations of CDSSs have not demonstrated risks per se. However, the effect of data quality—accuracy and completeness—has been explored in relation to CDSS functioning. For instance, Berner et al. explored the effect of incomplete patient data on CDSS accuracy and found that when the available data were input into the CDSS, the missing data elements resulted in inappropriate and unsafe recommendations in almost 77 per cent of the encounters.<sup>179</sup>

Similarly, Hasan and Padman investigated the effect of data quality on the accuracy of a CDSS using simulation and that:<sup>180</sup>

‘...this type of analysis can be beneficial to system designers and developers as well as healthcare organisations who can use the results to inform the development of procedures for minimising incorrect clinical decisions facilitated by these systems such as ensuring that the necessary data elements not only are present but accurate to maximise benefit and minimise risk.’

A lack of empirically demonstrated risk does not, however, necessarily indicate a lack of actual harm arising from use of CDSSs as this is a rarely assessed outcome in evaluations. This perhaps stems from an assumption of adequate safety which might be entirely unjustified in light of the above noted regulatory deficit of applications.

### **8.5 IMPLICATIONS FOR POLICY, PRACTICE AND RESEARCH**

There is no clear overriding message of the clinical-effectiveness of CDSSs and to search for one overriding message, as we hope the above critique has demonstrated, is a fruitless endeavour. Rather, it is important to try and



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understand what features in the design and development of, and the contexts in which deployment of CDSSs is most likely to generate favourable outcomes. As CDSSs perform best when integrated with other clinical information systems such as an EHR or CPOE, primary care within England provides an ideal infrastructure into which to incorporate CDSSs. As simple applications for reminders in preventative care have been demonstrated to be the most effective with regards to improving practitioner performance and are least likely to compromise safety, these would be the ideal area to begin with and the roll-out of the NHS Care Records Service into secondary care provides an ideal opportunity to incorporate this functionality.

When branching out into decision support applications for use in diagnostics, active disease management and prognostics it is important to be aware that the inherent uncertainty in clinical decision-making makes it very difficult to at present develop valid algorithms to underpin CDSSs. These clinical areas have hence surprisingly not been empirically demonstrated to be clinically effective to-date and when considering embarking on developing or procuring such applications it is important that their use be healthcare driven and not technology driven.

Experts such as Wyatt<sup>181</sup> and Bates<sup>182</sup> have published factors important for successful or effective CDSSs based on experience and expertise, and systematic reviews have been conducted by Garg et al., Nies et al., Holbrook et al., van der Meijden et al. and Kawamoto et al. (2003 & 2005) on the same topic.<sup>1;35;38;39;183;184</sup> Ensuring that industry is not only aware of such publications but makes use of them is important to designing and developing decision support applications.

Sim et al. provide useful recommendations for current CDSS designers, namely to:<sup>10</sup>

- adopt and use standard vocabularies and standards for knowledge representation as they become available
- incorporate into CDSSs' knowledge-base the current best literature-based and practice-based evidence and either provide mechanisms for keeping the knowledge-base up-to-date or explain why keeping up with the evidence is not applicable
- explicitly describe the care delivery setting and clinical scenarios for which the CDSS is applicable (eg that a CDSS for diabetes treatment is intended for the management of stable outpatient diabetics only)
- integrate CDSSs with EHR and other relevant clinical information systems using appropriate interoperability standards.

It is also important for policy makers, organisations and manufacturers is to



support the development and demonstration of inter-organisational sharing of evidence-based knowledge and its application in diverse CDSSs.<sup>10</sup>

All concerned with developing, procuring, using and evaluating CDSSs need to remain alert to the possibility that these applications may also introduce new errors; the quality assurance mechanism developed by NHS CFH is critical in light of the current regulatory deficit in relation to this eHealth application.

Similarly, improved evaluation—both formative and summative—of both the positive and negative impact on CDSSs on the quality and safety of healthcare is imperative to providing an evidence-base to potential end-users and informing system re-design and development.

Although numerous reviews have been conducted with regards to CDSSs, the validity of the evidence on their effectiveness for improving practitioner performance and, in particular, patient outcomes, remains questionable due to a variety of methodological concerns as discussed in Chapter 15. However, simply conducting more rigorous primary research will not in itself be sufficient as the degree of dissimilarity between CDSSs is problematic even for reviews seeking to answer very specific questions about CDSSs and consequently very few meta-analyses have been performed due to the heterogeneity of CDSSs studies. Demonstrating the complexity of variables that contribute to an evaluation of a CDSS is a taxonomy developed by Sim and Berlin (Table 8.1).<sup>185</sup>

Table 8.1 CDSS taxonomy

Category and axis	Description
<b>Context</b>	
Clinical setting	Setting where CDSS operates
Clinical task	Clinical activity CDSS supports
Unit of optimisation	Type of outcomes being optimised by CDSS
Relation to point of care	Temporal relationship between provision of decision support, moment of decision-making, and a shared clinician-patient encounter
External behaviour modification programs	Whether administrative or organizational incentives designed to affect acceptance and/or compliance with CDSS recommendations implemented along with CDSS
Potential barriers	Potential barriers to completion of the action recommended by CDSS
<b>Knowledge and Data Source</b>	
Clinical knowledge source	Source for the clinical knowledge used to generate recommendations

**Table 8.1 CDSS taxonomy**

Category and axis	Description
Data source	Source for the patient data used to generate recommendations
Data coding	Format of data entered into the CDSS
Degree of customisation	Degree to which CDSS recommendations are customized to individual patient clinical data and history
Update mechanism	Mechanism for updating CDSS clinical knowledge base to reflect real-world advances in clinical knowledge
<b>Decision Support</b>	
Inference mechanism	Method employed by reasoning engine to generate CDSS recommendation
Clinical urgency	Whether action being recommended by CDSS needs to be made in minutes to hours after recommendation generated
Recommendation explicitness	Whether recommendation generated by CDSS is explicit or implicit
Logistical complexity	Whether degree of logistical complexity of recommended action is complex or simple
Response requirement	Type of response required of target decision-maker to CDSS recommendation
<b>Information Delivery</b>	
Delivery format	Format of the recommendation provided by CDSS
Delivery mode	Whether the CDSS generates unsolicited recommendations to target decision-maker
Action integration	For relevant clinical tasks, whether CDSS provides tools for completion of recommended action along with recommendation
Explanation availability	Whether CDSS provides target decision-maker with explanation of recommendation
Interactive delivery	Whether CDSS allows the end-user to interface with information provided by CDSS in interactive manner
<b>Workflow</b>	
System user	Identity of the end-users interfacing with CDSS
Target decision-maker	Person whose actions the CDSS is designed to influence directly through its recommendations
Data input intermediary	Identity of intermediaries (if any) responsible for entering data from data source into CDSS
Output intermediary	Identity of intermediaries (if any) responsible for relaying recommendation generated by CDSS to target decision-maker

**Table 8.1 CDSS taxonomy**

Category and axis	Description
Workflow integration	Whether the operation of the CDSS requires novel procedures or responsibilities that would not otherwise be performed by clinic staff, and, for 'push' systems only, whether the target decision-maker is required to halt other workflow to respond to the recommendation generated by CDSS

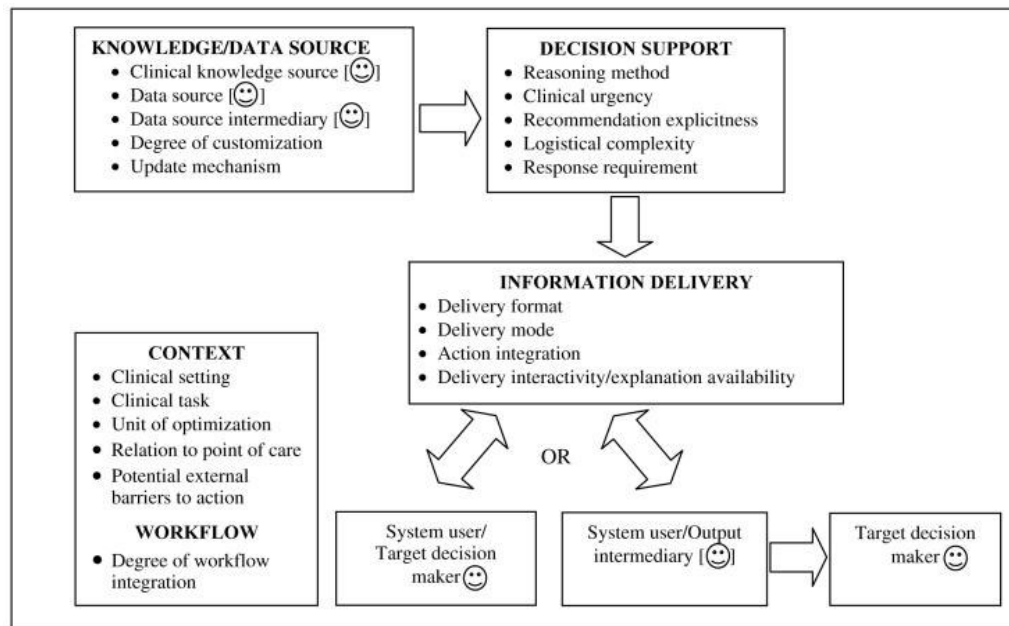
*Source: Sim (2003)<sup>128</sup> Reprinted with permission from the American Medical Informatics Association.*

If applied by evaluators of CDSSs to primary research of CDSSs the taxonomy should facilitate sub-group analysis and interpretation of results for secondary research furthering the science of CDSS evaluation.<sup>185</sup> It also provides readers of CDSS evaluations with a framework to more thoughtfully negotiate the literature as many highly cited reviews neglect to provide relevant details of included studies as well as to:<sup>185</sup>

- serve as a guide to CDSS investigators on how to improve the completeness with which they describe their CDSSs in the literature
- facilitate classification of reported CDSSs to characterise the types of CDSSs that are being developed and evaluated
- use the taxonomy's descriptors as potential explanatory variables in a meta-regression on a CDSS' success.

This is important work and future research should aim to refine the interplay between the taxonomic axes presented below in Figure 8.1 whilst ensuring robustness so that future evaluations of CDSSs make use of such a tool to improve usability of findings and facilitate secondary research.

**Figure 8.1: Overview of taxonomy axes**



Source: Sim (2003)<sup>128</sup> Reprinted with permission from the American Medical Informatics Association.

Secondary research employing sub-group analysis by level of sophistication (eg inference mechanism), may elucidate more meaningful findings. Aside from Lisboa's review on the use of neural networks,<sup>31;32</sup> reviews of CDSSs are rarely evaluated with regards to system sophistication. Critical analysis of these SRs of CDSS does, however, allow a natural hierarchy in complexity to be seen. Reminders, the simplest of algorithms, rule-based in nature and often derived from clinical practice guidelines, are demonstrated to be the most beneficial to practitioner performance. Diagnosis, prognosis and comprehensive disease management are more complex clinical processes. The more sophisticated CDSSs that are needed for these more complex clinical processes often do not, however, demonstrate benefit. This may be due to a variety of reasons, including the system's inability to mimic complex clinical decision-making and a reluctance of end-users to trust the application and its outputs. In fact, Sintchenko et al. report that '...decision complexity seems to impact on the extent and type of information support used by individuals when decision-making.'<sup>186</sup> In their study the authors found that '...decisions of higher complexity were associated with a lower frequency of CDSS use but required the use of the more cognitively demanding situation assessment tool for risk along with pathology data.'<sup>186</sup>

Studying the relationship between decision complexity and information seeking also opens up the possibility of helping predict the risk of human

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error when using CDSSs. Decision complexity may guide a designer's choice of decision support allocation and functionality to different tasks. Measuring decision complexity also seems to help understand how the adoption of CDSS is related to complexity of decision process variables.<sup>186</sup>

Practitioner performance is commonly assessed outcome in the evaluative literature on CDSSs. Contrary to what one might expect, it is not always improved by the use of CDSSs. In fact, Garg et al. found that one-third of studies included in their SR did not result in improved practitioner performance.<sup>187</sup>

Patient outcomes have been less commonly assessed, this being a noteworthy limitation as noted in a number of reviews. This finding is important considering that the taxonomic review conducted by Berlin et al. found that nearly all (96 per cent) of the CDSSs reviewed were designed to optimise the clinical outcomes of patients, with only three applications (four per cent) designed to optimise application-based outcomes such as cost or resource utilisation. This may simply be a logistical issue as when patient outcomes are evaluated, primary studies are almost always insufficiently powered to detect significant effects of patient outcomes. This is, however, problematic for those interested in the impact of CDSSs on patient outcomes such as patient safety and the potential risks to patient safety resulting from the use of such applications.

Many authors note the lack of diversity in sources of high quality literature regarding multi-functional eHealth applications.<sup>39</sup> Chaudhry et al. who did not conduct a review solely on CDSSs but which comprised the majority of included studies, commented that much of the evidence of quality improvement relates to primary and secondary care and therefore further research into the use of CDSSs in tertiary care is warranted.<sup>188</sup> Additionally, Handler et al. call for further study in the emergency setting as the characteristics of this setting are very different to other clinical care settings,<sup>13</sup> a concern supported by Tan et al. for neonatal care.<sup>28</sup> This lack of diversity impedes the generalisability of findings, especially for healthcare systems outside of the US where much of the literature originates. Little evidence is available on the effect of multi-functional commercially developed applications and as most healthcare organisations are looking to implement commercially available applications findings from current evaluations lack applicability.<sup>1</sup>

The design and development of CDSS when addressed in the literature, more often than not, is rarely to a degree of specificity worth noting.<sup>29;189;190</sup> Kawamoto et al. note that evaluations of CDSSs '...should provide as much detail as possible when describing the applications and the manner in which clinicians interacted with them, so that others can learn more effectively from previous successes and

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failures.<sup>139</sup> This is important as optimal design features for CDSSs have not been established although a few SRs have been conducted to determine successful design features of CDSSs usually for prescribing however. For instance, Thursky lists features of CDSSs likely to increase clinician adoption:<sup>3</sup>

- the primary determinant of user satisfaction is speed
- they should automatically provide decision support as part of clinician workflow (ie integrated with clinical practice)
- usability is very important
- the application should provide alternate recommendations rather than just an assessment (ie promotes action rather than inaction)
- physicians will often override reminders and or suggestions if they have strong beliefs about the medication or clinical situation
- the application should require documentation of reasons for not following the recommendations
- there should be justification of decision support via provision of reasoning and research evidence
- simple interventions work the best
- additional information should only be requested from the user if necessary (clinicians are poor at entering data elements for advanced decision support, arduous data entry results in poor application acceptance)
- the impact should be monitored and performance feedback should be provided to clinicians
- the applications should provide incentives to use such as paper-based output, complex calculations or feedback to users
- there should be an alignment of incentives between guideline developers and users (rather than be driven by profits)
- there should be local user involvement in the development process and local guideline development or adaptation
- applications should be accompanied by conventional education.

Based on expert opinion and first hand experience, Bates and Wyatt both published <sup>181;191</sup> similar pieces of work, much of which has been delineated within this section. This is of no small importance as to-date numerous CDSSs have failed to improve practitioner performance or patient outcomes for varying reasons. Liu and Wyatt propose the following reasons for example:<sup>192</sup>

- failure of clinicians to use the DSS, eg because they did not understand what it was for, the prevailing clinical culture was against it, their patients or peer group objected to it, it was too slow, or it was not linked to the electronic patient record (EPR)



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- the DSS did not produce an effective output in time to influence their decision, eg the output was not available in time or they could not understand the output
  - the output was not convincing enough to persuade the users to change their practice, eg the output showed poor accuracy, was badly worded, and or users had never before heard of this drug and required more details
  - the output was available and was convincing enough to influence user decisions, but the user was unable to change their practice, eg the drug was too expensive to prescribe, there was adverse peer or patient pressure, the user was missing some vital information, equipment or skill that they needed before being able to enact their decision
  - the performance of the clinicians was already optimal, given the circumstances and patient case mix.

Research into why CDSSs fail as opposed to succeed is important to establish an evidence-base to inform the redesign of current applications and design, development and evaluation of future applications. Sittig et al. delineate a list of ten ‘grand challenges’ in clinical decision support which should be researched further.<sup>193</sup> One such grand challenge is remedying those three aforementioned assumptions which have strongly influenced design and development deemed ‘mythological’ by one researcher are claimed to have partly contributed to the relative lack of success of CDSSs in clinical care.<sup>15</sup> Similarly, certain tasks do not benefit from automation; Sintchenko and Coiera developed a framework for the rational selection of clinical tasks for automation using a cognitive task complexity approach and to investigate its potential benefits.<sup>186</sup>

Other issues to consider are the potential inaccuracy of input (patient data) and its effect on output. Hogan and Wagner concluded that the knowledge of data accuracy in EHRs is not commensurate with its importance and further studies are needed.<sup>25</sup> Similarly, primary research does not evaluate the accuracy of system output, if practitioners are faced with inaccurate output this might translate into unimproved practitioner performance or failure. CDSS are a highly heterogeneous grouping of applications. In particular, the knowledge-base used in conjunction with the inference mechanism can take many forms. So when applications fail to demonstrate benefit to practitioner performance and patient outcomes, flaws in the knowledge-base or algorithm—which are not accounted for in the analysis—might be at fault. The inference mechanism and the output interface, can according to Randolph et al.,<sup>194</sup> each be evaluated as a separate intervention. Evaluation is key and an important recommendation

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for system developers is to incorporate functionality into applications that facilitates evaluation.<sup>195</sup>

Wyatt suggests, studying whether the effectiveness of the system depends to an extent on end-user skill levels (especially relevant to more sophisticated system).<sup>15</sup> Unimproved practitioner performance or failure might also relate to issues of usability. Handler et al. note that optimal interfaces for decision support have not been developed or studied and that this should be a high research priority.<sup>1;24;188</sup> This research is especially important in light of the clinical phenomenon of alert fatigue and the finding that many alerts are overridden in CDSSs especially with regards to applications targeting prescribing practices.<sup>23;188</sup> The field of human factors engineering or ergonomics is of particularly relevant for those wishing to gain insight on the introduction of errors resulting from the interfacing of end-user and system.<sup>196</sup> Building on the basic questions Coiera posed for CDSS developers, we have identified other important questions, namely:<sup>24</sup>

- is there a need—perceived or real—for a CDSS?
- is the information appropriate for representation in a knowledge-base?
- is the inference mechanism appropriate for the interpretation of the input and knowledge-base?
- should engagement with the system be active or passive?
- what are the essential inputs and what are the effects of missing data elements on system accuracy?
- how will the output be presented to the end-user?

A group of CDSS experts have proposed a series of helpful recommendations for system developers and researchers:<sup>10</sup>

- there is a need to continue development of a comprehensive, expressive, clinical vocabulary that can scale from administrative to clinical decision support needs
- continue to develop shareable computer-based representations of clinical logic and practice guidelines
- develop tools for knowledge editors to easily and accurately incorporate new literature-based evidence into CDSS knowledge-bases; specify the clinical context in which that knowledge is applicable (eg that a rule is for the treatment of stable outpatient diabetic patients only); and customise the literature-based evidence for local conditions (eg factoring in local surgical complication rates)
- explore and develop automatic methods for updating CDSS knowledge-bases to reflect the current state and quality of the literature-based evidence

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- develop more flexible models of decision-making that can accommodate clinical evidence of varying methodological strength and relevance, so that evidence from randomised trials is accorded more weight than evidence from case reports or expert opinion
  - develop models of decision-making that can simultaneously accommodate the beliefs, perspectives, and values of multiple decision-makers, including those of clinicians and patients.
  - develop methods for constructing and selecting among decision models of scalable granularity and specificity that are neither too general nor too specific for the case at hand.

And for evaluators of CDSSs:<sup>10</sup>

- evaluate CDSSs using an iterative approach that identifies both benefits and unanticipated problems related to CDSS implementation and use: all CDSSs can benefit from multiple stages and types of testing, at all points of the CDSS life cycle
- use both quantitative and qualitative evaluation methodologies to assess multiple dimensions of CDSS use and design (eg the correctness, reliability, and validity of the CDSS knowledge-base; the congruence of system-driven processes with clinical roles and work routines in actual practice; and the return-on-investment of system implementation); qualitative studies should incorporate the expertise of ethnographers, sociologists, organisational behaviourists, or other field researchers from within and without the medical informatics community, as applicable
- if preliminary testing suggests that a CDSS could improve health outcomes, the CDSS should be evaluated to establish the presence or absence of clinical benefits; any RCTs that are conducted should have sufficient sample sizes to detect clinically meaningful outcomes, should randomise clinicians or clinical units rather than patients and should be analysed using methods appropriate for cluster randomisation studies
- establish partnerships between academic groups and community practices to conduct evaluations.

Fox and Thomson recommend that ‘...the health informatics community should itself anticipate possible legal liabilities that might result from the use of their technologies and seek to establish best professional and engineering practice in this area before the courts do it for them.’<sup>18</sup>

This chapter has shown that research and in particular, evaluation, using novel methodologies into both the technical and psycho-social principles

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underpinning system design, development and evaluation is of considerable importance if we are to realise the potential that CDSSs undoubtedly offer.

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## CHAPTER 9

### Case study: Computerised decision support in mammography screening

#### SUMMARY

- Breast cancer is one of the leading causes of cancer death in the developed world. Screening mammography is recommended by many major institutions for women in order to reduce mortality from breast cancer.
- All women aged 50–70 years in England are routinely invited for breast cancer screening every three years.
- In England, “gold standard” screening mammography involves four images: two views per breast, read by a reader trained in mammography; these readings are then, in most cases, independently double checked by a second reader. This second reading increases sensitivity and specificity of cancer detection and is at present usually performed by a radiologist.
- Increases in the proportion of women being screened, the frequency with which they are screened and the lack of trained professionals places a considerable resource burden on health services. Although the gold standard for screening mammography, readings made by professionals are subject to factors that risk the quality of readings and therefore patient safety.
- Computerised decision support systems for image interpretation (most commonly referred to as computer-aided detection) denotes using the output of software analysis as a ‘second read’ before making a diagnosis. Computer-aided detection for screening mammography has the potential to improve the sensitivity and specificity of screening mammography and reduce the burden placed on health services.
- Computer-aided detection for screening mammography has the potential to improve the sensitivity and specificity of screening mammography and reduce the burden placed on health services.
- There is a lack of robust empirical evidence to inform decisions; however, the available evidence indicates that whilst sensitivity is high, specificity is far too low to render this a clinically useful application.

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- The NHS Screening Programme should continue with the current practice of double-reading of mammograms by humans.

## 9.1 INTRODUCTION

Computerised decision support systems (CDSSs) have been employed for a variety of clinical activities including image interpretation, with the intention of improving the quality and safety of healthcare (see Chapter 8). Although a type of CDSS, these applications are generally referred to in the literature as computer-aided detection (CAD). In this case study, we consider CAD for screening mammography as an example of a CDSS which illustrates some issues typically encountered while evaluating, implementing and adopting new eHealth applications. This case study demonstrates that, despite theoretically and empirically proven benefits, novel technologies do not always translate into improvements in everyday healthcare practice. On a related note, we also highlight some of the reasons underlying the lack of effectiveness of CAD in practice.

The purpose of a screening programme is to identify as many people as possible with pathological findings in the early stages of disease and therefore have the opportunity to initiate treatment early. Breast cancer is one of the leading causes of cancer death in women in developed world.<sup>1,2</sup> Detection of pathology and initiation of treatment in the early stages of breast cancer leads to better outcomes, lower morbidity and mortality, increased patient satisfaction and lower overall costs.<sup>3</sup>

Mammography is the “gold standard” procedure for breast cancer detection in screening programmes. Mammography is a technique that uses low dose x-rays to visualise early malignant changes in breast tissue. In England, it involves four images: two views per breast, read by a reader trained in mammography; these readings are then, in most cases, independently double checked by a second reader.<sup>4</sup>

Although considered the gold standard, this procedure is not ideal as up to one-third of visible cancers are missed by screening programmes.<sup>5</sup> There are several factors recognised as possibly contributing to suboptimal readers’ performance in screening programmes. These include:<sup>6–9</sup>

- difficulties resulting from reading large numbers of normal radiographs whilst at the same time needing to remain vigilant about the very few abnormalities, ie continuous reading of normal mammograms can be very monotonous and tiring, which can lead to reading fatigue with the resulting heightened risk of overlooking rare pathological findings
- low image quality



- inappropriate viewing conditions
- outside distractions
- oversight because of more obvious findings
- reliance on prior knowledge of the most probable locations of cancers
- lack of sufficient “reading” skills and or experience.

With increasing numbers of women being screened, an increase in views per person, coupled with a lack of radiologists trained in mammography has created conditions that have in the UK necessitated a number of other healthcare professionals—such as breast clinicians and radiographers—to become increasingly involved in reading mammograms.<sup>4</sup> Their training and experience remain critical to the accuracy of diagnosis.

Computer-aided detection in mammography refers to establishing a diagnosis with the help of specific pattern recognition software that marks suspicious features on mammograms thereby attracting readers’ attention to possible pathology.<sup>10;11</sup> CAD analysis typically takes place after the initial reading by a radiologist thus taking the place of a second human reader.<sup>12;13</sup>

The widespread use of CAD in many centres in the US<sup>14</sup> raises the possibility of this eHealth application being adopted in other healthcare settings. It is, however, important that prior to any such decision being taken that the benefits and risks associated with CAD for mammography be critically assessed.

## 9.2 THEORETICAL CONSIDERATIONS

### 9.2.1 POTENTIAL BENEFITS

Computer-aided detection has the potential to aid radiologists by marking suspicious lesions therefore reducing the possibility of missing pathological findings.<sup>12;15;16</sup> In other words, CAD could increase the sensitivity of screening mammography, i.e. reduce the number of false negatives. Increased sensitivity should in turn translate into fewer missed cancers and hence improved survival rates.

Approximately 95 per cent of women with abnormalities on screening mammograms do not have breast cancer and a variable proportion of these women undergo unnecessary treatment or additional diagnostic procedures.<sup>3;17</sup> Precise and accurate algorithms applied to mammograms could potentially “recognise” only the true positive lesions with few or no false-positives thus increasing specificity with the computer analysis. Increased specificity should translate into reduced recall rates, reduced number of unnecessary diagnostic procedures and treatments and consequently, reduced risks associated with these interventions.

In the case of high specificity, CAD could potentially reduce the time spent

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for the entire dual image reading process. In addition, radiologists as well as other specialities involved in additional testing or follow-up may as a result have reduced workload if recall rates were reduced and additional follow-on testing was less frequently needed, leading to decreased resource utilisation and costs. Furthermore, CAD systems have the potential to increase consistency and accuracy of less skilled readers.<sup>18</sup>

### **9.2.2 POTENTIAL RISKS**

Flaws in CDSSs' software design can lead to deterioration of patient safety. For example, recent research has shown that the use of CAD decreases specificity of screening mammography.<sup>19</sup> The rather low specificity of CAD systems results in any number of false-positive prompts per image. When considering false-positive prompts, readers might recall more patients or initiate additional testing, unnecessarily bringing anxiety to large numbers of women.<sup>20</sup> Also, additional invasive testing (biopsy) would introduce risk of complications with increased morbidity associated with these procedures.<sup>18</sup>

On the other hand, low sensitivity (the absence of clinically relevant prompts) might also detrimentally impact on readers' decision making. Alberdi et al. emphasise that readers might base their decisions to not recall patients on the absence of computer prompts.<sup>21</sup> Since CAD analysis is unable to identify all lesions,<sup>12</sup> some of the lesions will inevitably be missed by CAD analysis, and readers, if relying on computer output, might miss cancers undetected by CAD.<sup>21;22</sup> Theoretically, such reliance on the CAD support might result in a deskilling effect for readers—reducing their ability to interpret images without the support of CAD.

CAD can also result in organisational inefficiency by increasing the time needed for image interpretation by radiologists. Khoo et al. conducted a prospective study in the NHS Breast Screening Programme (NHSBSP) and found that the average time required for single reading was 25 seconds without CAD and 45 seconds with CAD; this significant increase in time was due to the need to consider prompts.<sup>23</sup> The authors calculated that readers had to dismiss 180 false prompts for one true prompt. This extremely high rate of false-positive prompts is very likely to result in alert fatigue and consequently clinically relevant prompts might go ignored thus decreasing the sensitivity of the reading and potentially leading to detectable cancers being missed.<sup>21</sup> Also, additional testing due to increased recall rates and increased biopsy rates and the associated need for human resources could substantially increase overall costs after CAD implementation.<sup>24</sup>

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### 9.3 EMPIRICALLY DEMONSTRATED IMPACT

To-date, there is no robust evidence from randomised controlled trials (RCTs) or systematic reviews (SRs) evaluating the effectiveness of CAD in screening mammography programmes. The available evidence is weak and shares a number of important shortcomings, these including:<sup>25</sup>

- retrospective designs<sup>22;26</sup>
- test sets (typical examples of mammograms representing a range of pathological mammography findings) being used such that they are not representative of screening settings (ie unrealistic proportions of positive and negative findings being used)<sup>27-29</sup>
- readers lacking sufficient CAD training<sup>30</sup>
- the number of readers participating being too small to reflect the differences in background (radiologists, breast clinicians, radiographers) and experience of readers involved in interpreting screening images<sup>31-33</sup>
- studies not reporting on objective clinically relevant outcomes such as decrease in interval cancer detection rate or decreased mortality<sup>34;35</sup>
- a lack of appropriate follow-up to confirm outcomes in patients with negative findings.<sup>36</sup>

Although the research in this field is not robust enough to make definitive recommendations, it does, however, suggest that CAD applied after the initial reading by a radiologist can benefit in terms of improving sensitivity. It is worth noting that these differences are not usually statistically significant. It is also worth noting that the design of many of the studies would not allow a reduction in sensitivity to be detected, since the outcome measure is the number of cancers detected only after looking at the prompts.

Freer and Ulissey, in a large prospective study, found a 20 per cent increase in the number of cancers detected (ie from 3.2 to 3.8 cases per 1000 women screened) when mammograms were re-evaluated considering CAD prompts after initial reading by reader alone.<sup>37</sup> Similarly, a number of other publications report higher sensitivity rates after application of CAD analysis compared to single reading by a radiologist without CAD.<sup>12;18;38</sup> This demonstrates that CAD systems may have incremental value on detecting pathological findings.<sup>39</sup> Thus, in practice, fewer cancers should be missed on screening examinations resulting in earlier treatment and reduced morbidity and mortality.

Although trends in the improvements (non-significant) of sensitivity have been demonstrated, evidence regarding improved specificity is inconsistent. For example, Freer and Ulissey reported that 97 per cent of CAD prompts were dismissed by radiologists, which translates into very low specificity rates for

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CAD alone.<sup>40</sup> For readers aided by CAD, as opposed to reader alone, specificity is decreased. The same study by Freer and Ulissey found that with CAD the number of false positive findings increased by 19 per cent therefore decreasing specificity and increasing recall rates. In contrast, however, some papers report no changes in specificity.<sup>12</sup>

In the NHSBSP most mammograms are double-read.<sup>4</sup> Double reading is important in mitigating differences in accuracy of interpretation across radiologists as different readers miss different lesions and two readers together increase sensitivity and specificity.<sup>18;41</sup> Evidence shows that double reading is very effective and that fewer cancers are missed.<sup>41–46</sup>

Bennett et al., in a recent review, explored whether or not the accuracy of a single reading with CAD could compare with that of double reading.<sup>47</sup> They found six eligible studies reporting both sensitivity and specificity of single reading with CAD and double reading. The authors concluded that current evidence is limited because of many potential biases in studies and that additional high quality research is needed to justify use of single reading with CAD instead of the double reading.<sup>48</sup>

In the absence of such rigorous evidence, it has been argued that well conducted observational studies might be able to provide important insights into the likely effectiveness of this technology.<sup>49,50,51</sup> In their SR, Britton et al. explored differences between RCTs and non-randomised study designs.<sup>52</sup> They concluded that in relation to questions that needed very large sample sizes and incurred prohibitive costs—as it may be argued is the case with CAD for screening mammography—it is important to consider undertaking well designed, non-randomised studies, rather than poorly designed underpowered randomised studies.

A recent well designed observational study by Fenton et al. on CAD in mammography assessed the largest number of mammograms to-date.<sup>53</sup> The authors compared diagnostic sensitivity, specificity, positive predictive value, biopsy rates, cancer detection rates and overall accuracy before and after implementing CAD system in screening centres. They found that the use of CAD was associated with reduced overall accuracy in the interpretation of screening mammograms reporting decreased specificity after CAD implementation ( $p < 0.001$ ) which resulted in higher recall rates. Higher biopsy rates were also reported (up by 20 per cent,  $p < 0.001$ ). It should be noted that on average, radiologists at facilities that did not implement CAD had more years of experience with mammography than did radiologists at facilities that implemented computer-aided detection.

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The insignificant ( $p=0.90$ ) increase in the cancer detection rate following the implementation of CAD in this study provided strong circumstantial evidence of the lack of clinical benefits from this technology.

## 9.4 IMPLICATIONS FOR PRACTICE, POLICY AND RESEARCH

Overall, there is very little clear evidence of benefit of CDSSs for diagnostics—whether for practitioner performance or patient outcomes (see Chapter 8)—as is exemplified by this case study of CAD in screening mammography. There is thus at present insufficient evidence to warrant the introduction of this technology into the NHSBSP, which should continue with the gold standard of independent readings by two practitioners. CAD for screening mammography could, however, be usefully considered as an adjunct in less resourced healthcare settings, which only have the means to support single practitioner readings.

Given the strong theoretical benefits associated with CAD, it is important to consider why this technology is currently failing to realise its potential. Different developers of CAD systems use different algorithms for image analysis<sup>12</sup> and this might, in some cases, result in different prompts for the same lesions. Although the output given by various brands and versions of CAD software is very similar, possible small differences in output have not yet been properly evaluated. And whilst application invalidity (low specificity for example) might play a part in its relative lack of diffusion, it appears that the automation of image interpretation also proves problematic for other reasons.

Providing reminders concerning preventative care and calculating drug doses are examples of activities that are readily automatable (see Chapters 8 and 10). The art of diagnosis or image interpretation is just that, and it is therefore extremely difficult to automate; though not well studied, but probably also important, is that professional autonomy might be perceived as being encroached by applications such as CAD. Although there are difficulties associated with reading mammograms there have been no calls to greatly improve the accuracy of double-reading and the use of CAD for screening mammography screening thus seems to be technology driven rather than fulfilling a genuine clinical need. If true, such eHealth applications are prone to failure (see Chapters 12 and 13).

Even though implementation of the Picture Archiving and Communication Systems (PACS) is now widespread in the NHS (see Chapter 3) and therefore provides the technological infrastructure to incorporate CAD, given the established standing of the NHSBSP in England and the lack of robust evidence of clinical benefit to-date, expensive large-scale multi-centre RCTs designed to

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compare the effectiveness of double reading versus single reading aided by CAD are not warranted. Rather, future research efforts should be focused on increasing specificity (sensitivity is already high comparable to that of double reading) of CAD before this is further tested in practice, as excessive alerts and prompts stemming from low specificity have been demonstrated to be detrimental to clinical workflow resulting in alert fatigue. Of even greater priority, however, is research evaluating the effectiveness of rigorous training of readings by new healthcare professionals—breast clinicians and radiographers, for example—who are increasingly taking on roles as readers of mammograms.

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## CHAPTER 10

### ePrescribing

#### SUMMARY

- There is considerable variation in the quality of prescribing. Medicines management errors are common, costly and an important source of iatrogenic harm.
- ePrescribing is defined as the use of computing devices to enter, modify, review and output or communicate prescriptions. ePrescribing applications are highly variable in functionality, configurability and the extent to which they integrate with other clinical information systems.
- ePrescribing has the potential to greatly improve the quality and safety of prescribing, through facilitating cost-conscious evidence-based prescribing and in particular reducing errors associated with knowledge gaps and routine tasks such as repeat prescribing.
- There is some evidence that practitioner performance is improved through improved access to this support. Patient outcomes are, however, less well studied and when assessed, most studies have not been able to demonstrate a clinical benefit. There is some evidence for improved prescribing safety; however, this has not been shown to translate into decreased adverse drug events.
- Evidence of benefit from ePrescribing applications has for the most part been demonstrated from evaluations of home-grown applications in a few centres of excellence. Most applications in use are, however, commercially procured and these systems typically lack the sophistication of the tailored home-grown systems. Poorly designed applications and a failure to appreciate the organisational implications associated with their introduction can introduce unexpected new risks to patient safety.
- In the UK, the Medicines and Healthcare Products Regulatory Agency does not consider ePrescribing applications to be a medical device and does not therefore require these systems to be quality assured. This is an important policy failing that needs to be addressed.
- Further research into design specifications (human factors), knowledge-bases and underlying inference mechanisms, interoperability and

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organisational issues is needed in order to replicate the benefits of ePrescribing that have been demonstrated in US centres of excellence.

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## 10.1 INTRODUCTION

Prescribing errors are common and are responsible for considerable potentially avoidable patient morbidity and mortality. Given the vast array of drugs now available and the considerable scope for their interaction either with aspects of the patients' history and or other co-prescribed treatments, it is simply no longer feasible for clinicians to know about, retain and judiciously draw on all such information from memory. Electronic prescribing has the potential to support professionals in this respect through helping them to identify and select potentially appropriate treatments and doses, and also through drawing on patient specific data to guide treatment decision. In this chapter we review the main potential and empirically demonstrated benefits and risks associated with ePrescribing, building here on the more generic discussions on CDSS in Chapter 8.

## 10.2 DEFINITION, DESCRIPTION AND SCOPE

### 10.2.1 DEFINITION

There is no standard definition of ePrescribing, this term having the potential to mean different things depending on the context in which it is applied. In essence, however, it invariably refers to computerised provider (prescriber, or physician) order entry (CPOE) and, increasingly, also incorporates computerised decision support functionality. Electronic order entry is best defined as the use of computing devices to enter, modify, review and output or communicate orders relating to requesting laboratory tests (see Chapter 5), radiological images, prescriptions and other treatments.<sup>1</sup> Computerised decision support is discussed in detail in Chapter 8.

NHS Connecting for Health (NHS CFH), which is implementing ePrescribing applications within secondary and tertiary care through its National Programme for Information Technology (NPfIT), has formulated a definition of ePrescribing that encompasses both the above dimensions, ie:<sup>2</sup>

‘The utilisation of electronic systems to facilitate and enhance the communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine through knowledge and decision support and providing a robust audit trail for the entire medicines use process.’

### 10.2.2 DESCRIPTION

Ideally, ePrescribing applications assist in garnering the appropriate information required by clinicians to make an informed decision, eg patient data and evidence-



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based information, including clinical decision support.<sup>3</sup> Most ePrescribing applications rely on other sub-applications including:

- **Clinical data repository of patient or population data such as the electronic health record (EHR) or electronic medication administration record (eMAR):** the EHR is discussed in detail in Chapter 7; the eMAR is an electronic record in which the clinicians who actually administer drugs record what has been given.<sup>4</sup>
- **Knowledge-base:** this includes the details of all items that can be ordered electronically, such as tests and drugs available on the local formulary. The associated costs of drugs and tests can also be included. More advanced databases also list drug interactions, contraindications, dose limitations, possible allergic reactions and other related information. Often such more sophisticated databases are provided by third party companies specialising in such products, rather than from the ePrescribing system supplier. These additional functionalities allow the ePrescribing system to perform drug focused safety checks as prescriptions are entered.<sup>3;5</sup>
- **Standards-Based clinical messaging systems:** These communicate the orders with other clinical information systems, using, for example, the Health Level Seven (HL7) messaging standard (see Chapter 5) and potentially using standards for test or procedure names such as Logical Observation Identifiers Names and Codes (LOINC).<sup>3;5</sup>
- **Computerised decision support systems:** CDSSs are incorporated into most ePrescribing applications although with a varying degrees of sophistication. These applications provide support for prescribing in the form of computerised advice regarding drug doses, routes and frequencies; perform checks for drug-allergies, drug–laboratory values or drug-drug interactions; and can provide reminders about corollary orders or drug guidelines. Included is an inference mechanism—the logic (a set of algorithms, typically called rules)—that is applied to information retrieved from the knowledge-base and patient clinical data repository to generate clinical decision support recommendations, safety alerts and warnings, and suggestions for cost-savings. Some rules are pre-programmed and others can be modified or added from internal or external sources, such as other healthcare institutions.<sup>3;5;6</sup>

### 10.2.3 SCOPE FOR USE

Improving the quality of prescribing and preventing drug errors has been one of the main focuses of applied research investigating the effectiveness of IT on

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improving the quality and safety of healthcare.<sup>7–10</sup> Errors in medicines management encompass those relating to: prescribing; dispensing; administration; monitoring; and repeat prescribing.<sup>11</sup>

Estimating the frequency of errors related to medicines management is problematic due to the various definitions used and to the various methodologies to detect or measure errors. For instance, Dean et al. report that prescribing errors occur in 1.5 per cent of UK hospital prescriptions (95 per cent confidence interval (CI) 1.4–1.6) with potentially serious errors occurring in 0.4 per cent of prescriptions (95 per cent CI 0.3–0.5).<sup>12</sup> Many of these errors are, in theory at least, entirely preventable. Prescribing errors in UK primary care were estimated by Sandars and Esmail to occur in up to 11 per cent of prescriptions.<sup>13</sup> This nearly 10-fold difference is worrisome for a variety of reasons, not least because virtually all UK primary care employs some form of ePrescribing, this therefore raising the possibility that ePrescribing systems may actually be increasing the risk of errors. A more plausible explanation is, however, that the data on the estimates of prescribing errors are on the whole still rather poor; this in part reflecting a lack of agreed criteria as to what represents a prescribing error.

Detailed analysis and classification of errors in medicines management suggests that prevention strategies targeting systems rather than individuals are most likely to prove effective in reducing errors (see Chapter 4).<sup>14</sup>

ePrescribing has been suggested as the means by which errors relating to medicines management will be significantly reduced.<sup>14–17</sup> The general premise underpinning ePrescribing is the automation of inefficient or error-prone processes coupled with the provision of decision support at the time of ordering to improve prescribing. Knowledge-bases can supplement the gaps in prescribers' clinical knowledge and inference mechanisms can aid in the interpretation of clinical data to improve clinical decision-making. ePrescribing can be used in all settings and areas of clinical care by anyone with the authority to prescribe. ePrescribing therefore has the potential to impact, dramatically, on the quality—the effectiveness, efficiency, and economics—and perhaps most importantly, the safety of healthcare.

## **10.3 THEORETICAL BENEFITS AND RISKS**

### **10.3.1 BENEFITS**

#### *Quality of care*

The two generic domains of eHealth that are supported by ePrescribing are Storing and managing data, this support being provided irrespective of the level of functionality of the ePrescribing system and Informing and supporting of

decisions when applications have decision support capabilities (see Chapter 4). For a list of more specific benefits see Box 10.1.

**Box 10.1 Main potential benefits of ePrescribing applications on healthcare quality**

- Reduction in lost orders
- Improved communication amongst prescribers and dispensers (eg call back queries, instant reporting that item is out of stock, alerts for unfilled, unrenewed prescriptions)
- Shorter process turn-around time such as the transit time to dispensing site, time until first dose, prescription renewal or refill
- Data are available for immediate analysis including post-marketing reporting, drug utilisation review, etc
- Generation of economic savings by linking to algorithms emphasising (offering as a first choice when a drug is selected) cost-effective drugs
- Reduced underprescribing and overprescribing
- Instant provision of information about formulary-based drug coverage including on-formulary alternatives and co-pay information
- Standardisation of prescribing practices via the provision of guidelines.

*Patient safety*

Although healthcare quality and patient safety are inextricably inter-linked,<sup>18</sup> much of the premise underpinning the use of ePrescribing relates in particular to improving the safety of medicines management by reducing errors. Errors related to medicines management are probably the most prevalent type of medical error in both primary and secondary care within the UK.<sup>19</sup> Of all types of medicines management errors—prescribing, dispensing, administration, monitoring, repeat prescribing<sup>11</sup>—errors in prescribing decision are typically the most serious.<sup>19</sup>

ePrescribing applications should facilitate improved communication between healthcare providers, patient identification, and improved decision and safety support (see Chapter 4). Improved communication is an inherent benefit of ePrescribing. Improved identification is on the other hand dependent on whether the system is integrated with other clinical information systems such as an EHR. Improved decision and safety support is in turn dependent on how alerts are configured and whether decision support is integrated, again the degree to which this is improved is also dependent on integration with other clinical information systems.

Most notably, ePrescribing has the potential to considerably improve patient safety by decreasing errors in prescribing, monitoring and repeat prescribing. The reduction in these types of errors is clearly dependent on the level of system

sophistication, ie the degree to which the system is integrated with patient data and decision tools such as drug ontologies and the degree to which it is configured (customised) to the needs of individual prescribers.<sup>1;20</sup> Table 10.1 provides a schematic framework of the extent to which different applications are likely to improve prescribing safety.

**Table 10.1 Levels of system sophistication**

Level 1	Standalone electronic prescription writer
Level 2	Electronic drug reference manual
Level 3	Electronic prescription writing and electronic transmission of prescriptions—connectivity to dispensing site
Level 4	Patient specific prescription creation or refilling
Level 5	Basic decision support functionality (integrated or interfaced)— dosage (default and frequencies) and formulary support
Level 6	Drug management—access to eMAR checks for allergies, drug interactions and duplicate therapies
Level 7	Integration with an EHR
Level 8	Integration with EHR <i>and</i> other clinical information systems (radiology, laboratory and pharmacy information systems)
Level 9	Advanced decision support functionality (integrated or interfaced): adjusting dosages in light of patient characteristics (eg ethnicity), physiologic status (eg uraemia) and co-morbidities; other medications currently being taken; previous response to the drug, single, daily and life dose limits
<i>Adapted from: Electronic Prescribing: Towards Maximum Value and Rapid Adoption and Kuperman et al. (2004 &amp; 2006)<sup>1;21</sup></i>	

The types of drug errors potentially mitigated relative to the level of ePrescribing applications' sophistication include:

- **Miscommunication of drug orders:** due to poor handwriting, confusion between drugs with similar names, misuse of zeroes and decimal points, confusion of metric and other dosing units and inappropriate abbreviations (Levels 1, 2, 3 and 7)
- **Inappropriate drug(s) selection:** due to incomplete patient data such as contraindications, drug interactions, known allergies, current and previous diagnoses, current and previous therapies, test results etc (Levels 4, 5, 6, 8 and 9)
- **Miscalculation of drug dosage:** incorrect selection of route of administration; mistakes with frequency or infusion rate (Levels 2 and 5)
- **Out-of-date drug information:** for example, in references to alerts,

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warnings etc or information on newly approved drugs (Levels 2 and 6)

- **Monitoring failures:** results of laboratory test monitoring and drug administration monitoring not being taken into account (Levels 6, 7 and 9)
- **Inappropriate drug(s) selection:** due to clinical incompetence (Level 9).

The use of ePrescribing facilitates identification of the prescribing clinician—the author and the date of prescription—thereby allowing quality control measures to be targeted at specific clinicians. It is also possible to configure a system so that it will not process certain orders that are considered dangerous, for instance the accidental prescribing of oral methotrexate for daily use when the intended prescription is for weekly use.<sup>22</sup> Additionally, the applications are capable of linking to other clinical information systems for adverse drug event (ADE) monitoring and reporting<sup>23</sup> and electronic-based representations of prescriptions can form the basis for additional safety measures related to dispensing and administration errors (eg automatic dispensing machines and bar-coding of drugs to ensure that patients receive the ordered drug in the correct dose at the specified time).<sup>3</sup>

### 10.3.2 RISKS

#### *Organisational inefficiency*

Although the use of ePrescribing is intended to improve the quality of healthcare processes by reducing complexity, the complexity of care often increases by the incorporation of technology into health service delivery. This is primarily due to the significant process changes associated with ePrescribing implementation. Theoretically, introducing organisational inefficiency by implementation of ePrescribing applications is a major barrier to provision of high quality healthcare; examples include:<sup>24</sup>

- more or new work for clinicians
- unfavourable workflow changes
- problems related to persistence of paper
- negative emotions
- unexpected changes in the power structure.

#### *Patient safety*

How is the safety of these applications ensured? In the US, the Food and Drug Administration (FDA) has classified medical software as a medical device since 1976 and has therefore required proof of software verification by demonstrating consistency, completeness and correctness of the software at each stage and between each stage of the development life cycle and proof of software validation

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by determining the correctness of the final software product with respect to the users' needs and requirements for three types of medical software:<sup>25</sup>

- software as accessory
- software as a component or part
- stand-alone software.

However, ePrescribing is exempted if it is '... intended to involve competent human intervention before any impact on human health occurs.'<sup>25</sup> In the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA; the UK FDA equivalent) does not consider medical software to be a medical device and therefore does not undertake quality assurance activities.<sup>26</sup> In recognition of this regulative deficit, NHS CFH has created a mechanism based on other safety critical software industries' guidance for medical software products that will be delivered as part of the NPfIT. This involves a three phased approach to quality assessment and assurance:<sup>27</sup>

- **Phase 1:** risk assessment of products in the context in which they will be used
- **Phase 2:** producing a safety assessment explaining how identified hazards will be mitigated
- **Phase 3:** production of a final safety report, clearly documenting that these safety concerns have been satisfactorily addressed.

This quality assessment and assurance only applies to products developed for NHS CFH and no regulatory paradigm exists in either the US or the UK for commercially available medical software products, these being excluded by the 'competent human intervention' clause (as discussed above).

This issue is important because although the use of ePrescribing applications for the ordering of drugs should in theory reduce the burden of some types of drug errors, these applications might also introduce new errors. These errors in system design and oversights in development might lead to:<sup>28</sup>

- incorrect decision support provided → incorrect medicines ordered and administered → e-Iatrogenesis.

Theoretically, risks to patient safety by ePrescribing applications could occur at any point in the use of applications due to errors made by the end-user, such as:

- Incorrect patient data input → incorrect decision support → incorrect medicines ordered and administered → e-Iatrogenesis
- Incorrect orders selected → incorrect medicines ordered and administered → e-Iatrogenesis
- Incorrect patient selected → inappropriate medicines ordered and



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administered → e-Iatrogenesis.

Dependence on the support provided by the application can put patients' safety at risk when support is not available as usual or prescribers change practices or hospitals. Similarly, not understanding the nature of the support provided, such as its limitations, can lead prescribers to misjudge the robustness of the support provided.

## 10.4 EMPIRICALLY DEMONSTRATED BENEFITS AND RISKS

We identified a number of systematic reviews focusing on ePrescribing (see Appendix 5 for details). Many of these reviews focused on electronic order entry and decision support in relation to supporting prescribing.<sup>54,62,69,29,31–33,38,39,41,42,68</sup>

We focus in the discussion below on selected SRs that have included studies evaluating the ePrescribing element of electronic order entry excluding reviews in which ePrescribing is included, but is not a major focus of the publication. We detail most reviews below, omitting those where there is duplication of studies (and conclusions) included in reviews discussed either here or in Chapter 8 on CDSS.

### 10.4.1 BENEFITS

#### *Healthcare quality*

Studies of ePrescribing included in reviews assessing the impact on the quality of care delivered tend to focus on the ordering of prophylactic prescriptions, adherence to prescribing guidelines and organisational efficiency. Quality outcomes vary in the ways defined and measured and therefore generalising across organisational settings is difficult.

As part of their systematic review on ePrescribing in an outpatient setting, Eslami et al. assessed adherence to guidelines.<sup>29</sup> The authors concluded that there is evidence on the ability of ePrescribing applications to increase health-care professionals adherence to guidelines in outpatient settings. The authors hence hypothesised that cost reduction can be achieved when guidelines are specifically geared towards this goal.<sup>29</sup> The authors based their conclusions on 11 studies evaluating the impact of ePrescribing with a CDSS on the adherence to a guideline or another standard.<sup>30–39</sup> Among these, four studies showed that there was a significant positive effect on adherence;<sup>30,34–36</sup> two studies showed a positive effect without reporting on statistical significance;<sup>33,38</sup> and five studies did not find a significant difference between the control and the intervention groups.<sup>31,32,37,39</sup>

The study by Dexter et al. found that a computerised reminder system

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identified 54 per cent of hospitalised patients as eligible for preventive measures that had not been ordered by the admitting clinician. For patients with at least one indication, computerised reminders resulted in higher adjusted ordering rates for prophylactic heparin (32 per cent vs 19 per cent,  $p < 0.001$ ) and prophylactic aspirin at discharge (36 per cent vs 28 per cent,  $p < 0.001$ ).<sup>40</sup>

Reasonable evidence for improved organisational efficiency in healthcare was found by Clamp and Keen in their review related to turn-around time in particular.<sup>41</sup> Mekhijan et al. found a statistically significant reduction in turn-around times following the implementation of ePrescribing (64 per cent reduction;  $p < 0.001$ ).<sup>42</sup> Turn-around time from ordering to dispensing was shown to decrease by up to 2.5 hours in a study by Lehman et al.<sup>43</sup>

Clamp and Keen also note that although there was no evidence of reduction in pharmacists' time spent dealing with prescriptions, there were changes in their working patterns. The authors argued that pharmacists have an important quality control role in checking prescriptions, in fact so much so that one study found that pharmacists only spent 5–20 per cent of their time on direct clinical care.<sup>44</sup> Prescription monitoring and adaptation was reduced to less than 10 per cent in a UK hospital using ePrescribing, allowing pharmacists to spend around 70 per cent of their time on direct patient care.<sup>45</sup> In a US study, the pharmacists spent 46 per cent more time on problem-solving activities and 34 per cent less time filling in prescriptions.<sup>46</sup> The authors noted that with regards to time, three studies—including one randomised controlled trial (RCT)—showed that the total time for direct and indirect patient care increased due to the introduction of the ePrescribing system and a reduction in pharmacist interventions for prescriptions.<sup>31;47;48</sup>

Garg et al. included 29 trials of drug dosing and prescribing with single-drug dosing improving practitioner performance in 15 (62 per cent) of 24 studies; another 5 applications used electronic order entry for multi-drug prescribing with 4 of these applications improved practitioner performance.<sup>49</sup> Of the 29 included trials, 18 assessed patient outcomes with only 2 studies demonstrating a benefit to patient outcomes namely reduced hospital length of stay in patients receiving theophylline from 8.7 to 6.3 days;  $p = 0.03$ ,<sup>50</sup> and aminoglycosides from 20.3 to 16.0 days;  $p = 0.03$ ,<sup>51</sup>

Nies et al. however, assessed the same studies included in the aforementioned review by Garg et al., but came to a different conclusion, namely that '... drug dosage adjustment was less frequently observed in positive studies (29 per cent) than in negative studies (71 per cent).'<sup>52</sup> Whilst Nies et al. noted that their conclusions differed to those made by Garg et al. they did not posit

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why this contradictory finding might have occurred. This discrepancy may in part have resulted from differences in the way success was defined by these two systematic reviews, but merits further exploration.

An overview by Kuperman et al. evaluated the benefits, costs and organisational issues associated with electronic order entry.<sup>53</sup> One study included in the review, conducted in two inpatient nursing units in an academic health system, found statistically significant reductions in medication turn-around times following the implementation of CPOE (ie 64 per cent reduction, from 5:28 hours to 1:51 hours;  $p < 0.001$ ); in addition, CPOE combined with eMAR eliminated all doctor and nursing transcription errors.<sup>42</sup>

Both Chatellier et al. and Fitzmaurice et al. concluded that there was evidence on the effectiveness of CDSSs for oral anticoagulation therapy based on their systematic reviews.<sup>54;55</sup> Garg et al. found that 8 of 13 studies included in their review found the use of a CDSS for anticoagulation care to be of benefit to practitioner performance.<sup>49</sup> We direct readers to the case study presented in Chapter 11 to provide insight into why this particular ePrescribing scenario has worked.

Shebl et al. concluded that use of CDSSs in prescribing antibiotics was beneficial,<sup>42</sup> with three of five RCTs included and all six before-and-after studies found significant benefits of CDSS. However, since most studies were conducted in the US at only a few centres of excellence, the generalisability of these findings, particularly to a UK context, is unknown.

### *Patient safety*

The impact on patient safety by ePrescribing has been the subject of many reviews.<sup>21;29;53;56–61</sup> Sub-standard prescribing practice such as inappropriate drug selection—due to allergies or contraindications—and incorrect dosing are frequently evaluated outcomes assessed by researchers investigating the impact of ePrescribing. Again differences in the way errors are defined and measured make generalising across organisational settings difficult. For example, Classen and Metzger citing Nebeker et al. write that:<sup>62</sup>

‘One of the ongoing controversies in medication safety is how to measure the safety of the medication system reliably and how to assess the effect of interventions designed to improve the safety of medication use. Clearly, common nomenclature, definitions, and an overall taxonomy for medication safety are essential to this undertaking and the lack thereof has significantly hampered the comparison of various medication safety interventions among different centres.<sup>63</sup> At the heart of an even more fundamental controversy is whether the focus of patient safety

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should be on errors or adverse events as a means of assessing and improving the safety of the healthcare system.’

Kaushal et al. conducted a systematic review on the effectiveness of ePrescribing with integrated CDSS on improving drug safety in inpatients.<sup>58</sup> Five studies were included, four of which were conducted at the same institution, Brigham and Women’s Hospital (BWH).<sup>58</sup> The first BWH study demonstrated a 55 per cent decrease in non-intercepted serious drug errors ( $p < 0.01$ ).<sup>64</sup> As a secondary outcome, this study found a 17 per cent decrease in the preventable ADE rate, which was not statistically significant.<sup>64</sup> The ePrescribing application at the time of this study included only basic decision support, with limited checking for allergies and drug-drug interactions.<sup>64</sup> The second study, a time series analysis, evaluated drug error rates before ePrescribing and in the three years subsequent to its implementation.<sup>65</sup> It demonstrated an 81 per cent decrease in drug errors and an 86 per cent decrease in non-intercepted serious drug errors ( $p < 0.001$  for both).<sup>65</sup> This study found a non-significant decrease in the rate of ADEs per 1000 patient-days from 14.7 to 9.6 during the study and a decrease in the number of preventable ADEs from five to two ( $p < 0.05$ ).<sup>65</sup> The remaining three studies assessed more specific types of drug errors. The third BWH study published in 2000 demonstrated five prescribing improvements in types, doses, and frequencies of drug use with the implementation of CDSS with statistically significant improvements ( $p < 0.001$ ) in each of the five prescribing activity comparisons.<sup>66</sup> The fourth and final BWH study demonstrated a 13 per cent decrease in inappropriate dose and a 24 per cent decrease in inappropriate frequency for nephrotoxic drugs in patients with renal insufficiency ( $p < 0.001$  for both).<sup>67</sup> The BWH studies were consecutively published a year apart and as no mention was made of modifications to the applications it is assumed that the applications were largely the same. The fifth study measured corollary orders as an outcome and not drug practice per se; however, corollary orders are necessary to monitor adverse events.<sup>68</sup> The same five studies were also included in another review by Kaushal et al., *Information technology and drug safety: what is the benefit?* No new studies were cited in the section on ePrescribing.<sup>61</sup> The conclusion drawn, that ePrescribing ‘... significantly decreases drug errors in adult inpatients’ is in contrast to the more appropriate conclusion drawn from their earlier systematic review which noted that ePrescribing for the ordering of drugs decreases drug errors and serious drug errors rates only at two institutions with home-grown applications.<sup>58</sup>

Oren et al. conducted a review of the impact of emerging technologies on drug errors and ADE, again in an inpatient setting.<sup>59</sup> Aside from the previously

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mentioned five studies, six additional studies were included. Evans et al. evaluated the use of an antibiotic and other anti-infectives computer-assisted management programme.<sup>69</sup> Their findings are as follows: a significant reduction in orders for drugs to which the patients had reported allergies (35 vs 146 during the pre-intervention period;  $p < 0.01$ ); a significant reduction in excess drug dosages (87 vs 405,  $p < 0.01$ ); and a significant reduction in antibiotic susceptibility mismatches (12 vs 206,  $p < 0.01$ ). Marked reductions in the mean number of days of excessive drug dosage (2.7 vs 5.9,  $p < 0.01$ ) and in adverse events caused by anti-infective agents (four vs 28,  $p = 0.02$ ) were also found.<sup>69</sup> Anglim et al. found that overall use of vancomycin decreased 47 per cent (from a mean of 103 g per 1,000 patient-days to 54 g per 1,000 patient-days) ( $p < 0.001$ ) and that appropriate use of vancomycin increased from 39 per cent to 70 per cent ( $p < 0.001$ ) after the implementation of computerised guidelines to restrict ordering in response to an outbreak of vancomycin resistant *Enterococcus faecium* (VRE).<sup>70</sup> However, Shojania et al. noted that the intervention Anglim et al. described was implemented without a comparator control group of providers, so the effect of the intervention itself cannot be separated from general changes in ordering practice that may have occurred at the time. Shojania et al. also noted that there was already a secular trend of decreasing vancomycin use before the study began and thus the 50 per cent reduction in vancomycin orders observed by Anglim et al. could represent the combined effect of the computer intervention and secular trends resulting from heightened awareness of the problem of VRE and other infection control strategies.<sup>71</sup> Shojania et al. evaluated the implementation of a computerised guideline shown at the time of order entry for appropriate vancomycin use. Compared with the control group, intervention physicians wrote 32 per cent fewer orders (11.3 vs 16.7 orders per physician;  $p = 0.04$ ) and had 28 per cent fewer patients for whom they either initiated or renewed an order for vancomycin (7.4 vs 10.3 orders per clinician;  $p = 0.02$ ). In addition, the duration of vancomycin therapy attributable to clinician in the intervention group was 36 per cent lower than the duration of therapy prescribed by control clinician (26.5 vs 41.2 days;  $p < 0.05$ ).<sup>71</sup> Based on the included studies, Oren et al. were reluctant to draw any firm general conclusions about CPOE as 9 of the 11 included controlled studies on CPOE took place at only two centres of excellence; furthermore, all the applications studied were home-grown systems.<sup>59</sup>

Rothschild et al. also assessed ePrescribing in the critical care and inpatient setting.<sup>72</sup> The authors included 11 studies already presented in the reviews by Oren et al. and Kaushal et al. with one additional study on prescribing.



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Mullett et al. found no difference in ADE rates and rates of antibiotic-bacterial susceptibility mismatches remained similar. Although the rate of pharmacy interventions for erroneous drug doses declined by 59 per cent, the change was not significant.<sup>73</sup> The rate of anti-infective sub-therapeutic patient days decreased by 36 per cent ( $p < 0.001$ ) and the rate of excessive-dose days declined by 28 per cent ( $p < 0.001$ ). The number of orders placed per anti-infective course decreased by 12 per cent ( $p < 0.001$ ). The type of anti-infectives ordered and the number of anti-infective doses per patient remained similar.<sup>73</sup>

Eslami et al. included four studies evaluating the effect of ePrescribing,<sup>29</sup> all with a CDSS, on drug safety in the outpatient setting.<sup>74–77</sup> One retrospective observational study showed that there were no ADEs found in a set of randomly selected cases in which the clinician accepted the alert on drug allergy or on high severity drug interaction.<sup>74</sup> However, among the randomly selected cases in which alerts were ignored there were three ADEs found. Since the number of cases ( $n=189$ ) was limited, these results did not amount to a significant difference ( $p=0.55$ ).<sup>74</sup> Another prospective cohort study could not show a statistically significant difference in number of ADEs and preventable ADEs between computerised and manual prescription systems.<sup>75</sup> An RCT showed that there was no significant difference in the actual number of clinically relevant drug interactions between a control group and the intervention group which received alerts on interactions. However, usage of the system in this study was optional and almost non-existent (2.8 per cent of drug orders were prescribed using ePrescribing).<sup>76</sup> Also of interest are the findings from a related study, which has found that providers did not complete the drug order of 18 high-volume and high-risk drugs when an alert for an abnormal rule associated laboratory result was displayed ( $p=0.03$ ); this study did not show a statistically significant reduction in percentage of definite or probable ADEs ( $p=0.23$ ).<sup>77</sup> Eslami et al. concluded that ‘... in spite of the cited merits of enhancing safety published evaluation studies do not provide adequate evidence that ePrescribing applications provide these benefits in outpatient settings.’ The authors posited that a possible explanation is the small number of such studies conducted to date and the relatively weak study designs used. A second conclusion arising from the review is that there is much to be gained in insight when more direct outcome measures on safety are included such as ADEs and drug errors, but the authors also noted the difficulties in doing so due to scattered patient information and the non-controllable environment in outpatients.<sup>29</sup>

A highly cited systematic review with meta-analysis conducted by Walton et al., which evaluated the effects of computerised prescribing on a range



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of outcomes, also has implications for patient safety.<sup>78</sup> This review included studies of computer generated support for prescribing or administration and studies on computer controlled administration. The finding most relevant to ePrescribing is that the most successful applications were those in which the computer administered drugs directly to patients under medical supervision. This review suggested that substantial benefits result from computer support for determining the dose of certain drugs in acute hospital settings.<sup>78</sup> However, computer controlled administration of drugs is very different to providing dosage support to clinicians at the time of prescribing as clinicians have more of an opportunity to accept or reject the support provided; this issue of computerised administration, whilst important, is beyond the current scope of this chapter and will therefore be explored in more detail in future planned work.

#### **10.4.2 RISKS**

A main limitation to studies reporting negative consequences associated with the use of ePrescribing is that they tend to not indicate which of the many possible mechanisms might have resulted in the adverse effect.

##### *Organisation inefficiency*

A few studies of ePrescribing have demonstrated a negative effect on organisational efficiency. For instance, Tierney et al. found that interns in the intervention group spent an average of 33 minutes longer (5.5 minutes per patient) during a 10-hour observation period writing orders than did interns in the control group ( $p < 0.001$ ).<sup>79</sup> Another BWH study published by Bates et al. using time motion techniques found that for both medical and surgical house officers, writing orders on the computer took about twice as long as using the old-fashioned method, these differences being both clinically and statistically significant ( $p < 0.001$ ).<sup>80</sup> However, medical house officers recovered nearly half the time due to the facilitation of some administrative tasks, eg looking for charts.<sup>80</sup> Additionally, a pilot of ePrescribing standards in the US found that providers noted that '... everything interacts with everything' making for an overwhelming amount of alerting and therefore additional work.<sup>81</sup> Other than writing orders, one observational study by Almond in the UK found that the time to complete the ward drug administration rounds doubled for healthcare assistants.<sup>82</sup>

A study by Overhage et al. demonstrated the problem posed by persistence of paper, finding that clinicians in the intervention group continued to perform certain tasks using paper-based methods even though the computer was

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automatically performing those tasks for them. Their findings have implications for organisational efficiency as the time wasted on these unnecessary or duplicative tasks was more than a minute per patient.<sup>83</sup> This duplicate recording can also result in safety breaches.

Sittig et al. found strong and widely-felt negative psychological responses to in a qualitative study exploring emotional responses to ePrescribing amongst 50 prescribers. These emotions included: shame and guilt; anger and annoyance; sadness and melancholy; hostility and animosity; and disgust and loathing.<sup>84</sup>

Ash et al. found three shifts in the status quo due to ePrescribing implementation: (1) shifts in the power structure through forced work redistribution and mandated safety pursuits; (2) shifts in control with a perceived loss of clinician control; and (3) shifts in autonomy and a move towards coalitions.<sup>85</sup>

#### *Patient safety*

It should be noted that organisational inefficiency itself can result in risks to patient safety. For instance, Han et al. describe the most serious of risks to patient safety, mortality.<sup>86</sup> The authors found that the unadjusted mortality rate increased from three per cent before ePrescribing implementation to seven per cent after ePrescribing implementation ( $p < 0.001$ ). Observed mortality was consistently better than predicted mortality before ePrescribing implementation, but this association did not remain after ePrescribing implementation.<sup>86</sup> The Han et al. study demonstrated that increased mortality can be associated directly with modifications in standard clinical processes: 'After ePrescribing implementation, order entry was not allowed until after the patient had physically arrived to the hospital and been fully registered into the system.'<sup>87</sup> Although accurate patient registration is clearly important to patient safety, the care and treatment of a severely ill patient should never be made to wait for a computer system.<sup>88</sup>

However, Rosenbloom et al. noted that the implementation process for the application described by Han et al. did not incorporate steps or elements known to ensure system dependability and usability.<sup>87</sup>

Bradley et al. has also noted that total error reports increased post-implementation of ePrescribing, but found that the degree of patient harm related to these errors actually decreased.<sup>89</sup> Furthermore, Shulman et al. noted that the proportion of drug errors fell significantly from seven per cent before ePrescribing introduction to five per cent thereafter ( $p < 0.05$ ), but that this occurred against the backdrop of a strong declining linear trend of the proportion of drug errors over time ( $p < 0.001$ ).<sup>90</sup> These authors, however, reported three important errors intercepted by ePrescribing which could otherwise have

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resulted permanent harm or death; these errors were identified and then acted upon by pharmacist or nurse intervention, ie:<sup>90</sup>

‘A potentially fatal intercepted error occurred when diamorphine was prescribed electronically using the pull down menus at a dose of seven mg/kg instead of seven mg, which could have lead to a 70-fold overdose. In a separate case, amphotericin 180 mg once daily was prescribed, when liposomal amphotericin was intended. The doses of these two products are not interchangeable and the high dose prescribed would have been nephrotoxic. In the third case, vancomycin was prescribed one g intravenously daily to a patient in renal failure, when the appropriate dose would have been to give one g and then to repeat when the plasma levels fell below 10 mg/L. The dose as prescribed would have lead to nephrotoxicity.’

Koppel et al. conducted a study on drug errors introduced by ePrescribing. The authors ‘. . . identified 22 previously unexplored drug error sources that users reported to be facilitated by ePrescribing through their assessment.’<sup>91</sup> The sources were grouped as: (1) information errors generated by fragmentation of data and failure to integrate the hospital’s several computer and information systems; and (2) human-machine interface flaws reflecting machine rules that do not correspond to work organisation or usual behaviours.<sup>91</sup> However, this study, whilst often cited, has been much criticised due to the high risk of bias with respect to their key findings. In response this study, Bates, for example, notes that:<sup>92</sup>

‘A main limitation of Koppel et al.’s study was that it did not count errors or adverse events, but instead measured only perceptions of errors, which may or may not correlate with actual error rates. Furthermore, it did not count the errors that were prevented. As such, it offers no insight into whether the error rate was higher or lower with ePrescribing. Unfortunately, however, the press interpreted the study as suggesting that ePrescribing increases the drug error rate. While the authors did not state this, a press release put out by the journal that published the article did so.’

Risks to patient safety may arise indirectly from application use. For instance, a survey of UK GPs found that some respondents erroneously believed that their computers would warn them about potential contraindications or if an abnormal dose or frequency had been prescribed, highlighting how lack of knowledge and training in how ePrescribing systems function can compromise patient safety.<sup>93</sup>

Risks to patient safety can arise not only from system use but also from a lack

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of actual usage undermining the ability of ePrescribing applications to confer the envisaged benefits to patient safety. A sub-section of the review by Eslami et al. looked at system usage, the authors noted that there was wide variability in the degree of ePrescribing usage.<sup>29</sup> Four studies found that of all prescriptions, 3–90 per cent were entered electronically.<sup>31;76;94;95</sup>

## **10.5 IMPLICATIONS FOR PRACTICE, POLICY AND RESEARCH**

### **10.5.1 TECHNICAL CONSIDERATIONS FOR IMPLEMENTATION**

A number of overviews of ePrescribing provide recommendations, often based on expert opinion and the available literature, on resources to consult and issues to consider when embarking on implementation.<sup>1;5;21;52;81;96–103</sup> There are a number of recurrent themes in this literature on technical issues relating to implementation, for example: differences in actual functional capacity to that perceived by users; issues with customisation; keeping knowledge bases up to date; and interoperability or integration versus interfacing ability of the applications used.

The findings from a recently published, descriptive field study of 10 commercially available ambulatory ePrescribing applications (with an established market presence) supports the notion that ePrescribing applications are often not as comprehensive in their functional ability as is commonly thought.<sup>104</sup> The study by Wang et al. was conducted to assess the actual capabilities of ePrescribing applications compared with expert recommendations for capabilities that would improve patient safety, health outcomes or patients' costs. Each recommended capability was judged as having been implemented fully, partially, or not at all by each system to which the recommendation applied; vendors' claims about capabilities were also compared with the capabilities found in the site visits. The authors found that:<sup>104</sup>

'On average, the systems fully implemented 50 per cent of the recommended capabilities, with individual systems ranging from 26 per cent to 64 per cent implementation. However, only 15 per cent of the recommended capabilities were not implemented by any system. Prescribing systems that were part of EHRs tended to implement more recommendations.

Substantial discrepancies between the capabilities that vendors claimed for their products and the capabilities that were actually identified in site visits were found. Some of these discrepancies were attributable to decisions made at the practice site not to implement features that were actually available from the vendor. These findings highlight the fact that vendors may not be fully aware

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of the details about how their systems are implemented.

The expert panel that developed the recommendations used in the study also produced quantitative ratings for each recommendation's expected effects. We found no relationship between these ratings and the implementation of the recommendations; the recommendations expected to have greater benefits for patient safety and health outcomes were not implemented more frequently than those expected to have lesser effect.'

The Emergency Care Research Institute (ECRI) also assessed three commercially available applications. It noted that all applications evaluated allowed the entering of some unsafe orders (such as ordering the administration of vincristine through an intrathecal route, which would be fatal). Furthermore, these ePrescribing applications did not come pre-programmed with a set of mandatory fields that had to be filled in before an order could be processed.<sup>5</sup> For instance, the applications as delivered, would allow prescriptions to be entered without specifying frequency or route and therefore, the organisation would have to define all mandatory fields on each order form to ensure that all information necessary to fulfil an order was captured during the ordering process.<sup>5</sup> Although the report assessed only three commercially available applications, it is likely that other suppliers' applications would perform comparably. These two assessments suggest that even if a healthcare provider or organisation procures what they believe to be an already sophisticated ePrescribing system that is fully integrateable with other clinical information applications, the capacity to decrease drug errors and related ADEs is still dependent on the configuration of commercially available applications, all of which require some degree of customisation or addition of rules and alerts after instalment.<sup>5;56</sup>

Kuperman et al. conclude that organisational staff must be capable of reviewing, editing and perhaps even creating alerts,<sup>21</sup> and defining local needs by in-house specialists.<sup>105</sup> However, Health Devices argue that even when customised by the facility, these applications would not yet provide the guaranteed levels of safety envisaged.<sup>5</sup>

Without an effective knowledge-base and design briefs, procurement decisions will be flawed and solutions unlikely to be effective.<sup>106</sup> According to a recent review on ePrescribing, '... the knowledge base vendor market still in its infancy, therefore, organisations wishing to implement ePrescribing with clinical decision support must develop it themselves.'<sup>107</sup> Some experts feel that most organisations currently do not have the resources and expertise to do this.<sup>21</sup> (for a more in-depth look at issues with commercial knowledge bases see

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Kuperman et al. *Using Commercial Knowledge bases for Clinical Decision Support: Opportunities, Hurdles and Recommendations*<sup>107)</sup>

The immaturity of the knowledge base market is made evident by the problems suffered by clinicians using ePrescribing applications with regards to the alerts generated by these applications. Of five studies addressing user response to alerts in ePrescribing applications in the outpatient setting included in a review by Eslami et al. four showed that most of the alerts (from 55–91 per cent) were ignored by the prescribing clinicians. Two studies found that that clinical ‘irrelevance’ was the main reported reason for overriding alerts.

Clinical irrelevance has resulted in a phenomenon known as “alert fatigue” and consequently a large proportion of alerts go ignored.<sup>108</sup> van der Sijs et al. also noted that the importance of the treatment prescribed did not allow for a drug change, clinicians’ faith in their own knowledge or other information sources obtained, incorrect information, patients’ resistance to drug change or lack of time also contribute to ignoring alerts as well as alert length, difficulties in interpretation and lack of clarity surrounding clinical consequences.<sup>108</sup>

The clinical irrelevance of alerts, aforementioned inability to detect important patient specific clinical situations and a variety of other contributors have resulted in a movement to improve the sensitivity and specificity of alerts to produce ePrescribing applications that are fit-for-purpose.<sup>29</sup> Kuperman et al. outline a number of issues contributing to the suboptimal support provided to clinicians, and recommendations for the different kinds of prescribing support that should be incorporated into ePrescribing applications.<sup>21</sup>

Another way in which the support provided by ePrescribing can be more clinically relevant is demonstrated by a recently published report by Avery et al. for NHS CFH which aimed to:<sup>96</sup>

- identify those drugs most commonly associated with preventable patient harm in primary and secondary care
- identify the commonest reasons why those drugs cause preventable patient harm
- identify methods of computerised decision support that would have the greatest likelihood of reducing risks to patients from these preventable drug-related problems
- outline the computerised decision support functions or design elements required to deliver a reduction in patient harm from the drugs identified.

The work involved a literature review and expert consensus and is intended to inform the NPfIT’s aforementioned ePrescribing Programme.<sup>96</sup> This is one way



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in which, theoretically, the knowledge base can be developed using evidence-based approaches.

In light of the aforementioned difficulties in interpreting CDSS research as it relates to ePrescribing<sup>49</sup>—the findings that the commercial ePrescribing marketplace may be misinforming buyers of this technology as to its functional capacity and might not be selecting for capabilities that would most benefit patients<sup>104</sup> and that much configuration of applications takes place post procurement<sup>5</sup>—a mechanism for certification should be created.<sup>109</sup>

In fact, according to Wang et al., ‘. . . certification processes should not be based solely on vendor reports about their products or on demonstrations by vendors outside of an actual practice setting. Furthermore, certification may need to take place for individual provider organisations in addition to taking place at the vendor level.’<sup>104</sup>

Owing to the disparities in how applications are configured in practice, the Leapfrog Group has devised certification framework to ensure a minimum level of safety. In order to fully meet the group’s ePrescribing Standard, hospitals must:<sup>110</sup>

- assure that physicians enter at least 75 per cent of drug orders via a computer system that includes prescribing-error prevention software
- demonstrate that their inpatient ePrescribing system can alert physicians of at least 50 per cent of common, serious prescribing errors, using a testing protocol now under development by First Consulting Group and the Institute for Safe Medication Practices
- require that physicians electronically document a reason for overriding an interception prior to doing so.

In order certify that the second requirement of the ePrescribing Standard has been met, a hospital must complete an independent test, consisting of over 130 adult and over 50 paediatric order sets, addressing the following elements:<sup>110</sup>

- is linked to prescribing error prevention software
- enables the review of all new orders by a pharmacist before administration of the first dose of the drug
- permits the notation of all pertinent clinical information about the patient, including allergies, in one place
- categorises drugs into families (eg penicillin and its derivatives) to facilitate the checking of drugs within classes and retains the information over time
- internally and automatically checks the performance of the information system

- requires prescribers to document the reasons for any override of an error prevention notice
- performs dose range checks to prevent excessive doses from being inadvertently ordered
- distinguishes between different doses of the same drug used for multiple indications, including off-label uses.

Classen et al. suggest that, based on the increasing experience with ePrescribing implementations, it seems prudent for an organisation undertaking implementation to consider measuring a number of parameters during a routine implementation. These measures at a minimum would include:<sup>111</sup>

- easily available metrics such as mortality rate and length of stay in areas in which implementation is done
- performance on any quality measures targeted by ePrescribing and other Hospital CORE Measures targeted by the Joint Commission on Accreditation of Healthcare Organizations
- some measures of efficiency such as drug turn-around time or time to first dose of antibiotics in community acquired pneumonia
- how many warnings or alerts go off of various types in drug ordering including allergy, drug–drug, and drug–laboratory, and how often they were heeded.

Post-implementation, the data in the knowledge base of an ePrescribing system (the clinical term repository, CDSS) must be validated and regularly maintained by designated members of staff, both clinical and non-clinical (eg financial and administrative personnel), by the system developers or third party database suppliers.<sup>5</sup> Clinical data must be updated to keep drug information current and to add, modify or deactivate hospital clinical guidelines.<sup>5</sup> The non-clinical data must also be regularly updated to maintain accurate billing and to present cost consideration (eg the cost of a particular test or less expensive alternatives) to users for instance.<sup>5</sup> Most applications undergo retooling or re-configuration to iron out problems that arise after more extensive use and upgrades should also be expected.<sup>92</sup>

Aside from configuration, another deterrent to procurement and implementation of ePrescribing applications is interoperability and whether to integrate or interface. A recent report to the US Congress on ePrescribing noted ‘. . . the inability of multiple applications to share information effectively. Lacking a standard format and vocabulary, applications do not always effectively and unequivocally communicate the necessary information among all participants in the transaction. This reduces the effectiveness and attractiveness of using

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an ePrescribing system.’<sup>81</sup> Procurers of ePrescribing applications must choose whether to integrate or interface their to-be implemented applications with their other existing clinical information systems if that is the case.<sup>5</sup>

### **10.5.2 IMPLICATIONS FOR NHS CONNECTING FOR HEALTH**

As very few secondary and tertiary care institutions use ePrescribing,<sup>2</sup> much of the focus on the NHS CFH has been on the development of ePrescribing for the acute care sector; the first version of the functional specification for the technology has recently been published.<sup>112</sup> Excerpts from the specification demonstrate an awareness of many of the issues surrounding ePrescribing discussed in this chapter and Chapters 13 and 14; for example:<sup>2</sup>

‘Electronic prescribing has not been widely implemented within the acute sector in the UK. There are many reasons for this but one is the complexity of the functionality required to meet different clinical specialty requirements. Without this complexity it is likely that systems will not meet clinical need and thus not support clinical practice.

It is important that systems deployed nationally contain all the necessary functions to allow their use in daily clinical practice as well as delivering additional benefits to support patient care. It is equally important that they are delivered to consistent standards of content and functionality. The functional specification contains many features that will not be available in the short-term and should not be seen as defining a system in which clinical practice will be constrained. It seeks to identify how functionality may evolve but does not dictate how it will be used in practice. A degree of local configuration will be important in determining to what extent the functionality is utilised in specific areas.

To ensure that system development meets clinical needs this document aims to identify and describe in more detail the functional requirements for ePrescribing systems.

As ePrescribing promises much in terms of reduction in clinical risk and process change, it is important that the views of healthcare professionals are reflected in system design. We have incorporated the comments of a wide range of healthcare professionals made at workshops and during the subsequent consensus building process into this specification.

The functional specification is designed to facilitate the delivery of an electronic prescribing medicines administration and medication management system by Local Service Providers. This specification provides greater clarity around the clinical requirements to support the development of this functionality. The scope

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of the functionality encompassed by this specification will facilitate the creation of electronic prescriptions in the managed service for inpatients, outpatients, daycase attendees, attendees at Accident and Emergency departments and other situations where a prescription of the supply of a medicine needs to be communicated.

The specification also supports the development of the administration of medicines and the management of medicines from the perspective of review and supply and also clinical audit and management reporting purposes. The specification facilitates the development of systems to support care in all sectors of healthcare including mental health, community services, acute hospitals and specialist care settings such as cancer networks.

The document outlines areas of desired functionality for both the short and longer-term. The delivery of ePrescribing may be best achieved in a “phased approach” allowing users to gain experience with system functionality before introducing “smart” functionality and advanced decision support. Similarly, as users gain more experience with ePrescribing systems their requirements will evolve and this specification will need to reflect these evolving requirements in future releases.

The priorities will also change as clinical practice and policy develop and as processes change following the introduction of technology. Thus, it is intended that this will be updated on a regular basis. All such updates will be undertaken following input from practising healthcare professionals.’

It is encouraging to see that NHS CFH is going to great lengths to draw on previous experiences in relation to ePrescribing implementation in the acute care sector. However, the importance of upgrading ePrescribing functionality in primary care should not be overlooked. In contrast with secondary care, ePrescribing is the norm in primary care. Upgrading with more advanced decision support functionality, however, still needs to occur, perhaps under the auspices of the ePrescribing Programme. Improving the capacity to improve the safety of prescribing in primary care is important because: firstly, errors in the medicines management process represent an important source of iatrogenic harm in primary care and most errors result from underlying systems-based problems that are amenable to intervention and thus potentially preventable;<sup>11</sup> and secondly, at present, the applications in use in primary care have only basic decision support functionality and suffer from many deficiencies in capacity to improve prescribing safety as is discussed at length in a series of publications by Avery et al. For instance, in 2003 Avery et al. reported that GPs have come to rely on hazard alerts when they are not foolproof and that furthermore GPs

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do not know how to make best use of safety features on their applications.<sup>113</sup> Two years later in 2005, Avery et al. concluded that ‘... there are significant opportunities for improving the safety of general practice computer systems. Priorities include improving the knowledge base for clinical decision support, paying greater attention to human ergonomics in system design, improved staff training and the introduction of new regulations mandating system suppliers to satisfy essential safety requirements.’<sup>114</sup> Furthermore, in 2005, Avery et al. using the Delphi technique, established consensus on the most important safety features of GP computer systems, with a particular emphasis on prescription management. Statements indicating issues considered to be of considerable importance (rated as important or very important), related to: computerised alerts; the need to avoid spurious alerts; making it difficult to override critical alerts; having audit trails of such overrides; support for safe repeat prescribing; effective computer-user interface; importance of call and recall management; and the need to be able to run safety reports. The high level of agreement among the expert panel members indicates clear themes and priorities that need to be addressed in any further improvement of safety features in primary care computing systems.<sup>115</sup>

Also of relevance is the survey by Morris et al., who surveyed GPs’ views from six primary care trusts on the importance of computer system patient safety features. Three hundred and eighty one GPs (64 per cent) completed and returned the questionnaire. Although patient safety features such as alerts regarding drug interactions, contraindications, allergies, dose frequencies and seriously abnormal laboratory test results were considered to be an important part of their computer system by the vast majority of GPs (more than 95 per cent), many were unsure as to what features the system they were currently using possessed. Some respondents erroneously believed that their computers would warn them about potential contraindications or if an abnormal dose frequency had been prescribed and only a minority had received formal training on the use of their system’s patient safety features.<sup>93</sup> This finding is made especially concerning in light of a study by Fernando et al. who showed important weaknesses in generating alerts in four commonly used commercial applications in English general practice.<sup>116</sup> None of the applications were able to generate all 18 pre-defined established alerts for contraindicated drugs and hazardous drug-drug combinations.<sup>116</sup>

The NHS CFH is addressing system design and development in a judicious manner, and recent tenders made by the NHS Connecting for Health Evaluation Programme (NHS CFHEP) have demonstrated an increased appreciation for

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the importance of organisational issues surrounding the implementation of eHealth applications. The success of these technological innovations is as much dependent on the validity of the system as it is on the socio-technical factors as elaborated on in Chapter 16. NHS CFH should also make use of publications more specific to electronic order entry such as Ash et al.'s considerations for successful CPOE implementation<sup>117</sup> and more generic publications such as Greenhalgh et al.'s *How to Spread Good Ideas: A systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation*.<sup>118</sup> Above all else, NHS CFH should not lose sight of the importance of maximising the potential from ePrescribing in primary care, where the infrastructure and professional experience with using these systems already exist, as indeed also does the need.

### **10.5.3 AREAS FOR FURTHER RESEARCH**

Consensus does not seem to have been reached regarding the impact of ePrescribing on the quality of healthcare. For instance, whilst Garg et al. found that two-thirds of CDSSs for prescribing were found to be of benefit, Nies et al. arrived at a contradictory conclusion although both systematic reviews were based for the most part on the same studies.<sup>49;52</sup> This is in part due to the difficulties associated with defining good prescribing.<sup>119</sup>

Whilst organisations such as the Leapfrog Group believe that ePrescribing applications improve the safety of drug practices, there is very little generalisable evidence to underpin this notion although a number of reviews have been conducted on the topic. As much of the beneficial impact on the quality and safety of healthcare seen from ePrescribing has been empirically demonstrated by only a few centres of excellence, there is a pressing need to understand the extent to which these findings are replicable in other centres, which are in the main procuring commercial applications. Understanding why commercial applications do not result, for the most part, in the reduction of drug errors seen in home-grown applications is a top priority for future research. It may be that the applications employed in such centres of excellence are more robust due to continual quality improvement through evaluation than those available off the shelf and due to a variety of socio-technical factors that have been absent from the published evaluations, but are nonetheless critical to the applications success.

Optimal system design has yet to be established. Whilst there are a number of design features that have been identified by SRs as leading to system “success”, our overall understanding of the range of factors and how these inter-



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relate remains incomplete. This is at least in part due to the methods used to determine the features. Systematic reviews tend to include trials, randomised or otherwise, which assess clinical impact that also happen to report system design features.<sup>52;120</sup> Determining successful design features in this way is likely to result in measuring what is easily measurable, with the risk of overlooking important but less quantifiable features important to application design.

Holbrook et al., for example, systematically reviewed the literature to determine predictors of success in CDSSs for prescribing which found that a great number of predictors and barriers had been described within the literature.<sup>121</sup> They found that successful applications tended to include: (1) active, real-time decision support based on patient-specific data); (2) display of costs of tests and therapies to clinicians; and (3) availability (few clicks) of guidelines, general drug information and patient education materials. The authors conclude that ‘. . . clinicians need flexible, fast interfaces, convenient access to computers and organized charting forms.’<sup>121</sup> However, design features are best determined using multi-disciplinary methods such as the end-user and expert consensus building workshops such as the ones recently held by NHS CFH.<sup>2</sup> For example, some key features that were identified at all the workshops that must underpin ePrescribing applications included:<sup>2</sup>

1. safety
2. security
3. accessibility—both in terms of location and access to hardware
4. flexibility
5. intuitiveness
6. fast
7. it must also be possible to retrieve data from the system quickly and easily to facilitate clinical audit and more general reporting.

Further research should continue into what constitutes successful application design and in particular for whom. Much of the research tends to focus on doctors at the expense of nurses who often interact in a different manner with computing systems in healthcare due to a variety of reasons and often have divergent perceptions of the utility and usability of clinical information systems;<sup>122</sup> increasing the focus on nurses is particularly important given that increasing numbers of nurses in the UK now have prescribing rights.<sup>123</sup>

As ePrescribing applications are multi-functional, research should be conducted to try and elicit which sub-components are beneficial and which are not—this is a limitation to findings of multi-functional ePrescribing applications where the results cannot be pinned to more specific application elements. This

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sort of research is integral to informing system design, development and further evaluation as demonstrated, for example, by Jalloh and Waitman who used data mining techniques to detect which orders were selected most frequently in order to redesign the system to improve usability.<sup>124</sup> Similar research could be conducted to elicit the degree to which functions are utilised to inform system re-design or development of future applications. Understanding which functions are used and more importantly not being used provides a backdrop to contextualise impact or conversely lack of impact of ePrescribing applications.

One sub-component held by virtually all researchers of ePrescribing to be of in need of refinement and certainly a contributing factor to unimproved practitioner performance and patient safety, is the support provided by ePrescribing applications, ie in relation to alerts, warnings and suggestions.. We direct readers to Chapter 12.3.6 for further discussion on human factors engineering as it relates to alerts. As previously mentioned, clinically irrelevant alerts undermine the extent to which patient safety can be improved. Kuperman et al. suggest that research should continue into how to make alerting as effective as possible and that the way alerts are presented to providers should be improved in part through differential display based on the severity of the anticipated event.<sup>21</sup>

A disheartening finding begging further study into the ergonomics of ePrescribing is that clinicians tend to ignore the alerts and warnings presented by the decision support component of ePrescribing. Such questions in need of answer include:<sup>21</sup>

- To what extent does alerting impact on clinician behaviour and patient outcomes?
- What is the optimal way to present alerts to prescribers? What are the most effective ways to differentiate high-severity alerts?
- How can clinicians' sense of satisfaction with alerts and other kinds of decision support be increased, ie so clinicians find decision support useful and not annoying?
- When does alert fatigue happen?
- Where there are multiple presentation modes, which mode is most appropriate for any given alert?
- Which member(s) of the healthcare team—for example, physician, nurse, pharmacist, or other—is the best recipient of any kind of alert? Or to multiple members simultaneously?

To-date, the majority of ePrescribing research findings have arisen from only a handful of centres for excellence utilising applications developed in-house

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and evolved over many years, implemented almost exclusively in academic teaching hospitals.<sup>125</sup> The findings arising from evaluations taking place within these settings are of little utility in comparison to evaluations taking place in more transferable settings with “off-the-shelf” products as these represent the applications most in use.<sup>126</sup> Kuperman et al. argue that the commercial knowledge-base market is still in its infancy and research should be conducted to determine:<sup>107</sup>

- What is the best way for organisations to share alert knowledge?
- Is there scope for a national repository of executable drug-related alerting rules?
- How can commercial drug knowledge-bases be edited to yield clinically valuable knowledge-bases?

Bell et al., based on a literature review and telephone interviews with ePrescribing vendors, identified distinct ePrescribing functional capabilities within currently available applications and developed a conceptual framework for evaluating ePrescribing applications’ potential effects based on their capabilities.<sup>20</sup> The framework is organised using a process model of drug management.<sup>20</sup> This represents one way in which to evaluate ePrescribing applications in a more useful way, a way in which can facilitate comparative research. However, the work is far from mature and research should be conducted to determine:

- what is the best way to classify ePrescribing to facilitate comparative research and provide another mechanism in which to conduct secondary research, ie creating taxonomy, of ePrescribing applications?

As with CDSSs, much research has been conducted, however conducting future research sensitive to the numerous issues presented here will facilitate realisation of developing and evaluating ePrescribing applications that result in the benefits envisioned.

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## CHAPTER 11

### Case study: ePrescribing for oral anticoagulation therapy in primary care with warfarin

#### SUMMARY

- Anticoagulants are highly efficacious treatments for a range of conditions; they are, however, also associated with considerable risk of iatrogenic harm if monitoring of treatment and dosage adjustments are poorly managed. Monitoring has thus historically taken place in a hospital clinic setting.
- Widening indications for the use of oral anticoagulation therapy has, however, in recent years led to overstretch of many hospital-based anticoagulation services. Coupled with the political imperative to provide more accessible patient-centred models of care, has catalysed the recent move of anticoagulation services to primary care.
- There are concerns about the safety of prescribing and monitoring of warfarin therapy in primary care.
- ePrescribing for oral anticoagulation therapy, specifically the use of computerised decision support systems, has the potential to provide prescribers with real-time advice on prescribing and monitoring decisions.
- There is strong and consistent evidence that these theoretical benefits in relation to computerised clinical decision support for oral anticoagulation therapy with warfarin can be realised in primary care resulting in greater therapeutic control than might otherwise be possible.
- The automation of dosage calculations and determination of time until next appointment has proved to be suitable with primary care prescribers and has the potential to be readily implemented.
- There are strong arguments for the rolling out and integration of this decision support tool into future upgrades of ePrescribing systems in English primary care.
- Understanding the reasons underpinning the success of computerised decision support for oral anticoagulation therapy—which to a large extent relate to the fact that this meets a genuine clinical need rather

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than a technologically driven “solution”—should provide useful insights into the contexts in which it is best to prioritise development of other computerised decision support tools.



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## 11.1 INTRODUCTION

Over a million people in the UK are prescribed anticoagulant medication annually.<sup>1</sup> According to the National Institute for Health and Clinical Excellence (NICE), available data suggest that the benchmark population rate for people requiring oral anticoagulation therapy (OAT) at any one time is 1.4 per cent per annum, or 1400 per 100,000 persons.

The indications for OAT have broadened in recent years, in particular following publication of the evidence for the effectiveness of warfarin in stroke prevention for patients with atrial fibrillation.<sup>2</sup> This increase in the number of patients treated has, in the UK at least, led to overburdened anticoagulation services and has, coupled with other broader policy developments, necessitated a change in how these services are delivered, namely an outsourcing from secondary to primary care.<sup>3–5</sup> When the transition was first being made in the early 1990s, general practitioners (GPs) were on the whole recalcitrant to run their own anticoagulation clinic, with reasons typically given including: insufficient time, knowledge and training; lack of facilities; and a lack of financial incentives.<sup>6</sup>

Regardless of GPs initial apprehension, where OAT was once delivered exclusively in specialised secondary care clinics, it is now regularly delivered in primary care in England.<sup>2,7</sup> The average number of patients expected to require OAT at any one time is likely to be approximately 3,500 for a typical primary care trust with a population of 250,000 or 140 for a typical general practice with a list size 10,000.<sup>8</sup>

This reorganisation of the provision of anticoagulation services in England, however, remains controversial, embodied by the criticism of the quality of OAT when administered in primary care compared with its delivery in a specialist secondary care setting.<sup>9</sup> The benefit to risk ratio of anticoagulants depends heavily on keeping anticoagulation control within relatively narrow limits, ie the therapeutic range (often known as the International Normalised Ratio or INR) for avoiding both adverse events due to overtreatment and undertreatment.<sup>10</sup> Successful control thus depends on skilled dosing and effective laboratory quality control.<sup>11</sup>

The Department of Health in its 2003 report *Improving Medication Safety* highlighted problems in prescribing anticoagulants, reporting that in primary care, anticoagulants are one of the three classes of medication most commonly associated with fatal medication errors.<sup>12</sup>

Of particular relevance is that a systematic review (SR) and meta-analysis of studies conducted in both primary and secondary care anticoagulation clinics

### Box 11.1 Actions that can make anticoagulant therapy safer

- Ensure all staff caring for patients on anticoagulant therapy have the necessary work competences. Any gaps in competence must be addressed through training to ensure that all staff undertake their duties safely.
- Review and, where necessary, update written procedures and clinical protocols for anticoagulant services to ensure they reflect safe practice and that staff are trained in these procedures.
- Audit anticoagulant services using British Society for Haematology and NPSA safety indicators as part of the annual medicines management audit programme. The audit results should inform local actions to improve the safe use of anticoagulants, and should be communicated to clinical governance, and drugs and therapeutics committees (or equivalent). Commissioners and external organisations should use this information as part of the commissioning and performance management process.
- Ensure that patients prescribed anticoagulants receive appropriate verbal and written information at the start of therapy, at hospital discharge, on the first anticoagulation clinic appointment and when necessary throughout the course of their treatment.
- Promote safe practice amongst prescribers and pharmacists to check that patients' INR is being monitored regularly and that the INR level is safe before issuing or dispensing repeat prescriptions for oral anticoagulants.
- Promote safe practice for prescribers co-prescribing one or more clinically significant interacting medicines for patients already on oral anticoagulants to make arrangements for additional INR blood tests and to inform the anticoagulant service that an interacting medicine has been prescribed. Ensure that those dispensing clinically significant interacting medicines for these patients check that these additional safety precautions have been taken.
- Ensure that dental practitioners manage patients on anticoagulants according to evidence-based therapeutic guidelines. In most cases, dental treatment should proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.
- Amend local policies to standardise the range of anticoagulant products used, incorporating characteristics identified by patients as promoting safer use.
- Promote the use of written safe practice procedures for the use of anticoagulants in care homes. It is safe practice for all dose changes to be confirmed in writing by the prescriber. A risk assessment should be undertaken on the use of Monitored Dosage Systems for anticoagulants for individual patients. The general use of Monitored Dosage Systems should be minimised as dosage changes using these systems are more difficult. Ensure all staff caring for patients on anticoagulant therapy has the necessary work competences. Any gaps in competence must be addressed through training to ensure that all staff undertakes their duties safely.

*Source: NPSA Patient Safety Alert 18 (2007)<sup>14</sup> Reprinted with permission from the National Patient Safety Agency.*

found that improved therapeutic control could decrease the likelihood of almost half of all adverse events associated with anticoagulants.<sup>13</sup>

In response to a risk assessment of anticoagulation therapy conducted by the National Patient Safety Agency (NPSA), a report was issued recommending that *all* healthcare organisations take a range of actions (Box 11.1) under the auspices of *Patient Safety Alert 18* to make anticoagulant therapy safer.<sup>14</sup>

The NPSA and the British Committee for Standards in Haematology (BCSH) have identified safety indicators (Box 11.2) for outpatient OAT.<sup>15</sup> Monitoring these indicators should help to identify risks and promote appropriate action to minimise risk. The safety indicators can also be used to audit the implementation of the recommendations made in the NPSA's *Patient Safety Alert 18*.<sup>15</sup>

#### **Box 11.2 Patient safety indicators for outpatient oral anticoagulation therapy**

- Proportion of patient time in range (if this is not measurable because of inadequate decision support software then a secondary measure of percentage of INRs in range should be used).
- Percentage of INRs  $\rightarrow$  5.0.
- Percentage of INRs  $\rightarrow$  8.0.
- Percentage of INRs  $\rightarrow$  1.0 INR unit below target (eg percentage of INRs  $\leftarrow$  1.5 for patients with target INR of 2.5).
- Percentage of patients suffering adverse outcomes, categorised by type, eg major bleed.
- Percentage of patients lost to follow up (and risk assessment of process for identifying patients lost to follow up).
- Percentage of patients with unknown diagnosis, target INR or stop date.
- Percentage of patients with inappropriate target INR for diagnosis, high and low.
- Percentage of patients without written patient educational information.
- Percentage of patients without appropriate written clinical information, eg diagnosis, target INR, last dosing record.

*Adapted from BCSH (2007).<sup>15</sup> Reprinted with permission from the National Patient Safety Agency.*

Employing an ePrescribing application, specifically the use of a computerised decision support system (CDSS) which provides support for determining dosage and time until next appointment, has been shown to be successful at improving therapeutic control whilst being cost-effective in the English primary care context.<sup>7;16–18</sup> The use of CDSSs could facilitate adherence to NPSA recommendations and aid in the monitoring of BCSH safety indicators to support the provision of anticoagulation services in primary care.

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## 11.2 THEORETICAL CONSIDERATIONS

### 11.2.1 POTENTIAL BENEFITS

Computerised decision support systems for OAT utilise input which takes the form of a target INR (this being a measure for ‘blood’s time to clot’), the therapeutic range for a specific condition, bleeding problems, number of prior visits to the clinic, variability of prothrombin over time, cost of complications and cost of visit.<sup>11;19</sup> Systems employ a number of inference mechanisms to arrive at the output (see Chapter 8) although simple and valid pharmacological models of anticoagulation control exist.<sup>10</sup> These include a ‘... dynamically controlled stochastic model based on nonlinear optimisation theory’ or ‘Bayesian prediction technique to a mathematical model of the pharmacokinetic-dynamic response to warfarin’; other examples of inference mechanisms include pharmacokinetic and pharmacodynamic concepts and the use of the linear regression method.<sup>10</sup>

The use of ePrescribing for OAT has the potential to benefit patients, provider and the health services organisation as a whole. Patients should benefit from improved therapeutic control, spending more time within therapeutic range, thereby reducing the number of INR tests and visits required to maintain therapeutic control in comparison to therapy delivered without a CDSS.

In an analysis of patients’ costs in primary versus secondary care, a patient’s cost per visit was significantly higher in secondary care. The average patient cost per visit in primary care was £6.78 vs £14.58 in secondary care. The authors noted that this finding was driven, in part, by a statistically significant difference in travel time (in primary care the average return journey time was 24 minutes vs 49 minutes in secondary care), but also by a greater tendency to travel by car or public transport to secondary care clinics. Similarly, primary care patients also spent less time in the clinic than patients in secondary care (an average of 23 minutes vs 34 minutes).

Depending on whether primary care employs near patient testing (NPT; also sometimes known as ‘point-of-care’ testing) with coagulometers, the need for laboratory monitoring could be almost entirely removed with the added benefit of increased patient convenience. The use of NPT also virtually eliminates turn-around time for results compared with centralised testing, making the process of anticoagulation management faster and more convenient.

Providing anticoagulation services in primary care enables clinicians to provide more comprehensive and continuous healthcare; and more complete clinical knowledge about patients should enable clinicians to make more informed clinical decisions.

As the use of CDSSs allows for the management of patients by non-clinicians,

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some workload can be shifted away from clinical staff, thus creating new roles and responsibilities for other healthcare providers. An inherent facility of CDSSs for audit facilitates performance review and therefore help to ensure maintenance of clinical standards.<sup>20</sup>

### **11.2.2 POTENTIAL RISKS**

The quality of health services delivery is likely to suffer initially as organisational efficiency will decrease due to the resource and opportunity costs associated with system implementation. Cognisance of the disruptive effect on clinical workflow associated with implementation is therefore important. The requisite training is also likely to disrupt clinical workflow before and at the beginning of implementation; training can, however, minimise this disruption and is furthermore paramount to successful adoption by clinicians and maximisation of benefit. The National Centre for Anticoagulation Training cautions that the use of a CDSS should be restricted to those staff that have completed appropriate training and recommend a training record log is kept for all staff members working in such clinics.

Although there have been no reports of CDSSs providing care inferior to that delivered without CDSSs, this might occur if the support provided by the CDSS is predicated on an invalid knowledge-base or algorithm. Even though it is in the manufacturers' best interests to produce systems that have been rigorously evaluated, there is no third party assurance of validity and safety. As such, patients might actually suffer from a worsening in therapeutic status, ie spend more time outside the therapeutic range, which is associated with an increased risk of adverse events associated with anticoagulants.

The provision of less effective OAT might not be detected initially and if detected, could result in abandonment of the application and subsequent financial loss for primary care. Careful monitoring and evaluation of the impact of the application on the quality and safety of healthcare is thus imperative in order to reduce risks and attend to problems expeditiously.

## **11.3 EMPIRICALLY DEMONSTRATED IMPACT**

### **11.3.1 BENEFITS**

The most recently published SR by Garg et al. included a number of trials, randomised or otherwise, of warfarin dosing systems.<sup>21</sup> Seven of twelve trials for warfarin dosing improved practitioner performance as measured in the main by time to achieve therapeutic INR, proportion of time within therapeutic INR, proportion of patients with therapeutic INR, number of days between INR

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testing and number of test measurements.<sup>21</sup> This review, however, included initiation and maintenance phases of OAT conducted in both inpatient and outpatient settings. This is a major limitation to interpreting the findings from this review as the underlying algorithms differ between the initiation and maintenance phases.<sup>22</sup>

An earlier SR and meta-analysis of nine randomised controlled trials (RCTs) with a total of 1336 patients—the majority of which were also included in the review by Garg et al.<sup>21</sup>—focusing largely on systems for OAT with warfarin, found that the use of computer programmes for anticoagulation optimisation increased the proportion of visits where patients were within the therapeutic range by 29 per cent (pooled odds ratio 1.29 [95 per cent confidence interval (CI): 1.12–1.49]).<sup>10</sup> There was, however, significant heterogeneity ( $p=0.02$ ) between trials making this summary analysis open to question; to their credit, the authors subsequently conducted two additional analyses to investigate the source of the heterogeneity:<sup>10</sup>

- after excluding the only study for which the medication was heparin the results remained unchanged from that of the previous analysis thus demonstrating that the heparin study was not a major contributor to the original summary analysis
- after excluding one of the smallest studies with the largest effect the pooled odds ratio decreased slightly to 1.25 [95 per cent CI: 1.08–1.45], but also reduced the heterogeneity such that it was no longer significant ( $p=0.12$ ); this additional analysis thus uncovered the source of the heterogeneity and, importantly, demonstrated that even after removing this trial that CDSS for OAT resulted in significant improvements in INR control.

The unit of assessment in this meta-analysis was not the patient, but the anticoagulation test and the end point the proportion of tests within the target range; using this statistical unit, the sample size was 3416 dosages (carried out in 1327 patients).<sup>10</sup>

It should be noted that this SR and meta-analysis<sup>10</sup> also included studies of both initiation and maintenance phases and both inpatients and outpatients; it therefore poses the same challenges to interpretation as Garg et al's review.<sup>21</sup>

Another SR on the use of CDSSs for OAT, focusing on its use in primary care with NPT, was published in 1998.<sup>22</sup> Of the seven included studies (with little overlap of studies included by Garg et al.<sup>21</sup> and Chatellier et al.<sup>10</sup>), only one was deemed to be of high quality. The authors concluded from the one high quality study that there was evidence that a CDSS could achieve improved therapeutic



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control in terms of INR, when compared with human performance alone.<sup>22</sup>

The important series of studies by Professor Fitzmaurice and colleagues from the University of Birmingham, England are worth reflecting on in greater detail. The first study, published in 1996, assessed 49 patients treated with warfarin for 12 months using a RCT design.<sup>7</sup> There were significant improvements noted in the proportion of patients with INR control within therapeutic limits, from 23 per cent to 86 per cent ( $p < 0.001$ ) in the practice where all patients received dosage through a CDSS. In the practice where patients were randomised to either CDSS or hospital dosage, analysis showed a significant improvement in the CDSS group which was not apparent in the patients who received dosage in hospital ( $p < 0.001$ ). Mean recall times were significantly extended in patients who received dosage in the practice CDSS through the full 12 months, from 24 to 36 days ( $p = 0.03$ ). Patient satisfaction with the practice clinics was also high. This study, however, did not use NPT and specimens were sent to laboratory with results returned usually on the same day.<sup>7</sup>

An extension of the 1996 study with the addition of NPT was published two years later.<sup>16</sup> This was conducted outside trial conditions with data collected over the course of 12 months from a dedicated nurse-led OAT clinic within primary care. The cumulative results of the longitudinal study were that the overall mean percentage of patients in therapeutic range was 71 per cent and overall the proportion of INRs within the therapeutic range was 53 per cent. No adverse events were reported and no patients had to be referred back to secondary care.<sup>16</sup>

The same group published a second rigorously conducted RCT two years later in 2000.<sup>17</sup> Of the 248 practices within Birmingham, England, 12 were randomly selected from a list of 21 practices that had expressed interest in the study. The control populations used were comprised of patients individually randomly allocated as controls in the intervention practices (intra-practice controls) and all patients in control practices (inter-practice controls). Intervention practices' patients were randomised to the intervention (practice-based anticoagulation clinic) or control (hospital clinic) group. The main outcome measure was therapeutic control of the INR. Analysis of INR by percentage of time spent within the therapeutic range showed significant improvements for the intervention patients ( $p < 0.01$ ) and a significant difference in percentage of time spent in range was also found between the two groups during the study period ( $p < 0.001$ ), but the magnitude of this improvement was not significantly different from that seen in the two control populations.<sup>17</sup>

An extension of this study published in 2001 reported the degree of OAT

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control for patients from the same practices for an 18-month period after the original study's completion.<sup>18</sup> Of the nine intervention practices, six continued to run nurse-led dedicated primary care OAT clinics and continued to use the same CDSS for warfarin dosing. There were no significant differences between the two populations in terms of the percentage of time in range (69 per cent practice-based, 64 per cent hospital-based). The proportion of tests in range was, however, significantly higher in the practice-based group at 61 per cent vs 57 per cent for hospital-based ( $p=0.02$ ). Mean recall time was virtually identical in both groups at 36 days. There were no significant differences between groups for the number of clinical outcomes per patient. The authors noted comparable proportions of control to the original study, this demonstrating that primary care-based OAT supported by CDSS was of at least comparable quality to the hospital-based care.<sup>18</sup>

Fitzmaurice et al. in their 1996 study, using average hospital review rates, estimated 148 additional appointments would have been offered to 26 patients in an intervention practice during the 12 months if CDSS had not been used.<sup>7</sup> The authors assessed the total cost-savings to be non-existent in the first year of use (-£476), but estimated a savings of £2,604 for each subsequent year for the intervention practice with 26 patients. The authors also concluded that the greater the number of patients seen in a high cost provider environment, the more economically efficient a CDSS becomes.<sup>7</sup>

Extending their 1996 study<sup>7</sup> outside trial conditions with the addition of NPT, Fitzmaurice et al. estimated a total cost-savings of £539, from £2290 to £1751 from the use of their dedicated, nurse-led primary care anticoagulation clinic using a CDSS and NPT for the 12-month study period.<sup>16</sup>

### **11.3.2 RISKS**

There were no reported increased risk of adverse events reported in these studies of CDSS supported OAT being delivered in primary care over and above those associated with delivery of care in a hospital-based specialist-led setting. Furthermore, there were no significant new risks introduced indicating that the underlying algorithms are on the whole probably well constructed.

## **11.4 IMPLICATIONS FOR PRACTICE, POLICY AND RESEARCH**

Unfortunately, none of the SRs found evidence for improved important clinical patient outcomes. The principal outcome measures for any anticoagulation service are the prevention of thrombotic and avoidance of haemorrhagic events.<sup>23</sup> There is limited data regarding absolute and relative risks of OAT and most

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studies lack sufficient power to detect significant changes in these outcomes.<sup>10;17</sup> Even so, comparison is problematic due to the differing definitions used for major and minor adverse events. This is perhaps why evaluations tend to focus on time spent in therapeutic INR range, proportion of patients in therapeutic range (a proxy measure for the risk of adverse drug events) and recall rates.

As most of the research pertains to warfarin, further research into the applicability of integrating phenindione and acenocoumarol should also be conducted as the findings might not be transferable to other oral anticoagulants that may be used.

Finally, both the systematic reviews by Garg et al.<sup>21</sup> and Chatellier et al.<sup>10</sup> did not mention whether NPT was part of the intervention in the included primary studies. This is important as the degree to which an additional technology such as NPT contributes to the overall effect of CDSSs for anticoagulation is not yet well understood.<sup>16;17</sup> Furthermore, this information should have been included so that readers would not have to go to the primary studies for further information.

However, the automation of dosage calculation and determination of time until next appointment has proved to be readily adoptable. As outlined in the chapters on ePrescribing, computerised decision support systems, human factors and organisational issues in design, development and deployment (Chapters 8, 10, 12 and 13, respectively) the success of an application is dependent on a number of variables. We postulate that in this case this is most likely due to the relative ease of use of the technology, driven by a recognised need to improve the quality and safety of OAT (rather than primarily a desire to improve technology and application validity).

That said, there is still the need for further research, specifically to compare in a head-to-head fashion, the different algorithms that are currently being employed in CDSS applications for OAT using warfarin, to establish which, if any, is best at supporting practitioner performance.

A point worth noting about CDSSs for OAT is that the applications are for the most part stand-alone systems and this poses potential problems with regards to integration with existing records (see Chapter 5 for a further discussion on the matter). Concerns over interoperability might serve as a deterrent to implementation and adoption of the application in primary care and may also potentially compromise safety as a consequence of fragmenting the record of care. This concern should be mitigated by ensuring compatibility with primary care computing systems or incorporating the functionality within ePrescribing systems.

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In summary, given that the technical infrastructure exists within primary care in which to readily incorporate this particular ePrescribing application, the fact that there are also now clear financial incentives to provide OAT services in primary care and the clearly demonstrated beneficial impact on the quality of anticoagulation care, it is important that this eHealth application is now used much more widely in English primary care.

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## CHAPTER 12

### Human factors and human factors engineering

#### SUMMARY

- Human factors (also known as ergonomics) is the science of human behaviour and performance. Human factors engineering is the application of human factors principles and insights for the purpose matching people's material and social environments to their abilities and needs.
- Human factors issues relevant for eHealth include: users' work practices and workflow; the nature of the tasks to be supported by the eHealth system; users' capabilities and skills; training programmes; and the wider work and organisational context in which the system will be deployed.
- Healthcare has been slow to incorporate human factors into eHealth projects, despite the increasing dependency on eHealth applications for delivery of care and growing evidence of patients being put at risk.
- Users should be involved in all stages of design, development and deployment of eHealth applications. Feedback from users should not only be facilitated, but must also be actively encouraged so as to ensure that new applications are fit-for-purpose and so as to minimise risks to patient safety.
- Ease of use ("usability") and fit with working practices is as important as the functionality and reliability of eHealth applications such as the electronic health record, ePrescribing and computerised decision support systems. Confusion and frustration arising from poor usability will interfere with user acceptance, with an adverse subsequent knock-on effect on implementation and may also endanger the safety of patient care. There is, however, a lack of guidelines for evaluating the usability of eHealth applications.
- NHS Connecting for Health should ensure that human factors issues are incorporated into project planning and execution, that project deliverables are systematically evaluated against appropriate human factors criteria and that results are used to inform decisions to grant approval for the large scale roll out of new eHealth applications into the NHS.
- Embedding human factors engineering principles and thinking is not free;



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NHS Connecting for Health needs to ensure that adequate time, resources and prioritisation are given to this so as to maximise the chances of success of its various eHealth initiatives.

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## 12.1 INTRODUCTION

Understanding the ways in which end-users relate to and interact with computer systems is crucial to their successful implementation and adoption, but is a consideration that is frequently overlooked by system commissioners and designers. Drawing on insights from human factors (HF) research and human factors engineering (HFE) practice, this chapter seeks to summarise the state-of-the-art in these fields. We focus, in particular, on a series of recommendations for how HFE can be best incorporated into the design and development of eHealth applications. We will illustrate these recommendations with examples of HF issues arising in the design of a range of eHealth applications, including the electronic health record (EHR; Chapter 6), computer history taking systems (CHTS; see Chapter 7), computerised decision support systems (CDSS; Chapter 8) and ePrescribing applications (Chapter 10).

## 12.2 DEFINITION, DESCRIPTION AND SCOPE

The science of HF, also known as ergonomics, is the multi-disciplinary study of people's behaviour and how this is influenced by their material, organisational and social environments.<sup>1</sup> Human factors engineering is the methodical application of HF principles to the design of these environments, material, organisational and social: technical devices and applications; work procedures and workflows; work places; training; staffing; personnel management; and organisational structures are all issues that fall within the ambit of HF and HFE.<sup>1;2</sup> The ultimate goal is to ensure the safe, comfortable, and effective use of technologies.<sup>3</sup> To achieve this, HF sets out to '... understand people and their interactions, as well as the relationships between these interactions, and to improve those interactions in real-life settings.'<sup>4</sup>

Rapid advances in performance and falling costs have led to information technology (IT) being ever more widely used in all sectors of society. With this wider adoption has come a much closer integration of IT with people's work practices, such that the latter are now literally dependent on the former. As Grudin has observed:<sup>4</sup>

'... with the advent of "groupware" and applications to support organizations, we are beginning to see the focus of user interface design extend out into the social and work environment, reaching even further from its origin at the heart of the computer.'

What this means for HF is that its scope has widened progressively from an initial focus on physical and perceptual aspects of human performance and

their implications for the design of the material environment to now include cognitive, motivational and situational factors and how these might inform design of not only technical artefacts but also the working environment. The broad areas of interest and scope of HF practice today are outlined in Box 12.1.

While technical reliability remains a key objective for new eHealth applications, their successful deployment, adoption and dependability in use draws on a much wider range of insights and disciplines.<sup>1,2</sup> It is the recognition of the socio-technical character of this challenge which has motivated the incorporation of HFE within IT design and development practice. When HFE is applied early and consistently throughout the IT system design process, it can greatly increase the chances of higher productivity and process improvements and provide the foundations for planning an effective deployment strategy, which may in time decrease staffing and training costs and reduce the risks of user resistance to the new system.<sup>1</sup>

#### Box 12.1 The scope of human factors

**Physical and perceptual factors:** These include the bounds of human performance such as the accuracy of movements such as pointing, response times to simple stimuli and capacity to discriminate between levels of brightness, different colours and their implications for the design of the physical interface.

**Cognitive factors:** These include human performance relating to the speed of information processing and decision-making, recognition of and memory for information, the causes of errors, learning times and styles and the impact of prior knowledge. The aim is to inform guidelines for design user interface layouts, the representation of information, the sequencing of activities and measures to reduce the likelihood and impact of errors.

**Motivational factors:** These focus on people's attitudes, and beliefs and expectations of technologies and how these may be influenced by a person's status, role, profession, age, etc. One important aim is to try to arrive at an appropriate allocation of function between user and system such that the former is able to derive satisfaction from using the system while ensuring its safe and effective use.

**Situational factors:** These describe the social and organisational context within which the individual is expected to perform. They include how roles and divisions of labour are managed within a group or team, the collaborative dimensions of the work, how awareness and coordination is achieved and the implications of new technologies and work re-design for safety and reliability of the overall socio-technical system.

Key orientations for the application of HFE are summarised in Box 12.2.

The application of HFE is of critical importance to eHealth, not only to reduce the risk that they may be rejected by end-users, but also to reduce the risks that poor designs may pose to patient safety.<sup>1,5</sup> So, given that HFE is well

established in other sectors of society where the safe and dependable use of technology is of paramount importance (eg aviation, nuclear power, etc), it is somewhat surprising to note that, while problems with IT projects (especially those that are large scale and or innovative in their objectives) is by no means exclusive to the healthcare sector, overall, the adoption of HFE principles and practice in healthcare remains distinctly patchy.

#### Box 12.2 Key human factors orientations

- **To err is human:** people are not machines; machines are not perfect; design the user interface to tolerate errors of both.
- **People are the same, but individuals are different:** design for people sameness and tolerance of measured differences, especially in their skill and performance.
- **User performance affects system performance:** how people use the system is the measure of the system's capabilities and risks.
- **Performance and safety are influenced by design:** design decisions can improve or detract from users' performance and from the safety of the system
- **User performance is a function of aptitude and training:** training is part of the system engineering and safety performance package.
- **Evaluation is imperative:** make HF evaluation of every technical deliverable mandatory, and evaluate early and often.
- **Involve users:** ensure systematic and close user involvement from initial requirements gathering to final evaluation.
- **Human factors is not free:** plan the resources for HF programme support at the start of a project and protect them against any subsequent budget pressures.
- **Human factors requires experts:** the application of HFE is neither easy, nor common sense—except in retrospect of an incident or accident or poor design; co-locate HF resources near the project and or programme teams they serve.

*Adapted from: FAA (2000),<sup>1</sup> Sharit (2003)<sup>6</sup> and [www.saferhealthcare.org.uk](http://www.saferhealthcare.org.uk)<sup>7</sup>*

In the case of medical devices—where HFE is reinforced through standards and regulation<sup>8</sup>—the picture is generally encouraging.<sup>9</sup> Influenced by high profile cases such as the Therac-25 accidents,<sup>10</sup> there is growing recognition that errors in the use of medical devices often have their origins in poorly designed user interfaces and the fact that design-induced errors can lead to patient injuries and deaths is now well understood.<sup>11</sup> As Sawyer et al. point out:<sup>11</sup>

‘Mistakes made during device operation not only can hamper effective patient treatment, monitoring, or diagnosis but in some cases can lead to injury or death. It is important that medical devices be designed with consideration of the impact of design on safe use.’

In particular, user behaviour can be directly influenced by the operating characteristics of the equipment; user interfaces that are misleading or illogical

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can induce errors by even the most skilled users.<sup>11</sup> Medical devices can be used safely and effectively only if ‘. . . the interaction between the operating environment, user capabilities, stress levels, and device design is considered when the manufacturer designs the device.’<sup>8</sup>

It is therefore important to have a detailed understanding of how a device will be used in order to gauge the types of errors that may arise with its use.<sup>8</sup> As Kay and Crowley note:<sup>8</sup>

‘HFE considerations important to the development of medical devices include device technology, the users, environment in which the technology will be used, how dangerous device use is, and how critical the device is for patient care.’

Beyond the medical device arena, which is to say beyond a focus on physical, perceptual and cognitive factors in IT systems design, the HFE picture has generally been less encouraging<sup>12</sup>, despite the increasing reliance in the NHS and elsewhere on IT for the delivery of healthcare strategy. Poor conceived objectives, poor design and inadequate change management (see chapter 13) continue to lead to wasted investment in new IT applications that are not fit-for-purpose or are rejected by their prospective end-users<sup>13</sup> some cases, such as the London Ambulance Computer Aided Dispatch System failure,<sup>14</sup> patients’ lives have needlessly been put at risk. Improving patient safety, as in the case of the NHS Care Records Service, is often given as a key objective of new IT applications in healthcare. As Reason has noted, however, ‘IT does not eliminate error, it relocates it and can also change its form’.<sup>15</sup>

The reasons for this situation are inevitably complex and multi-faceted, but reflect how, just as Grudin observed, as eHealth applications become more closely integrated with work practices workflows and organisational goals, the scope of HF issues that must be addressed expands. Fortunately, through the efforts of researchers in, for example, UK the Dependable Interdisciplinary Research Collaboration (DIRC)<sup>16</sup> this unsatisfactory state of affairs is now beginning to change; that said, the need for further progress clearly remains.<sup>17</sup>

### **12.3 HUMAN FACTORS ENGINEERING AND EHEALTH**

We begin this review of HFE issues for eHealth with a summary of basic principles of system usability, ie a measure of how closely matched a system is to users’ capabilities and requirements. Maximising the usability of a system may be considered as the central goal of HFE. We then consider methods for evaluating usability before going on to review the central question which this raises, namely how to involve users effectively in the applications design and

development process. Finally, we address the question of how HFE can be accommodated within software engineering practice.

### 12.3.1 USABILITY PRINCIPLES

Usability can be defined as the ease with which a system enables users to achieve their goals.<sup>11</sup> While this may seem straightforward, usability is, in reality, a complex, multi-dimensional concept. At its most basic level, usability must address people's fundamental physical, perceptual and cognitive performance limitations.<sup>11</sup> As Sawyer et al. observe:<sup>11</sup>

‘... a person's most basic physical and sensory capacities include vision, hearing, manual dexterity, strength, and reach. A number of related design factors can interact with them to influence human performance: the legibility and discriminability of displayed symbols, audibility and distinctiveness of alarms, the strength required to make connections, and the requirements for reaching controls.’

#### Box 12.3 Excerpt from a taxonomy of human-computer interaction design issues

- Colour
- Resolution
- Meaning of labels
- Understanding of system instructions/error messages
- Layout/screen organisation
- Graphics
- Visibility of system status
- Response time
- Navigation, the ease of finding one's way around the system
- Consistency of operations
- Overall ease of use

*Adapted from: Kushniruk et al. (2004)<sup>20</sup>*

Over many years of research, these human performance parameters have become well documented and their implications encapsulated in a set of usability principles which practice and experience confirm are (more or less) generic to human-computer interaction (HCI) and user interface design (eg Dix et al.).<sup>18</sup> To complement these principles, there is an even larger set of more specific usability guidelines. Usability principles are intended to have wide applicability, whereas guidelines may require some interpretation in deciding which one(s) are most likely to be relevant to a particular usability goal. Guidelines may also be specific to the type of application. Usability guidelines are well documented in the ergonomics and HF literature (eg Mayhew, 1991).<sup>19</sup> Their provenance



varies: some guidelines have originated as in-house design rules (eg Apple, IBM), whilst others are the work of official standards bodies such as the International Organization for Standardization (ISO) (eg 9241, parts 1–17).

Box 12.3 illustrates the kinds of user interface design issues which might benefit from the applications of usability guidelines.<sup>20</sup>

Beyond these basic usability issues, however, lie an increasingly complex and interrelated set of concerns and HF orientations (see Box 12.4) whose resolution resists a guideline-based approach. These concerns reflect the growing awareness that the usability of a system is not a well bounded problem. It is not defined by human performance parameters and interface design but must be set in a context in which issues such as task design, user attitudes and preferences, and the workplace will play an important part. For example, a system should allow users to plan and select actions according to their individual preference (for example, see ePrescribing, Chapter 10). This will then allow users to familiarise themselves with and cope with any demands that were not expected beforehand.<sup>21;22</sup> Cognitive models within a system are also important as these allow the integration of other factors such as assumptions about tasks to be carried out.<sup>1</sup>

#### **Box 12.4 Human factors orientations**

##### **The individual user interface**

- Detailed displays and controls
- Screen layout and design
- User inputs & commands; information processing
- Physical and cognitive demands
- Product usability

##### **Task design**

- Work-station ergonomics
- Decision aiding; training and procedure development
- Individual workload; job design
- Product-product compatibility
- System usability

##### **Organisational and social context**

- Communication; co-ordination; team workload and performance
- Organisational structures; staffing levels
- Training strategies and resource requirements
- System-system compatibility

*Adapted from: FAA (2000)<sup>1</sup>*

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### 12.3.2 USABILITY EVALUATION

Even if usability goals could be narrowly defined around meeting human perceptual and cognitive performance, human variability is such that design decisions relying on even the most simple of guidelines should be subjected to validation. Usability evaluation attempts not only to identify problems, but also identify their causes such that they can be fixed. Because of the wide variety of factors to be assessed, there are a number of different usability evaluation techniques which are distinguished by:

- their timing in the design and development cycle
- how long they take
- the approach employed
- whom they involve.

Formative evaluation takes place as part of the process for establishing the design requirements. Summative evaluation takes place in the context of determining whether the goals of the system have been achieved.

There are a number of techniques for usability evaluation that can be undertaken by designers alone. This limits the scope and may limit the validity of their results. Heuristic evaluation uses experts in interface design to study the interface for features which they know from experience will lead to problems. One variation of the method uses software developers instead of interface experts, but equips them with a set of design principles and or guidelines. The list of guidelines (see Box 12.5), first proposed by Nielsen,<sup>23;24</sup> has been widely referenced and adapted for use in clinical settings.<sup>20</sup>

#### Box 12.5 Heuristic evaluation guidelines

- Visibility of system status
- Match the system to the real world
- User control and freedom
- Consistency and standards
- Error prevention
- Minimise memory load—support recognition rather than recall
- Flexibility and efficiency of use
- Aesthetic and minimalist design
- Help users recognise, diagnose and recover from errors
- Help and documentation

*Adapted from: Kushniruk et al. (2004)<sup>20</sup>*

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There are several stages to carrying out a heuristic evaluation delineated by Kushniruk et al.:<sup>20</sup>

‘First, a list of heuristics is given to the analysts who use them in evaluating the system or the interface. The analyst(s) then ‘steps through’ or inspects the user interface or system, and in doing so notes any violations of the heuristics described in the next section of this paper (this could be done in the context of carrying out a specific task in using the system). It is often advisable to have two to four usability experts (analysts) independently assess a system or its interface. Each analyst independently evaluates the user interface and generates a list of heuristic violations which can be compiled into a single list. The results of the evaluation can then be summarized (eg number and type of violations of usability heuristics) and presented to the design team along with recommendations for improvement.’

The cognitive walkthrough method involves designers and developers ‘walking through’ the interface, guided by the core tasks that the typical user would want to perform.<sup>20</sup> Actions and feedback are compared with users’ goals and knowledge. Cognitive walkthroughs are similar in a number of respects to the structured code walkthrough techniques of software engineering. Cognitive walkthroughs are particularly suitable for evaluating interfaces in the ‘walk up and use’ category, ie where the user is assumed to have never seen the interface before, or to use it very infrequently.

User participation-based evaluation techniques range from evaluation workshops where users perform a set of pre-defined tasks in a controlled setting, to observational studies in situ. In the former category are techniques such as co-operative evaluation where, as the name suggests, users are encouraged to articulate their opinions as they perform the evaluation tasks. In the latter category, the use of methods pioneered in the social sciences, such as ethnography, is becoming increasingly common.

User participant approaches share the need to gather data. Questionnaires are a useful tool for gathering data from a large number of subjects. With careful design, they can yield reliable, quantitative data. Verbal protocols, gathered through structured experiments in which the user is encouraged to think aloud in the presence of the evaluator. Subsequent analysis can reveal what problems users experience in what context and how these may arise. Video is a powerful medium for capturing and conveying information about how people interact with computers. It provides a record of sequential streams of natural observations, some of which are difficult to capture in any other form. Video also preserves the context as well as the content of a session and provides

multi-faceted, qualitative data that can be analysed on a number of different levels.<sup>25</sup>

The full analysis of a behavioural record such as verbal protocols captured on audio or video takes many hours. One way of expediting this is to focus on just two types of event: critical incidents and breakdowns. A critical incident is behaviour which is at odds with that expected, eg it is sub-optimal. A breakdown can be defined as any point at which the interface becomes part of the user's subjective experience. The principle underlying this is that in normal circumstances a good tool enables the user to focus on the task and what is being done, rather than how. Breakdown occurs when something happens to make the user conscious of the tool in the performance of the task.

#### Box 12.6 Comparison of usability evaluation techniques

Method	Advantages	Disadvantages
<b>Analytical</b> heuristic; walkthrough	Usable early; few resources required; strongly diagnostic; overview of whole; high potential return	Narrow focus; broad assumptions of users' cognitive behaviour; subject to bias; problems getting experts; cannot capture real behaviour
<b>Observational</b> co-operative evaluation; ethnography	Quickly highlights problems; verbal protocols are a valuable information source; rich data	Can affect user performance; analysis can be time-consuming
<b>Survey</b> interview; questionnaire	Addresses opinions and understanding; can be used on large groups; www-based delivery	Low response rates; possible interviewer bias; interviews time-consuming
<b>Laboratory studies</b>	Powerful; quantitative data; reliability good; replicable	High resource demands; time-consuming; artificial; questionable validity

*Reproduced with permission from Dix et al. (2004)<sup>18</sup>*

From numerous studies (eg Virzi et al.<sup>25</sup>) it is clear that evaluation techniques are not equivalent in their capacity to identify specific types usability of interface problems (see Box 12.6 for a summary). One study suggests that expert heuristic evaluation is likely to produce the best results, both in terms of types (eg severe and trivial) and numbers of problems uncovered. User participant techniques rate highly from the point of view of uncovering severe problems, but are the most costly. Non-expert heuristic evaluation was found to be good at finding recurring problems, ie those which are likely to present difficulties to users each time they are encountered, as opposed to just the first time. Heuristic

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usability evaluation was found by Li et al. to be a good methodology with which to economically identify any usability issues. They found it to be straightforward and necessary to highlight the importance of usability.<sup>23;26</sup> However, when they examined a ‘. . . highly domain-specific user interface’ such as is found in ePrescribing applications, they found relying exclusively on heuristic evaluation was unsatisfactory and pointed out that other approaches to usability testing must be incorporated so as to recognise issues that might not be observed by usability specialists because of their ‘lack of domain knowledge’.<sup>27</sup>

### 12.3.3 EVALUATING PERFORMANCE AND SAFETY

Where the quality and safety of care may be adversely affected by users’ mistakes, then evaluation criteria must reflect acceptable error tolerances; evaluation methods must thus be capable of measuring user performance with a new device or system in a clinically meaningful way. This, as Heathfield and Wyatt,<sup>28</sup> Heathfield and Buchan,<sup>29</sup> Heathfield et al.,<sup>30</sup> Kaplan<sup>22</sup> and Sharit<sup>6</sup> have argued, remains a challenging area for eHealth applications.

Healthcare has developed the clinical trial to measure the efficacy and safety of new medicines and it is a methodology which needs its equivalent in evaluation of eHealth applications (see Chapter 16). CDSSs provide a good illustration of how this approach may fail to address the use of eHealth applications in practice. For example, in a review of how physicians responded to drug safety alerts in ePrescribing applications, van der Sijs et al. found that with the exception for serious alerts for overdose, which were overridden in one-quarter of all alerts, safety alerts were overridden in 49 per cent to 96 per cent of cases.<sup>31</sup> The authors noted the reasons for overriding alerts included:

- **Alert fatigue:** this was the most important reason for overriding, caused by too many false positive alerts affecting physicians’ judgement
- **Disagreements:** professional disagreement with the recommendations being made: clinicians’ faith in their own knowledge or other information sources obtained, incorrect information, patients’ resistance to drug change
- **Poor presentation:** alerts were too long and difficult to interpret and the clinical consequences of overriding them were not clear
- **Lack of time:** insufficient time to pay adequate attention to the messages being generated and unnecessary workflow interruptions
- **Knowledge gaps:** lack of understanding about importance of the alert.

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Similarly, a review by Eslami et al. on alerts and the appropriateness of alerts assessed the impact of ePrescribing on the produced, accepted and ignored, alerts from two points of view: system weakness and user response.<sup>32</sup> Four studies showed that most of the alerts (from 55 per cent to 91.2 per cent) were ignored by the physicians, with two studies showing that ‘clinical irrelevance’ was the main reported reason for overriding alerts.<sup>32</sup>

The requirement for measurement and for repeatability favours an *in vitro* approach which is able to control for and isolate what are assumed to be the key factors. The issue is, of course, whether the results have ecological validity—that is, do they reflect the outcomes that will be found *in vivo*, ie in real situations of use? This question becomes especially important where the introduction of a new IT application is likely (either by design or as an unanticipated side effect) to lead to changes in working practices over time. Alberdi et al. describe a multi-disciplinary approach combining quantitative data from controlled clinical trials with qualitative data from ethnographic studies of clinical decision-making in context to the evaluation of a CDSS (see Chapter 8) which seeks to address this problem.<sup>33</sup> The results are promising, in that subtle interactions between human decision-making and computer-generated evidence were observed, but more work is essential to determine the efficacy of the approach and how it might be tailored to the needs of a particular evaluation study. One potentially important issue is the scale (and hence cost) of the study that would be required to ensure confidence in the representativeness and generalisability of ethnographic findings.

#### **12.3.4 USER INVOLVEMENT**

The need to set usability goals and to resolve problems raises fundamental questions about the nature and scope for the involvement of users in IT design and development. The fundamental principle around which HFE has focused is the close and meaningful participation of users throughout the design and development process. This is, however, not easy to achieve in practice. The practical issue is whether it is sufficient just to get user input at the beginning (formatively) and at the end (summatively) of a project and, if not, why? Some of the pitfalls reflect the wide mix of expertise that has to be accommodated. Others are more political in nature. Either way, the involvement of users in design leads to additional problems for the technical members of the team.

In principle, the case for user involvement in the design of IT design and development has long been accepted within the software engineering community.<sup>34</sup> Indeed, its importance was first articulated in the 1970s by Edith



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Mumford and her colleagues at the Tavistock Institute.<sup>35</sup> Since then, the users' cause has taken up and given a more radical edge by the participatory design movement<sup>36</sup> with its initial insistence on user empowerment, only to gradually orient around a rather more pragmatic role as the practice entered the mainstream.<sup>37</sup> In so doing, user involvement has acquired a plethora of approaches for affording communication between designers and users. Techniques for gathering user attitudes and requirements include: workshops, interviews, ethnographic studies; techniques for feeding back design ideas to users include: use-case scenarios, storyboards, mock-ups and prototyping; finally, there are techniques for formative and summative evaluation which are aimed at capturing user input on a somewhat more formal basis and, in the latter example, typically for achieving user "sign off" at the end of the project.

A number of recurring themes have emerged as evidence of the challenges of achieving effective user involvement. First, users often do not know what they want, a common situation where the aim of introducing a new system is to facilitate major changes in work practices. For reasons which are self-evident, this is often a goal of eHealth projects, with IT being used explicitly as a change agent.<sup>38;39</sup> In such cases, while high level requirements may be easy to identify, the details are likely to prove much more difficult to define and may be based on an oversimplified and abstract model of the work practices involved. Actual work processes are often more complex and even quite different from the procedures documented in organisational manuals.<sup>40</sup> Clarke et al. for example, studied how hospital managers monitor the availability of beds and how this relies on various important, but often taken-for-granted (and ignored by designers) affordances of the workplace.<sup>39;41</sup> The apparent lack of interest on the part of IT system designers in the real world of work—for example, in how clinical information is actually recorded and used—has dogged EHRs and other information management or integration projects for many years.<sup>41</sup> The impact of designers' ignorance is compounded by the fact that users, in their turn, may have limited knowledge of the technical possibilities and may find it difficult to re-conceptualise what they do in ways that are compatible with what is technically feasible. In such cases, it is important that users have sufficient time to experiment and learn as the project unfolds. This highlights the need for designers to support users with prototyping and the benefits of staging design, eg by piloting a small part of the overall system. Even where changes in working practices are not intended, the introduction of a new system can still have unanticipated consequences, sometimes because of poor design decisions,

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on other occasions because, over time, its users discover more effective ways of using the system<sup>42</sup>.

A second theme is that users and designers lack a common language. They typically do not inhabit the same work domain and may have radically different perspectives on the problem. Third, users' commitment to the project may be weak or decline as time goes by. Unlike the technical team members, user involvement in project work is likely to be discretionary and may be taken on as additional work. Users may experience difficulty in maintaining commitment to a project at its inception because the benefits may seem remote and intangible. Even if commitment is strong at the beginning, it may subsequently wane if there is a perceived lack of progress and of tangible outcomes. Fourth, users may have diverse and possibly conflicting opinions about requirements. These may reflect personal differences in work habits or possible political factors in the work place. This is almost inevitable in eHealth applications such as ePrescribing or the NHS Care Records Service (NHS CRS), where the range of users is very broad. Facilitators must be prepared to act when conflicts arise, identifying which of the above strategies is most appropriate and pressing its adoption. It is vital that there be no overall losers in the process, otherwise the commitment of some users may be undermined.

One of the reasons why the notion of what constitutes “best-practice” for user involvement continues to be elusive is, of course, because the problem it is trying to address keeps changing and becoming more complex.<sup>36</sup> To put it simply, as IT become progressively more deeply embedded within workplaces and organisations, and are increasingly seen (rightly or wrongly) as vehicles for innovating work practices, then uncertainty about what users' requirements really are grows. This is not just because there may be more and different kinds of users (“stakeholders”) with whom application developers must deal and who may have different—and possibly conflicting—interests (although this is, of course, an important factor). Perhaps more important, however, is that the likelihood that requirements will be difficult to establish a priori, but will change when the system is deployed and users get to use it “for real”. Innovation often has unpredictable consequences. For eHealth applications, of course, it is imperative that unforeseen consequences for patient safety are quickly detected and their causes resolved. The challenge is how to evolve applications so that an adequate fit with work practices is maintained. As Suchman argues, ‘... system function and human work processes must be addressed together.’<sup>42</sup>

Over the past 10 years, large-scale applications procurement strategy has moved from bespoke applications design towards the acquisition of commercial

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off-the-shelf (COTS) software packages. These COTS software represents design issues postponed, not resolved, however, and organisations face new challenges to select, assemble and configure COTS software so that they match their needs, and to reconfigure them as those needs change. The problem is to ensure that the generic models of work embedded in COTS solutions are evolved in locally meaningful ways.<sup>43;44</sup> So called enterprise resource planning (ERP) applications, for example, do not come out of the box ready to use in any organisational context or setting, but have to be adapted.<sup>45</sup> Often, however, this adaptation effort is compromised by the limited customisation options available with a package.<sup>46</sup>

### **12.3.5 REQUIREMENTS GATHERING AND DESIGN**

Many of the difficulties encountered in IT projects serve to illustrate the more general problem that, as noted in the previous section, computer applications are often introduced into the workplace without sufficient understanding of their social complexity. The all too common result is that the system disrupts rather than supports the work process. Such problems point to the need to review system design practices and interest has hence grown in sociologically-informed methods such as ethnography.<sup>47;48</sup>

Ethnography is concerned with the study of commonplace, everyday activities and the ways in which people experience, make sense of, and create the social world in which they live and work. It was originally developed by anthropologists as way of gaining understanding of social mechanisms in primitive societies. Now, however, ethnography is finding increasing application as a tool for understanding the social environments in which work is embedded and how these influence its performance. Ethnographic methods for applications design are committed to inquiring into patterns of interaction and collaboration. They rely upon observers going into the workplace and ‘learning the ropes’ through questioning, listening, watching, talking etc with users. The approach is sometimes referred to as design through immersion. The goal is to gain an understanding of how the social organisation of work is understood and achieved by the people in the particular work setting. Ethnographic applications design is based upon the principle that users’ needs can only properly be grasped by studying them in their workplace, because it cannot be known in advance what the relevant features of work and its environment will be.

Ethnographic studies of collaborative work highlight the informal and undocumented nature of much collaborative work. Often, it seems, it is difficult to distinguish reliably between individual and collaborative tasks. Instead of

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adherence to formal roles, what is more commonly observed is an emergent and flexible division of labour which allows people to lend support to the accomplishment of each others tasks, and thereby manage difficulties and crises. The important finding is that the informal interactions that occur within the workplace not only serve important psychological and social functions, but are crucial to the actual conduct of the work itself.

Unfortunately, the outputs of ethnographic studies do not necessarily match the needs of applications designers. Typically, they are rich in detail, but lacking in formal content. The ethnographic emphasis lies in the integration of work activities, whereas the designer's emphasis is typically in pulling them apart, and identifying component parts such as tasks. Ethnographic data is therefore often difficult to apply prescriptively in answer to the inevitable question 'what is to be done?' since its whole emphasis is on what is done now. It may be that ethnographic methods are better at answering the negative ie 'what should not be done'. Various approaches have been developed to address this issue.<sup>49</sup>

When considering which techniques to employ in a project, it should be noted that there is no single best technique, nor are they mutually exclusive; rather, they are likely to deliver the greatest benefit when used in combination. What there is rather less agreement on, however, is which of these techniques for user involvement are necessary or sufficient for a given project and how this user involvement should be scheduled and managed. For project management, for example, the concern is typically to achieve a balance: ensuring, on the one hand, that user input is adequate for the purposes of establishing and (tracking, possibly changing) user requirements while, on the other, preventing the project being thrown completely of schedule by a seemingly never ending series of demands for changes. The study by Martin et al.<sup>48</sup> provides a detailed account of project management issues in the context of an electronic health record project and why ensuring systematic and effective user participation is challenging. They note, for example, that not only the concerns of the project team that user participation may become unmanageable but—and this is the other side of the coin—the difficulties of securing the commitment of users to give their time on the project. The inevitable result is that what is achievable in terms of user participation 'in the wild' is almost always less than what the HFE guidelines call for.

Within any team, it is of paramount importance that there is a shared understanding of objectives and of the emerging design that is to be created and sustained. This in turn depends upon the achievement of appropriate social conditions within the design team, in particular trust and partnership. The

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context within which these are achieved is the design meeting. We will consider the purposes of design meetings and the roles the HF expert needs to play to make them successful. Underlying this are more general issues concerning the processes that go on within small groups, the study of which is the domain of social psychology and sociology; design is a social (as well as a cognitive) process.

The nature of HF design problems means that HFE practitioners may often be expected to contribute in ways which lie beyond the provision of domain expertise. The composition of HF design teams is such that some members may have little or no design experience. One of the most important roles for the HF expert, therefore, is that of group facilitator. Facilitation involves the observation of events and, by using a variety of mechanisms, intervening so as to foster the goals of the design team.

Prototyping is a way of providing empirical verification of requirements and specification.<sup>20</sup> The user interface (or, indeed, the system's requirements) evolves through trial and error, as a collaborative effort between users and designers. Prototyping techniques vary from creating static paper sketches, snapshots and dynamic mock-ups (facades) to implementations of designs with simulated (Wizard of Oz techniques) or real functionality (variants include rapid, incremental and evolutionary). The former are useful in the early stages of the process, where they help to maintain the focus of the discussion and make the issues concrete. As representations of ideas and decisions, they serve as documentation (though capturing decisions and not the reasoning behind them) and provide concrete evidence that users' views are being taken seriously. This is an important resource for maintaining users' continuing commitment to the project.

#### **12.3.6 SOFTWARE ENGINEERING AND HUMAN FACTORS**

The meeting of usability requirements poses new problems which HFE has devised its own set of techniques for requirements investigation, evaluation etc., to meet. These collectively emphasise the need for user involvement and iteration which traditional software engineering (SE) methodologies have struggled to handle. Over time, however, SE has attempted to adapt its approach so as to repair these weaknesses and to enable project management to accommodate the HFE agenda.

The feature common to all of these refinements of SE methodology is the iteration of requirements through cycles of prototyping and evaluation. Prototyping followed by evaluation allows issues to be highlighted early on in the



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development, and can help with the assessment of usability and functionality.<sup>20</sup> Rapid prototyping can involve a number of cycles of designing and testing and highlight areas where change is necessary. In principle, the end result is reached when the system is acceptable to the users and the functionality is satisfactory and the system is usable.<sup>50</sup>

Unfortunately, while the principle may seem straightforward, in practice, the results of integrating HFE within SE are often unsatisfactory and the resolution of this problem remains a major challenge. The former views system design and development as being inherently an experimental, error correcting process based upon prototyping and evaluation and typically draws upon a wider circle of expertise than conventional SE. These often bring quite different perspectives to the problem that may sit uncomfortably with the preconceptions and concerns of software engineers and project managers. Technical experts still tend to undervalue the potential contribution of users. As studies such as that by Martin et al.<sup>44</sup> have shown, design changes proposed late in the development cycle are likely to meet resistance for reasons that are entirely understandable from the perspective of project management: they may require members of the team to revise work they have already completed and documentation, quality control and performance analysis procedures, etc may need revision; all of which may jeopardise the completion of the project on time and on budget.

It is critical that we continue to explore ways in which the discipline of SE project management might be made to be compatible with the needs of healthcare projects, especially in relation to those, such as the NHS CRS, that are large in scale. Eason,<sup>51</sup> for example, has argued for following a phased implementation approach, using pilots and building on what is already in place (rather than a “big-bang” strategy of total replacement), in order to afford a local, ‘socio-technical’ development approach.

## **12.4 CONCLUSIONS**

Human factors considerations are of central importance to the achievement of the goals of NHS CFH and, in particular, to NPfIT. There can be little doubt, for example, that the lack of attention to HF issues hitherto in eHealth applications such as ePrescribing has limited their effectiveness and adoption and, quite possibly, posed a risk to patient safety.

In this chapter, while noting the breadth of HF issues for IT design, we have focused on user involvement in design and development and on the evaluation of eHealth applications. Regarding the former, the argument that effective involvement of clinicians in design and development is imperative to ensure



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that applications are fit for purpose is irrefutable. At the same time, it is clear that major problems remain if the HFE agenda is to be integrated effectively within SE practice and these need to be tackled. In many ways, the question of how eHealth applications should be evaluated exemplifies the problems. Patient safety demands that evaluation techniques be driven by clinical agendas and are capable of providing results which are meaningful in practice. It seems inconceivable that this can be achieved without close and effective user involvement throughout the design and development process, which, of course, is the very problem which SE is struggling to solve.

As, following the pattern now evident in other sectors, eHealth applications become steadily more 'organisationally embedded', understanding the organisational context assumes even greater importance for their successful adoption. In the following chapter, we explore the organisation issues surrounding the implementation and adoption of eHealth applications and we then, in chapter 14, seek to draw together these socio-techno-cultural considerations through a detailed case study exploring the timely and important challenge of introducing the NHS CRS into secondary care settings.

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## CHAPTER 13

### Importance of organisational issues in the implementation and adoption of eHealth innovations

#### SUMMARY

- The study of organisational issues as they pertain to eHealth innovations is a multi-disciplinary field utilising bodies of knowledge from organisational psychology, change management and human factors with clinical and information technology expertise.
- There is a general consensus that organisational issues are at the root of problems associated with the implementation and adoption of technological innovation in healthcare.
- While there is at present no overarching framework in relation to the implementation and adoption of eHealth innovations, a number of themes have been found to be important, these include: innovation attributes; end-users' attitudes towards the innovation; end-user capacity and competence; communication and concerns; strategic project management and effective leadership; evaluation and continual quality improvement.
- Assessing readiness for technological innovation and fostering readiness appear to be particularly important in relation to technological innovations in modern day healthcare organisations and systems.
- The empirical evidence-base for approaches to strategise implementation and adoption is at present very limited; this reflects amongst other things, the lack of rigorously conducted prospective studies that allow assessment of effectiveness and processes through which these effects are mediated.
- There is need for further research encompassing design, implementation and adoption considerations in relation to eHealth innovations.

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## 13.1 INTRODUCTION

Healthcare lags in the implementation and adoption of information technology (IT) relative to other industries<sup>1</sup> with its history littered by a history of failed projects. There is a general consensus that organisational issues are as, if not more, important than the technological considerations. Consequently, understanding organisational issues is imperative to strategising the implementation of eHealth innovations and in dealing with the altered organisations that technological innovation often creates as well as understanding the process of implementation and adoption.<sup>2</sup> In this chapter, we begin by discussing what we mean by organisational issues, what bodies of knowledge contribute to their study, and their scope for use. We then discuss the theoretical basis for attending to organisational issues when implementing eHealth innovations, the evidence-base and its limitations followed by themes we have deemed important in implementation to facilitate adoption, and the potential for assessing organisational readiness for technological innovation in healthcare. Finally, based on the above we discuss the implications for practice, policy and research. The case study of human factors considerations in relation to the design, implementation and adoption of electronic health records (EHRs), draws on the themes presented in this and the preceding chapter on design considerations.

## 13.2 DEFINITIONS, DESCRIPTION AND SCOPE FOR USE

The study of organisational issues in eHealth is not a clearly defined field of study, but rather a problem-based approach centring on the interaction between people (from individuals to organisations) and technology. We have found the following bodies of knowledge useful in contributing to the understanding of organisational issues and assert that principles from these fields are important components of any implementation strategy for technological innovation adoption:

- **Organisational psychology:** a subset of psychology is concerned with the application of psychological theories, research methods, and intervention strategies to workplace issues, relevant topics include: personnel psychology; motivation and leadership; employee selection; training and development; organisation development and guided change; organisational behaviour; and work and family issues
- **Change management:** a structured approach to change in individuals, teams, organisations and societies that enables the transition from a current state to a desired future state
- **Human factors:** this is an all-embracing term that covers; the science



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of understanding the properties of human capability (human factors science), the application of this understanding to the design and development of innovations (human factors engineering), and the art of ensuring successful application of human factors engineering to a programme (see Chapter 12).

Additionally, technological innovation in healthcare requires expertise in information technology (IT) and clinical expertise. These bodies of knowledge contribute to the design, development and deployment of eHealth innovations.

The scope for use is increasingly broadening due to a global move to employ eHealth innovations to improve the safety and quality of healthcare as evidence by national eHealth strategies such as that of NHS Connecting for Health (NHS CFH) and its National Programme for Information Technology (NPfIT).

### **13.3 THE CASE FOR ATTENDING TO ORGANISATIONAL ISSUES**

Sensitivity to the importance of organisational issues should aid in designing and developing technological innovations that are adoptable by end-users; (see Chapter 12 and section 13.5.1 for a discussion on successful technological innovation attributes) an implementation strategy that eases the introduction of technological innovation by minimising the degree of disruption arising from change related to technological innovation and put into place mechanisms to deal with the associated adverse effects, ie managing change effectively. Technological innovations are often employed to enable organisational change in healthcare, but the bulk of organisational issues stem from the change brought on by technological innovation. Managing change effectively reduces the potential for failure, this being particularly important in the context of technological innovations in healthcare that are not fit-for-purpose or highly disruptive implementations that result in clinician resistance and even abandonment with the potential for financial ruin or even risks to patient safety, as in the case of the failure of the London Ambulance Services' computer aided dispatch system.<sup>3</sup>

### **13.4 EVIDENCE-BASE AND ITS LIMITATIONS**

To-date, much of the available literature concerning organisational issues in relation to eHealth innovations is qualitative and retrospective in nature stemming from one organisations experience with the implementation of one eHealth application. There are many such anecdotes and markedly less rigorously studies with more generalisable findings. However, a few systematic reviews<sup>1;4-7</sup> have been conducted, mainly on the barriers and facilitators to

implementation and adoption of eHealth innovations and best-practices for implementation.<sup>8;9</sup> These higher level reviews and overviews are invariably based on those qualitative and retrospective primary analyses and their utility has not been prospectively tested. Similarly, important considerations for strategising implementation have in the contexts of these evaluations largely been established by expert opinion or consensus building.

#### 13.4.1 DIFFUSION OF INNOVATIONS THEORY

Some of the literature builds on Rogers' seminal theory on the *Diffusion of Innovations*, a simple descriptive model that explains the process of innovation diffusion.<sup>10</sup> In sum, Rogers discusses major elements (Box 13.1) that constitute the process, namely:<sup>10</sup>

##### Box 13.1 Major elements of Rogers' theory of Diffusion of Innovations

- Five attributes of innovation noted as facilitating adoption:
  - ❑ relative advantage
  - ❑ compatibility
  - ❑ low complexity
  - ❑ observability
  - ❑ trialability
- Adopters and their respective characteristics or traits:
  - ❑ innovators
  - ❑ early adopters
  - ❑ early and late majority
  - ❑ laggards
- Communication channels
- Innovation-decision process:
  - ❑ from first knowledge of innovation
  - ❑ to forming an attitude toward the innovation
  - ❑ to a decision to adopt or reject which encompasses the adoption process and its stages of: awareness, interest, evaluation, trial and adoption
  - ❑ to implementation of the innovation
  - ❑ to confirmation of this decision

*Adapted from Rogers (2003)<sup>10</sup> Reprinted with permission from the American Medical Informatics Association.*

However, the theory is actually most applicable to innovations that spread from individual without planned dissemination, which is not typically how eHealth innovations now "diffuse"; rather healthcare organisations tend to follow a more strategic approach to implementation of technological innovation using strategy and this is particularly true in relation to the NPfIT products and services.<sup>10</sup> The general nature of the theory lends itself well to use and although the use of Rogers' *Diffusion of Innovation* theory is widespread, it is not without

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its criticisms, these including its lack of predictive power,<sup>11</sup> oversimplification of an otherwise highly complex process as is made evident by the theory's focus on the individual,<sup>12</sup> the lack of focus on the organisation,<sup>11</sup> and the lack of acknowledgement of other often less easily described and categorised forces affecting adoption.<sup>13</sup>

Whilst the theory's simple and generic nature arguably underpins its predilection for use this breadth comes at the expense of depth. In light of these and other caveats, researchers employing Rogers' theory, tend to expand and amend it as required. Ash points out, '... innovation diffusion has been measured in so many different ways that Fichman has recently proposed a typology into which previously used measures seem to fit.'<sup>14</sup> These are: time of adoption, dichotomous adoption (has it been adopted or not?), aggregated adoption (how many on a list have been adopted?), extent of diffusion, level of infusion, and stage of assimilation (which stage of diffusion was reached at a particular time?).<sup>14</sup> The first three are more traditional measures, while the last three are newer, richer, and better suited to information technology studies.<sup>15</sup> Ash goes on to write that:<sup>15</sup>

'Extent of diffusion differs from the classic definition of diffusion because it measures diffusion within an organization, the extent to which use spreads across the people in an organization. It is especially useful when implementation occurs gradually on a person-by-person basis. It can be considered a breadth measure.

Infusion looks at comprehensiveness or sophistication of use of an innovation. It has been defined as the '... extent to which the full potential of the innovation has been embedded within an organization's operational or managerial work systems. It is the one measure of depth related to diffusion.'<sup>16</sup>

Ash clearly points out the need to contextualise and develop Rogers' theory to make it applicable to technological innovation in healthcare, especially fundamental innovations like clinical information systems where complete diffusion and infusion are the objectives.

#### **13.4.2 THEORY OF DIFFUSION OF INNOVATIONS IN HEALTH SERVICE ORGANISATIONS**

The systematic review on *Diffusion of Innovations in Health Service Organisations* delivery by Greenhalgh et al. is one such example of work drawing on Rogers' theory, but which goes far beyond this original work, providing both breadth and depth. A copious number of attribute contributing to facilitated implementation and improved adoption are detailed and categorised under the following headings.<sup>11</sup>

- 
- innovation attributes
  - individual adoption process
  - communication and influence
  - inner (intra-organisational) context
  - outer (extra-organisational) context
  - nature of any active dissemination campaign
  - nature of any active implementation process.

This work is, however, also not without its own limitations as it is somewhat cumbersome which is unsurprising as the authors note that whilst the literature was ‘. . . rich in potentially useful information’ it nonetheless appeared ‘. . . chaotic, contradictory, and lacking a unifying theoretical framework.’<sup>11</sup>

Regardless of the handicap implied by the authors, this work is arguably the most thoughtful and comprehensive of its kind and is as such a natural platform to build upon. We consider a selection of particularly relevant findings from this important systematic review of a broad body of literature that we believe have the potential to be strategised and operationalised in relation to technological innovations and that are supported by expert opinion in the field.

Despite the strength of this work, the lack of prospective empirical evaluation of this theoretical framework remains a major limitation. Some, however, consider this to be something of a holy grail, noting that although there are a number of themes that are individually important and in some cases necessary for successful implementation, they are in themselves insufficient to ensure success. Berg argues that due to the fundamental unpredictability of complex systems, it is not possible to define a set list of success and or failure factors and that even defining the very notion of success is in itself problematic:<sup>17</sup>

‘Different organizations, with different sizes, different leadership styles, different cultures, different financial situations, and different environments, may and will react very differently to a similar technological innovation, or to a similar implementation strategy.’

However,

‘This is not to say that we cannot outline certain insights that seem to be a *sine qua non* to the realisation of successful systems, however, defined. Yet any such discussion runs the risk of reducing what can only be fine-grained discussion of individual cases to bland, almost empty slogans such as “the importance of leadership” or “the involvement of users”. It is not that leadership is not important, but just how a specific leadership style in any given situation works out cannot be predefined. Likewise, involving users is essential, but there is no recipe for this

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that will work in any given case. More often than not, the proper leadership style for a specific implementation process, or the optimal way to involve users, can only be discovered during the process itself.'

### **13.5 FINDINGS ON STRATEGISING IMPLEMENTATION FOR EFFECTIVE MANAGEMENT OF CHANGE**

Berg argues that a whole systems approach should take precedence over the futile attempt to isolate individual contributors to either success or failure.<sup>17</sup> Building on Berg's notion of a whole systems approach Greenhalgh et al. indicate that the success of an implementation initiative depends on a number of inter-related and inter-dependent themes<sup>11</sup> most of which seem to be supported by expert opinion and follow closely the considerations and principles for successful implementation of clinical information systems, arguably the most difficult as they tend to be the most disruptive.<sup>18-20</sup> We divide this section into the themes identified from the available evidence:

- technological innovation attributes
- end-user attitude towards technological innovation
- capacity and competence
- communication and concerns
- strategic project management and effective leadership
- evaluation and continual quality improvement.

Many of these themes are inter-related and inter-dependent and on the whole can be characterised as effective management of change using human factors and organisational psychology principles.

For the sake of clarity and brevity, two key constructs will be employed in this and the following chapter: implementation and adoption. For the purposes of this report (and somewhat differently to the definitions used by some other authors), implementation encompasses the planned introduction of technological innovations, whereas adoption is construed as the acceptance of technological innovation into everyday practice regardless of the degree of infusion. This limitation is due to lack of distinction within evidence-base this report builds on, for instance Greenhalgh et al. use Roger's definition of adoption as '... the decision to make full use of the innovation as the best course of action available.'<sup>11</sup>

#### **13.5.1 TECHNOLOGICAL INNOVATION ATTRIBUTES**

The success of technological innovations is partly dependent on a number of traits that have been empirically demonstrated to facilitate adoption. Greenhalgh

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et al. argue that the five attributes previously described by Rogers as facilitating the adoption of innovations (relative advantage, compatibility, low complexity, observability, and trialability) are probably necessary, but not sufficient to explain the adoption of complex service innovations, which eHealth innovations and in particular clinical information systems can be thought of as.<sup>11</sup> The authors propose that a sixth attribute, potential for re-invention, may be particularly critical in the organisational setting, and further propose additional operational attributes such as the innovation's relevance to a particular task, the complexity of its implementation in a particular organisational context and the nature of the knowledge (tacit and or explicit) required to use it.<sup>11</sup> The rudimentary notion that innovations have '... fixed boundaries and measurable attributes that are independent of context has largely been superseded in the organisational literature by notions of congruence (suitability, appropriateness), fit (with existing values, norms, strategies, goals, skill mix, supporting technologies and ways of working of the organisation), adaptation (re-invention) and contingency (dependence)', conclude the authors.<sup>11</sup>

These factors as previously mentioned are, however, related to innovations in general and not specific to technological innovation. In conducting a systematic review of interventions to improve adoption of IT by healthcare professionals, a number of additional technology specific attributes have been identified by Gagnon et al. that supplement the above attributes:<sup>4</sup>

- reliability
- interoperability
- security, ie confidentiality and legal issues
- scientific quality of the information resources.

Systematic reviews have studied design features of eHealth innovations, in particular computerised decision support systems (CDSSs) and electronic order entry innovations, which result in success.<sup>21–27</sup> Some of the systematic reviews have included only controlled trials of eHealth innovations in an attempt to enhance methodological rigour. However, we feel this approach is misguided for determining successful attributes for a variety of reasons including the lack of reporting of both organisational context and technical specification in evaluations of innovations as well as the potential for 'measuring the measurable' bias.<sup>11</sup> Nonetheless, the findings of these reviews serve to highlight some of the aforementioned attributes outlined by Rogers, Greenhalgh et al. and Gagnon et al.

For instance, Holbrook et al. systematically reviewed the literature to determine attributes for CDSSs' success.<sup>22</sup> Only two trials were found to be successful



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and these addresses only relatively simple interventions (low complexity and the knowledge required to use it). One of the two trials specifically measured predictors of success of the CDSS and found that unidentified clinician characteristics and the patient's degree of clinical need for the intervention (relevance to a particular task, contingency or perceived usefulness) were the main predictors of success.<sup>22</sup>

This discussion on attributes is by no means exhaustive and we direct readers to see Chapter 12 for a discussion on human factors and eHealth innovations with regards to optimal application design.

### **13.5.2 END-USER ATTITUDE TOWARDS TECHNOLOGICAL INNOVATION**

End-users attitude towards the technological innovation is just as important. For instance, Gagnon et al. found that following to be relevant:<sup>4</sup>

- agreement with the IT:
  - cost beneficial
  - confidence in IT developer
  - challenge to autonomy
  - practical
  - clinical uncertainty
  - time consuming
- agreement with IT in general
- outcome expectancy (use leads or does not leads to desired outcome)
- self-efficacy (ie one believes one has the competence to use the IT)
- motivation to use the IT and inertia of previous practice
- perceived usefulness
- perceived ease of use.

The ease with which technological innovations integrate into existing workflows, is critical to its success. End users resent disruption of their patient care activities<sup>18</sup> and will strongly resist stopping according to Bates.<sup>28</sup> The degree of disruption encountered could lead to failure to adopt the innovation and abandonment of the implementation. Thus, implementers should carefully consider how the implementation of the innovation will impact workflow and communication amongst staff and monitor closely the impact during implementation and afterwards.<sup>18;29</sup>

Implementation of eHealth innovations is frequently performed without proper consultation with clinicians and understanding of their work practices and workflows according to Rigby.<sup>30</sup> Rigby cautions that introducing or changing existing eHealth technologies and systems without recognising the '... radical

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personal and organisational re-engineering involved, however well intentioned, is seriously ill advised and is in no way akin to rolling out e-working in other industries.<sup>30</sup>

As we argued in Chapter 12, design, development and deployment of technological innovations as well as implementation strategy is thus best-served by end-users involvement from the outset as this should serve to foster a sense of ownership of the technological innovation and improve the usability and fitness-for-purpose, all of which improve the adoptability of eHealth innovations.<sup>2</sup> Ash et al. write that a plan for involving end users must be developed prior to implementation, followed throughout but allowed to evolve.<sup>18</sup> However, Brender notes that fulfilling this need is somewhat paradoxical as a number of system development approaches assume that the end-users are able to specify their requirements, make explicit how they (really) accomplish their work, and use formal specification techniques with confidence which Brender says they are for the most part, unable to do.<sup>31</sup>

### **13.5.3 CAPACITY AND COMPETENCE**

End-users must be capable and competent. Competency in part arises from application specific training and education. According to Greenhalgh et al. appropriate training enhances the chance of effective implementation and of assimilation of innovation into everyday-practice. Aside from training end-users prior to implementation, Ash et al. note a constant theme identified by experts in their consensus building work is the importance of live help available ‘at the elbow’ during implementation to trouble-shoot.<sup>18;19</sup>

Ash et al. note that ‘. . . most successful implementations have had more post-go-live support than pre-go-live training. Most sites have had round the clock support for at least several days post go-live.’ They authors outline the following questions to be considered:<sup>18;19</sup>

- Is there a training plan for support staff?
- Do support staff able to act as translators between clinicians and information technology staff?
- Have provisions been made for online help as well as direct assistance by support staff?
- Will users train and mentor other users (and with what methods)?

Aside from providing application specific training, and support at the elbow, the provision of more generic education and training in IT would address the current skills gap in the health sector work force and should serve to increase the degree of “computer literacy” and maximise envisaged benefits from

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current technological innovation whilst facilitating future implementations of technological innovation.

Ash et al. write of other individuals essential to the process of implementation, the ‘... talented people who speak the languages of both medicine and technology. These are the staff members who can train and support end users.’<sup>18;19</sup>

Health informaticists could largely fill the roles (and should) in this group of essential people and indeed the development of the profession; their expertise, solidarity and place in healthcare service delivery is thought to be an integral move in establishing long-term viability of eHealth innovations. Pagliari advises for greater involvement in the design and development of innovations by health informaticists who by the very nature of their expertise should engender innovations more fit-for-purpose, which would in turn lead to easier integration into everyday practice.<sup>32</sup>

#### **13.5.4 COMMUNICATION AND CONCERNS**

Simply put, Ash et al. note that employees (ie clinicians in the context of eHealth innovations) must be kept informed, engaged, and content through planning and communication.<sup>18</sup>

Communication is key to a successful implementation Greenhalgh et al. found evidence that ‘... adoption of an innovation is more likely if adequate feedback is provided to the intended adopter on the consequences of the innovation.’<sup>11</sup> Keeping end-users well informed can favourably influence their perceptions of the technological innovations ease of use, utility, expected outcomes associated with use, self-efficacy and serve to motivate end-users. This, as Finkelstein observes, was a key failing in the London Ambulance Service’s computer-aided dispatch system project.<sup>3</sup>

Alleviating concerns in end-users is an important project management skill in any organisation change programme and keeps end-users content. Greenhalgh et al. found strong evidence that addressing concerns prior to and during the implementation process facilitates adoption, specifically: end-users should be aware of the innovation; have sufficient information about what it does and how to use it; and be clear as to how the innovation would affect them personally, for example, in terms of costs, continuing access to information about what the innovation does, and to sufficient training and support on task issues or in other words, about fitting the innovation in with everyday-practice.<sup>11</sup> As Rigby states ‘... whilst policy may be developed for sound reasons, it is not the policy-makers who have to make it work but rather the operational staff of the healthcare sector.’<sup>30</sup>

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### 13.5.5 STRATEGIC PROJECT MANAGEMENT AND EFFECTIVE LEADERSHIP

Careful project management is necessary in organisational change programmes especially those that are executed through technological innovation; implementation of technological innovation should be completed in carefully planned stages and generic project management skills are necessary such as those delineated by Ash et al.<sup>18</sup>

Lorenzi and Riley suggest assessing organisational climate and analysis of previous technological innovation implementations should be conducted.<sup>33</sup> The authors caution that the inability to conduct these activities is indicative of an underdeveloped set of ‘organizational antennae’ and this circumstance would perhaps benefit from expert outside support to assist in these organisational analyses such as that provided by external change agents or agency.<sup>33</sup>

Consideration of the integration of the hardware and software within the existing technological infrastructure such as other clinical information systems is also necessary. Lack of interoperability has proven to be an impediment to implementation of eHealth innovations and might pose risks to patient safety, and hence is a potential deterrent to adoption by risk-averse clinicians (see Chapter 5).

The disruptive nature of technological innovation necessitates an organisation-wide change management strategy and, equally, contingency plans must be devised to deal with disruptions caused by system downtime.<sup>18</sup>

Defining scope and establishing clear, reasonable and measurable goals are integral to establishing progress through monitoring.<sup>18</sup> A salient point raised by Lorenzi et al. is that an organisation needs to ‘. . . continue to manage the expectations of both the organizational leaders and the end users as an important component of success.’<sup>2</sup>

Ash et al. argue that ‘. . . early milestones must be selected to produce “wins” that help maintain momentum toward more difficult long-term objectives’, but caution, however, against overplanning.<sup>18</sup> Similarly, the authors argue that metrics for success should be determined beforehand and evaluated over time, and that accountability for objectives, large and small, must be established and maintained.<sup>18</sup>

The use of consultants or change agents requires careful consideration, their roles must be delineated and specific objectives defined.<sup>18</sup> When selecting change agents Greenhalgh et al. note that those employed by external agencies will be more effective if they are: selected for their similarity and credibility with the end-users of the innovation; trained and supported to develop strong interpersonal relationships with end-users and to explore and empathise with

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end-users' perspectives; encouraged to communicate end-users' needs and perspective to the developers of the innovation; and able to empower end-users to make independent evaluative decisions about the innovation.<sup>11</sup>

Likewise, prior to implementation, the organisation should identify implementation leaders, solicit involvement from key people, perhaps opinion leaders (peer and or expert) or champions, and plan for human resource needs.<sup>11;18</sup>

Greenhalgh et al. note that '... interpersonal influence is the dominant mechanism for promoting the adoption of innovations, and certain individuals have particular influence on the beliefs and actions of their colleagues.'<sup>11</sup> The authors differentiate between expert opinion leaders who influence through their authority and status versus peer opinion leaders who influence by virtue of representativeness and credibility.<sup>11</sup>

The authors further note that whilst opinion leaders have a following they may or may not support an innovation, and that individuals who dedicate themselves to supporting, marketing, and 'driving through' an innovation are collectively known as champions.<sup>11</sup>

Individuals' capacity to influence, perhaps even heavily, the process of adoption of eHealth innovations has been mentioned often elsewhere within the literature. For instance, a systematic review of CDSs postulated that an underlying reason that innovations evaluated by individuals who were also involved in the design and development were more successful than those evaluated independently was due to the effect of champions.<sup>21</sup> Unfortunately, Greenhalgh et al. note that: '... there is remarkably little direct empirical evidence on how to identify and systematically harness the energy of champions.'<sup>11</sup>

Human resources must be considered and needs must be planned for. During implementation, the organisation should hire and deploy staff where and when most needed, prioritise organisational issues by maintaining staff morale, and use communication, publicity, and personnel management skills effectively to maintain project momentum.<sup>11;18</sup>

Post-implementation, the organisation should establish maintenance routines, create an environment for ongoing application improvement, and provide management systems for the long-term.<sup>18</sup>

Effective leadership is needed at the '... executive level to promote a shared vision and provide funding at the clinical level to ensure buy-in and should commit unwaveringly and visibly. At the project management level, leadership is necessary to make practical, effective, and useful decisions.'<sup>18</sup>

A shared vision exists in the organisation regarding the purpose of the

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innovation, eg to improve patient care, as well as a common understanding of why the current state is suboptimal and change is needed. Leaders should have a realistic overall understanding exists of the efforts required to implement coupled with the ability to communicate the vision.

Ash et al. argue that administrative and clinical leaders, preferably at the highest levels of organisation, are essential to implementation with opinion leaders and champions also critical to the process.<sup>19;34</sup> They detail a multitude of behaviours these various ‘special people’ exhibit at various levels of authority are provide an provide outline of important skills that these people should embody.<sup>34</sup> However, the authors report that preparation for leadership roles is currently inadequate.<sup>34</sup> Specifically, administrative leaders lack clinical knowledge, as well as technological expertise. Clinical leaders often lack administrative know-how or technological expertise and so forth.<sup>34</sup>

### 13.5.5 EVALUATION

One activity that is integral to effective management of change is evaluation. Rather unsurprisingly, the capacity to evaluate the consequences of implementation was found by Greenhalgh et al. to facilitate adoption through feeding back into system modification and implementation re-strategising. As stressed in Chapter 12, formative evaluation is crucial to designing and developing technological innovations that are usable. Evaluation should be used prior to implementation to assess readiness for technological innovation (see section 13.6) by unearthing concerns amongst end-users about what to expect or deficiencies in competence and capacity. Pilot evaluation is necessary to assess the technological innovation’s fitness-for-purpose. Evaluation throughout implementation serves to assess end-users’ attitudes towards the technological innovation to inform re-design of the technological innovation or the implementation strategy itself. Greenhalgh et al. assert that throughout implementation measures must be in place to capture and respond to the different consequences of the innovation, specifically those that are:<sup>11</sup>

- intended and predicted, beneficial and detrimental
- unintended and predicted, beneficial and detrimental
- unintended and unpredicted, beneficial and detrimental.

Evaluation of both beneficial and detrimental consequences is necessary as the former can be exploited to boost morale whilst the latter are critical to adoption by informing modification of the technological innovation and implementation as well as ensuring the safety and quality of healthcare is not risked.<sup>35</sup> A rise in the number of evaluative publications assessing negative consequences arising



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from the implementation of eHealth applications demonstrates an increased awareness of the potential risks imposed by the introduction of technological innovations in healthcare.<sup>36–41</sup>

Evaluation post-implementation should be conducted to improve existing innovations and aid in the design and development of new innovations. Wyatt writes that ‘. . . even if a application is effective when installed, it may rapidly lose its edge as the health system around it changes, making repeated evaluation necessary, to take account of the changing healthcare context.’<sup>42</sup>

Finally, as the practice of healthcare is increasingly evidence-based, establishing evidence through evaluation is integral to furthering the science of implementation and adoption of technological innovation in healthcare.

There are a number of barriers to evaluation and the development of loci where evaluation can proceed unhindered by constraints should also provide a means to improve implementation and adoption of technological innovations. Soar and Ayres describe the establishment of a trial and demonstration facility for new products, technologies, methods and procedures in an acute-care hospital ward noting that a project like their Model Ward can promote innovation as part of the corporate culture.<sup>43</sup> In fact, Greenhalgh et al. report that ‘. . . there is some empirical evidence (and there are also robust theoretical arguments) for building strong links between different parts of the system’, for example:<sup>11</sup>

‘If the innovation is formally developed (for example, in a research centre), it is more likely to be widely and successfully adopted if the developers or their agents are linked with potential users at the development stage in order to capture and incorporate the user perspective (moderate indirect evidence). Such linkage should aim not merely for “specification” but for a shared and organic (developing, adaptive) understanding of the meaning and value of the innovation-in-use, and should also work towards shared language for describing the innovation and its impact.’

Chaudhry et al. exemplify this finding with one of their own, based on a systematic review of eHealth applications, which concluded that one quarter of the studies included in their review came from one of only four academic centres of excellence.<sup>44</sup> For the most part, these are the organisations demonstrating a beneficial impact on the safety and quality of healthcare, where their technologies and systems have been developed in-house and extensively evaluated over long periods of time.<sup>44</sup>

One of the most important motivations for evaluation should be the use of findings for continual quality improvement. Implementation is an ongoing effort

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and as such it is important that mechanisms for feedback and modification of the technological innovation and the implementation be in place.<sup>18;19</sup>

Unsurprisingly, Greenhalgh et al. found strong evidence from health service organisations that ‘... rapid, tight feedback enhances the organisation’s ability to respond to the impact of the consequences arising from the introduction of innovation.’<sup>11</sup> This undoubtedly serves to tackle problems as they arise in a timely manner improving the likelihood of a successful implementation.

Ash et al. note that the importance of an organisational culture, or creation, that values constructive feedback, changes made for quality improvement, and continuous learning—kept in balance by leadership that can tell the difference between clinicians’ requests for ‘what would be nice’ versus ‘what is essential or critical for success’.<sup>18;19</sup>

### **13.6 RECEPTIVE CONTEXT FOR TECHNOLOGICAL INNOVATION IN HEALTHCARE**

As healthcare becomes increasingly technologically dependent, many of the aforementioned themes that facilitate implementation and adoption of eHealth innovations can be targeted to cultivate a receptive context for technological innovation in general. Subsequently, some of the findings on the intra-organisational context by Greenhalgh et al. are perhaps the most relevant to today’s healthcare organisations. Greenhalgh et al. note that:<sup>11</sup>

‘Different organisations provide widely differing contexts for innovations and a number of features of organisations (both structural and cultural) have been shown to influence the likelihood that an innovation will be successfully assimilated.’

Unfortunately:

‘... little empirical evidence exists to support the efficacy of interventions to change organisational structure towards these preferred characteristics, except that establishing semi-autonomous multi-disciplinary project teams is independently associated with successful implementation of an innovation.’

Whilst altering an organisation’s structure to encourage receptiveness does not seem to be a worthwhile endeavour or even feasible, changing an organisation’s *modus operandi*, culture and objectives is more likely the way forward. For instance, Greenhalgh et al. note that:<sup>11</sup>

‘An organisation that has the general features associated with receptivity to change will be better able to assimilate innovations. These features include strong leadership, clear strategic vision, good managerial relations, visionary staff in key

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positions, a climate conducive to experimentation and risk-taking, and effective monitoring and feedback systems that are able to capture and process high-quality data.’

The various concepts of organisational change and innovation, innovativeness and readiness for innovation and change have subtle differences in meaning which are not well delineated within the literature and are often used synonymously.<sup>45</sup> Greenhalgh et al. define organisational innovation as ‘. . . the implementation of an internally generated or a borrowed idea—whether pertaining to a product, device, system, process, policy, program or service—that was new to the organisation at that time.’ According to Snyder-Halpern, organisational readiness for innovation has been characterised as the level of fit between new technological innovation and the organisation.<sup>46</sup>

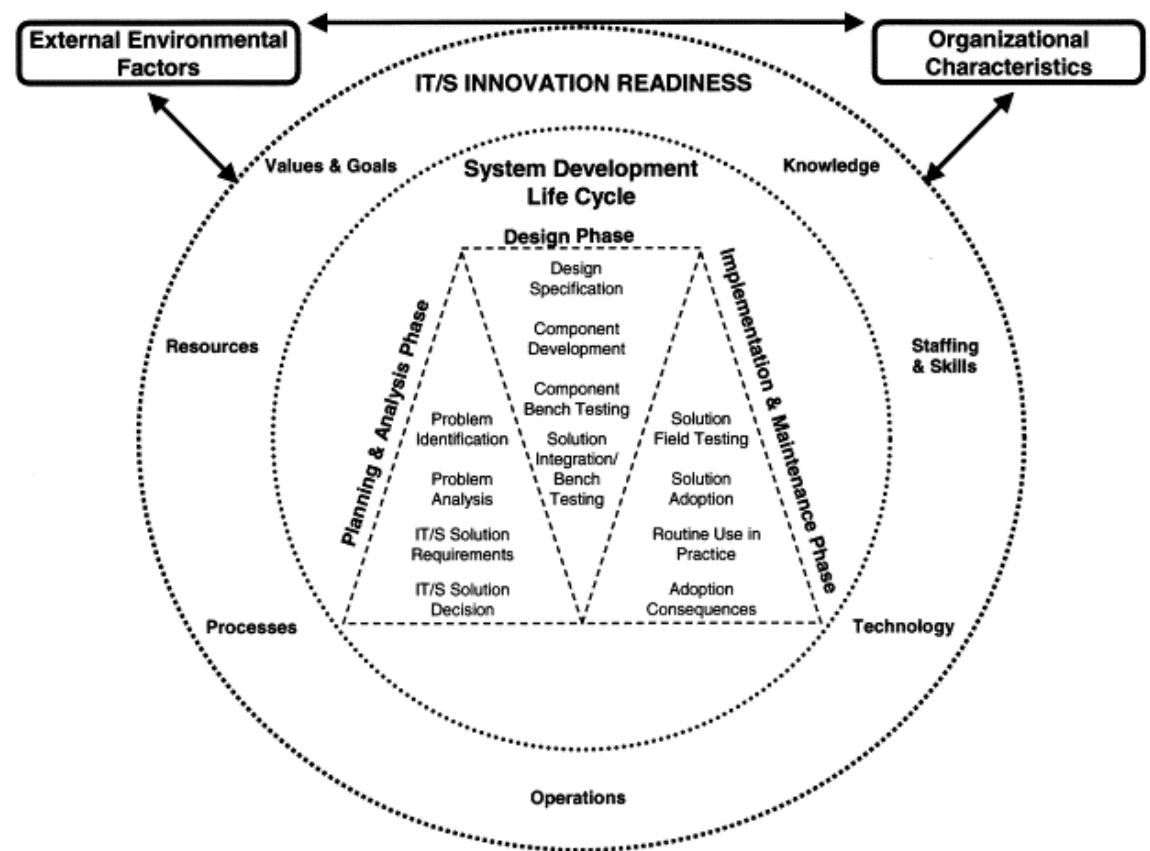
Since there is sufficient evidence that a receptive context facilitates adoption of innovations,<sup>11</sup> the assessment of readiness for technological innovation has rightly received recognition in the field of eHealth as a potentially highly useful activity to be conducted prior to implementing an eHealth application.

Snyder-Halpern argues that a higher level of readiness leads to a lower level of technological innovation risk and a more successful technological innovation outcome. She further speculates that a lack of information about a healthcare organisation’s readiness for new technological innovations increases uncertainty for decision makers and decreases their ability to mitigate technological innovation risks. The key point is that although ‘. . . this literature highlights the importance of organisational readiness for successful technological innovation, it does not clearly identify what indicators must be evaluated to determine the level of organisational readiness.’<sup>46</sup>

A multi-phased research project led by Snyder-Halpern attempted to do just that—develop indicators of readiness for evaluation with a particular emphasis on clinical information systems. Phase one began with an extensive literature review where Snyder-Halpern identified seven hypothetical sub-dimensions for innovation readiness: resources; staffing & skills; technology; knowledge; processes; values & goals; and operations.<sup>46</sup> From these sub-dimensions, the Organisation Information Technology/System Innovation Model (OITIM) was developed (see Figure 13.1).

Phase two consisted of an exploratory two-round Delphi study with national eHealth experts recruited from amongst the members of the Healthcare Information and Management Systems Society (HIMSS). The study aimed to identify and validate the aforementioned OITIM innovation readiness sub-dimensions and their assessment indicators.<sup>46</sup>

**Figure 13.1: Organisation Information Technology/System Innovation Model (OITIM)**



Source: Snyder-Halpern (2001)<sup>50</sup>

The OITIM is based on four assumptions:<sup>46</sup>

- technological innovations function as healthcare organisation interventions
- increased technological innovation readiness leads to lower innovation risk and increased innovation success
- external environmental factors and organisational characteristics interact to influence the level of technological innovation readiness and the innovation development life cycle
- tightly linked innovation development life cycle sub-dimensions enhance technological innovation readiness.'

Phase three was focused on further development<sup>47</sup> and phase four saw the model applied prospectively with the author concluding that the findings supported

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the use of the OITIRS to assess hospital readiness for computer provider order entry system innovation.<sup>48</sup>

Whilst this is not the first programme of research conducted on readiness for innovation, it is one of the very few tools to be developed with an emphasis on technological innovations to be used for clinical care such as clinical information systems. The value of this type of research will only be truly demonstrated when applied prospectively and independently however.

After assessing readiness for innovation, a next step would be the enhancement of any detected deficiencies in order to improve innovation readiness and implementation outcomes. This is, however, confined to theoretical deliberations at present; how practically to do so has yet to be empirically demonstrated.

Until all or even one facet of innovativeness can be fostered, a way forward might be the identification of particular units of an organisation that might be more amenable to innovation. Implementing technological innovations in these areas or units could provide the atmosphere to encourage early successes bolstering organisation-wide implementation and adoption.

The Vanderbilt University Medical Center in the US provides an example of such targeted efforts. When the Centre began an intensive electronic health record effort, a process was carefully designed to select the clinical areas where new tools could be developed and pilot tested.<sup>49</sup> The Success Factor Profile was created to guide the selection of sites most likely to have innovation success, early results demonstrated that the tools provided structure for the decision-making process, making side-by-side comparison of clinical areas or units once incomparable more amenable.<sup>49</sup> The authors posit that selecting the site most likely to succeed with application innovation and early implementation has broad applicability in eHealth as failure to succeed with early application users is not only costly but also discourages users and developers alike, and may damage the reputation of the innovations across the institution.<sup>49</sup>

A report on managing change in the NHS noted that ‘... the modernisation agenda for the NHS requires a high degree of innovation in the models of healthcare delivery. The factors that lead to the successful development of these models and the rate of their adoption also need to be explored. For example, the characteristics of an innovation that have been found to influence the success and rate of adoption are as much to do with the perceptions of the players as they are inherent in the innovation itself.’<sup>50</sup>

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## 13.7 IMPLICATIONS FOR PRACTICE, POLICY AND RESEARCH

Despite the above body of work, it is clear, as Lorenzi et al. note, organisational issues have not received their dues and they identify a number of reasons why these might be initially discounted.<sup>33</sup> Organisational issues are experienced subjectively and in different ways by different actors. As result, they are difficult to measure objectively, difficult to predict and are time consuming to plan for. As a consequence, technical staff often respond by downplaying the importance of organisational issues or by refusing to take responsibility for them. A further factor is that dealing with organisational issues is often viewed as delaying the "real work".

Nonetheless, organisational issues are coming to the forefront of the eHealth agenda due to a general consensus within the field that technological innovation is not designed, developed nor deployed in a vacuum. The importance of organisational issues has important implications for practice, policy and research.

Findings from the study of organisational issues have yet to be prospectively applied with any rigour. An ideal place to start with would be a model specific to eHealth to test empirically (see Chapter 14). With enough empirical testing and refining, development of best-practice guidelines for implementation is possible; for example, guidelines for involving users during the design and implementation of large scale systems. In contrast to the points made by Lorenzi et al. on the unpredictability of innovations making strategies for success to difficult to pin-down, Braude note that '... predictability comes from research. When a sufficient body of research in a field is available, it becomes possible to predict outcomes based on prior experiences. Research into people and organisational issues surrounding implementation of innovations is equally scattered throughout the literature of different disciplines with the amount of research is still relatively small.'<sup>51</sup>

The numerous disciplines or bodies of knowledge which contribute to the study of organisational issues are rich in potential to facilitate implementation and adoption of innovations in an ever increasingly complex health services system.<sup>2</sup> With that in mind, research employing expertise in these fields is central to furthering knowledge on organisational adoption and best-practices for implementation.

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## CHAPTER 14

### Case study: Design, implementation and adoption of the NHS Care Record Service in secondary care

#### SUMMARY

- Many information technology innovations fail to realise their potential and this unfortunately has also been true with respect to the history of eHealth applications.
- Major factors contributing to these failures—some of which are spectacular—include the lack of appreciation and attention being paid to human factors during product development and deployment. These socio-techno-cultural factors can have a profound effect on the usability, implementation and adoption of eHealth innovations.
- There is a burgeoning change management literature, dating back to Rogers' influential Diffusion of Innovations Theory and stretching to the more recent Diffusions of Innovations in Health Services Organisation theory.
- The Diffusions of Innovations in Health Services Organisation theory highlights the importance of paying particular attention to the nature of the innovation as perceived by end-users, strategies by which potential adopters can be targeted, the role of effective communication in introducing innovations, the importance and role of both organisational and environmental context and how implementation is most effectively achieved and then change is sustained.
- Using an adaptation of this generic Diffusions of Innovations in Health Services Organisation theory to render it more specific to eHealth technologies, we sought to derive possible insights into how the success of complex eHealth applications such as the NHS Care Record Service into English hospitals could be promoted.
- In so doing, we extracted what we believe to be relevant components of the model in relation to eHealth innovation, highlighting the need to pay attention to strategically target end-user perceptions and to create an

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organisational and environmental context for facilitating the adoption of the NHS Care Record Service.

- Our new Infusion of eHealth Innovations in Health Service Organisations Model incorporates issues surrounding design, implementation, adoption and evaluation of eHealth technologies
- Connecting for Health has already taken on board several key lessons from this model, mainly relating to implementation and adoption.
- It is, however, very important that design and evaluation issues are incorporated—issues which have thus so far not been adequately addressed.
- The success (or failure) of this central plank of the multi-billion pound investment in the National Programme for Information Technology will ultimately depend only in part on technological competence; far more important will be the attention awarded to understanding and managing the socio-techno-cultural dimensions and to maximise the chances of success we recommend that greater time, attention and resources are focused on these human factors considerations.

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## 14.1 INTRODUCTION

The NHS Care Record Service (NHS CRS) represents the backbone of NHS Connecting for Health's (NHS CFH) National Programme for Information Technology (NPfIT) and as such represents a potentially fundamentally transformative and, conversely, also potentially very disruptive eHealth innovation. Considering its centrality within the Programme it is of considerable importance that in the development and deployment of this technology—which has the potential to yield great benefits to patients—NHS CFH is cognisant of the human factors considerations that are likely to have a major impact on the acceptability and likely effectiveness of this innovation. In this case study, drawing on the theoretical and empirical evidence reviewed in Chapters 12 and 13, we consider in detail potentially important socio-techno-cultural issues that may impact on the successful implementation and adoption of NHS CRS in secondary care. In so doing, we hope to identify possible strategies and approaches that NHS CFH might wish to consider in taking forward the roll-out of the NHS CRS, whilst at the same time contributing to the theoretical and relatively limited empirical base for understanding IT adoption in healthcare.

We begin by briefly reviewing the nature, structure and implementation timeline of NHS CRS, before turning in some detail to our adaptation of the generic *Diffusion of Innovations in Health Services Organisation* theory,<sup>1</sup> with a view to rendering it more relevant to eHealth considerations. We then use this *Infusion of eHealth Innovations in Health Services Organisations* Model to reflect on NHS CHF's current approach to ensuring a successful deployment of the NHS CRS and outlining areas which, we believe, based on this model, need further attention.

## 14.2 THE NHS CARE RECORDS SERVICE

NHS CRS is a computerised care record that is currently being introduced as the quintessential headline deliverable of NPfIT. This is a complex innovation consisting of several inter-related components, which are summarised in Table 14.1 (see Chapter 4 for details), together with a timeline for their implementation. It is clear from this timeline, which has been extracted from a number of sources,<sup>2–5</sup> that the implementation of the various components of the NHS CRS is noticeably behind schedule.



**Table 14.1 Components of the NHS CRS with a timeline for implementation**

Timeline	Component
From 2004	National Spine including the basic capabilities of the application
From April 2004	National Network for the NHS (N3) allowing electronic data exchanges across organisations
From June 2004	Personal Demographics Service (PDS) containing demographic patient details
From summer 2004	Images in Picture Archiving and Communication System (PACS)
From 2006	Summary Care Record (SCR), which is held on the national Spine and contains a record of essential clinical information
From 2006	Detailed Care Record (DCR), containing far more comprehensive clinical information than the SCR
From August 2007	Secondary Uses Service (SUS) for integration of data from different sources
2010	Full implementation

The introduction of the NHS CRS into secondary care represents a dramatic change from the current model of working as English clinicians working in hospital settings are currently typically using paper-based records (with all the associated difficulties of storing, retrieving and interpreting written records; see Chapter 6). The introduction of the new paperless system is therefore likely to have a significant effect on organisations, healthcare teams and individual practitioners, as well as patients.<sup>6</sup>

Although it is possible that the introduction of the new application will, if successfully implemented and adopted, in the longer-term result in cost-savings, the initial investment is significant, estimated at anywhere between £6-12 billion.<sup>4</sup> Given the scale of the financial spend and the fact that so many other aspects of the Programme depend on the success of this initiative, it is vitally important that the implementation of NHS CRS is successful.

However, historically the introduction of new IT applications into healthcare organisations has proved problematic, which is a major concern. For example, Sicotte et al. describe the introduction of electronic health records (EHRs) into four US hospitals.<sup>7</sup> The cost of this introduction was considerable at \$45 million, but the venture failed due to the application being rejected by healthcare staff who refused to use it as they felt the application did not fit in with existing care processes. This, and other examples,<sup>8;9</sup> illustrate the importance of considering the human dimensions of implementation of innovative technologies into

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existing organisational structures.<sup>10;11</sup> These factors do not only relate to practicalities and technical issues, but crucially to the design considerations and socio-cultural dimensions of organisational change. It is, as discussed in the previous two chapters, particularly important that sufficient attention is given to these factors in order to maximise the chances of realising the vision of successfully developing an integrated and used EHR.<sup>6</sup>

### 14.3 SOCIO-CULTURAL DIMENSIONS OF ORGANISATIONAL CHANGE—THEORETICAL CONSIDERATIONS

One of the most influential theories with regard to the socio-cultural dimensions of organisational change is Roger's theory of the *Diffusion of Innovations*.<sup>12</sup> This is a thoughtful model of how individuals in organisations adopt innovations and how this knowledge then diffuses into organisations (see Chapter 13).

Building on this seminal work, Greenhalgh et al. recently reported the findings of a comprehensive systematic review in which they, drew on several research traditions (see below) to develop a multi-faceted model of the socio-cultural dimensions of organisational change in the specific context of healthcare organisations.<sup>1</sup>

They divided existing research traditions into the following three broad categories:

- **Early diffusion research:** including rural sociology, medical sociology, communication studies and marketing
- **Later diffusion research:** including development studies, health promotion, evidence-based medicine
- **Research from the organisation and management literature:** including studies of the structural determinants of organisational innovativeness, studies of organisational process, context, and culture, inter-organisational studies, knowledge-based approaches to innovation in organisations, narrative organisational studies, complexity studies and organisational psychology.

They then further considered factors that can facilitate the successful implementation of innovations and proposed a framework of socio-cultural dimensions that need to be considered in this context. This framework (see Chapter 13) suggests several key considerations, which include:

- the nature of the innovation as perceived by end-users
- strategies by which potential adopters can be targeted
- the role of effective communication in introducing innovations
- the importance and nature of both organisational and environmental context

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- how implementation is done most effectively and change is sustained
  - the role of external agencies in influencing successful implementation.

Greenhalgh et al.'s framework is, however, based on a review of the literature and although the issues discussed here may help to facilitate adoption, they are context dependent and are therefore not necessarily universally applicable.<sup>1</sup> It must also be emphasised that this framework has yet to be empirically tested; following it therefore clearly does not guarantee success in itself.

Although this framework represents the most comprehensive and most mature understanding of socio-cultural factors in innovations in health service contexts to date, it is very much a generic model and does not therefore have a focus on specific issues relating to our area of interests, namely eHealth innovations. When applied to the introduction of the NHS CRS, the theory therefore clearly lacks attention to issues relating to the design and usability characteristics of the NHS CRS (see Chapter 12).<sup>13</sup> This is a very important issue as introduction of the NHS CRS will involve a substantial increase in human technology contact, necessitating a careful user-informed design.

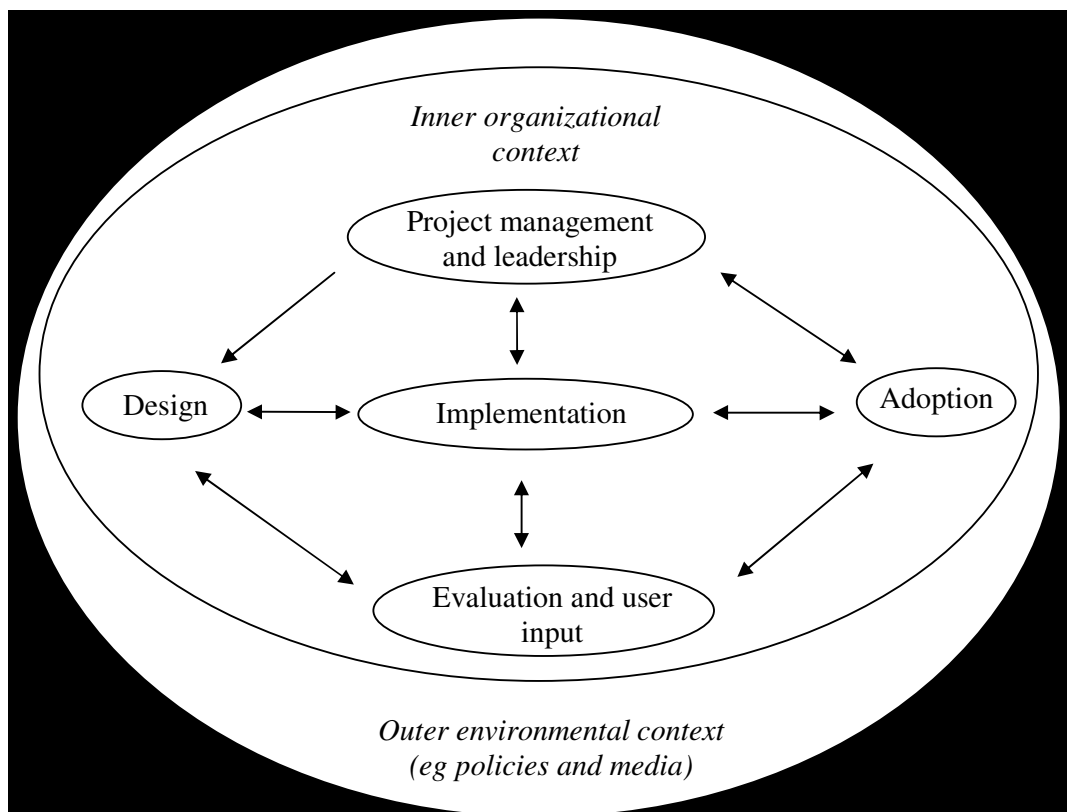
Several studies of technology adoption in healthcare have shown that usability and user friendliness of applications are crucial in facilitating adoption by healthcare staff,<sup>14;15</sup> whilst technical problems such as long response times and problems with saving data can inhibit adoption of technologies.<sup>16</sup> The importance of design issues has also been highlighted by Mair et al.,<sup>17</sup> who found that facilitators and barriers to eHealth adoption centred around three broad themes, namely: design; interactions between healthcare professionals; and organisational factors. Ease-of-use and flexibility of the application were consistently identified as facilitators for adoption, whilst lack of testing, performance limitations and intrusiveness of the application were identified as important barriers. May et al. also highlight the importance of design in the successful implementation of eHealth.<sup>18</sup> Reporting on an ethnographic study of telemedicine, they conclude that problems during implementation of the new application included the '... system's incompatibility with the set of practices that already constituted the 'technology' of the consultation'. Also, as discussed in Chapter 13, a review by Gagnon et al. outlined several issues that are specific to eHealth innovations, these in the main relating to application design and usability issues.<sup>19</sup>

There is thus the need to integrate previous theoretical work, particularly Greenhalgh et al.' *Diffusions of Innovations in Health Services Organisation* theory, and develop a new model focusing on eHealth innovations.<sup>1</sup> The key development that we have undertaken in this respect is not only to focus

on the implementation and adoption of eHealth innovations, but also to broaden the vision so as to integrate design and evaluative considerations when considering these interventions in health services organisations (see Figure 14.1). We have labelled the new model *Infusion of eHealth Innovations in Health Service Organisations model* to indicate a move away from passive spread to a more comprehensive spread and establishment of the innovation in the organisation.

In developing their work, Greenhalgh et al. describe several case studies, one of which relates to the introduction of electronic health records.<sup>1</sup> Employing the above model, we aim to build on this original work through undertaking a detailed more up-to-date case study of the implementation of the NHS CRS into hospital-based care. In so doing, we aim to reflect, using these complementary frameworks, on the utility of the above model and using this on NHS CFH's current efforts at implementation. Our aim throughout is to identify, where possible, additional strategic steps that NHS CFH might usefully take to maximise the likelihood that the NHS CRS will successfully be used by hospital clinical staff.

**Figure 14.1: Infusion of eHealth Innovations in Health Services Organisations Model**



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## 14.4 INFUSION OF EHEALTH INNOVATIONS IN HEALTHCARE ORGANISATIONS

### 14.4.1 DESIGNING THE APPLICATION

In designing the application, developers need to ensure that the NHS CRS (and any future iteration) is designed in such a way that additional staff training needs are minimised.<sup>20</sup> This necessitates creating logical and standardised ways of finding and accessing information such as providing adequate links for help and shortcuts for commonly used functions (for example, click the right mouse button if in doubt). Human support needs to be readily available if required and additional concise printed manuals on how to use the application are necessary to ensure that staff can readily access help if needed. Visual alerts may be a way of simplifying the application and these are already planned to be implemented in the DCR in the form of computerised decision support systems (CDSSs).<sup>21</sup> Other ways of ensuring usability of the application, include utilising colour and graphics as well as a straightforward layout of the screen and ensuring ‘visibility of system status’ (so that the user knows what the application is doing at any one time).<sup>22</sup>

In addition, studies of adoption of innovations in healthcare have shown that speed of the application is a major facilitator for adoption as well as some degree of flexibility (users need to be able to use the application tailored to their individual needs).<sup>14;16;23</sup> The latter has already been addressed as staff will only have access to information that is relevant to their role, which is in turn dependent on having a “legitimate” relationship with the patient.

Some concerns have, however, been expressed that the SCR may, for example, be too complex to use, which can be an important barrier to adoption.<sup>24</sup> Logging on with smartcards and pin number to verify identity is a good way of addressing concerns surrounding confidentiality, but the resulting length of the logging in process may compromise valuable time in the case of emergencies. There may here be a potential for using biometric technologies, but this has obvious additional cost implications. Conversely, systems need to be in place to ensure that after use, healthcare staff will be logged out after a certain amount of time to minimise risk of inadvertently breaching confidentiality.<sup>16</sup>

Another crucial factor is providing an adequate workspace for users of the new application,<sup>20</sup> as the lack of access to computers has previously been identified as a barrier for use.<sup>23;25</sup> This means thinking through the positioning of computers throughout the hospital and may involve access testing for simulated emergency situations. Similarly, it may be helpful to incorporate emergency functions such as a red button providing critical information, such as drug allergies, when needed promptly.

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The literature suggests that the best way of achieving application usability will be through a close collaboration between the designers of application and end-users.<sup>6;16</sup> This may take the form of continuous testing of prototypes in different groups of end-users and re-design if necessary.<sup>17;20;25</sup> Hartswood et al. have applied an ethnographic method called ‘co-realisation’ to help achieve user-informed IT design.<sup>26</sup> They argue that a facilitator is important in this context in developing a partnership between users and designers of the IT application. NHS CFH has already made efforts of increasing user involvement during deployment, which will be discussed in more detail below. There have so far been only limited efforts focused on incorporating user input into application design, although an evaluation of the Early Adopter programme (where four primary care trusts are piloting SCRs) is planning to address this. Such engagement needs to occur with a range of user groups.

An inevitable potential problem with the implementation of eHealth innovations is the possibility of application failure. Although NHS CFH is increasing efforts to ensure applications are reliable through working closely with application designers and incident reporting and analyses, they acknowledge that it is not fail-safe. It will therefore be necessary to have systems in place and disseminate a plan of action of what to do in such situations. This will mean devising alternative forms of accessing and storing data in collaboration with application designers.

It also has to be kept in mind that the NHS CRS will depend on user input. Setting clear standards on what and how information will be entered into the application and compulsory update or input of information to keep the application up-to-date are therefore one of the main responsibilities of NHS CFH. Such standards should also be devised for how the applications are linked together as a variety of computer applications is likely to operate in secondary care.<sup>27</sup> Standards have already been adopted to authenticate the identity of users and to ensure the secure transfer of information across applications (electronic Government Interoperability Framework) and to outline the technical requirements regarding the specification of the application (OBS—Output Based Specifications).<sup>28;29</sup> But these certainly need to be extended to cover information input.

#### **14.4.2 INNOVATION ATTRIBUTES AND ADOPTION**

In order for successful implementation and adoption to occur, a strategic targeting of end-users (adopters) of the innovation is crucial. The NHS CRS is likely to be used by a variety of healthcare professionals as well as patients in a



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range of settings. Groups of adopters may, however, differ in terms of particular needs and or existing skills which may in turn influence individual adoption. A potential problem is that end-users of the NHS CRS have thus far not been mapped out and can therefore not be systematically targeted and motivated to use the application.

Once prospective end-users have been mapped out it is important to consider in which capacity they will utilise the NHS CRS. This is best informed by users themselves in order to develop a sufficiently rounded understanding.<sup>30</sup> A potential problem is, however, that there is still some confusion of how exactly the SCR will be used—this uncertainty within NHS CFH has a knock-on effect on professionals and patients—and there is a pressing need to address this.<sup>4</sup> There is also still confusion over who exactly will use DCR applications and which organisations will be enabled to share information. The NHS Care Records Service Registration Authority is a designated authority for registering staff to use the NHS CRS and may have a role to play in this context.

In line with our Infusion of eHealth Innovations in Health Service Organisations model, to be successfully implemented, innovations need to be perceived by adopters as having certain attributes. If this is the case then successful adoption is more likely. The first of these, relative advantage, refers to the perceived value of introducing the new application. For the NHS CRS this is most likely to be viewed in terms of it improving care and having advantages over paper-based records in terms of facilitating communication and saving time. Several studies in the context of eHealth adoption in healthcare have supported the importance of the perceived relative advantage in facilitating adoption. If a programme is perceived as valuable and useful it will be more readily adopted,<sup>31</sup> whereas if the new application is perceived as meaningless this inhibits adoption.<sup>16</sup> Similar concepts include task relevance and task usefulness, which highlight the necessity for healthcare staff to be clear in what way the NHS CRS can help to improve their personal performance in delivering high quality care to patients.

Compatibility is another important attribute of the innovation. The NHS CRS needs to be perceived to fit in with existing work patterns of healthcare staff. It is therefore of prime importance that staff needs are clear in relation to how this may be done and what additional resources may be needed. In line with this, Docherty and Sandhu,<sup>31</sup> for example, have explored potential facilitators and barriers to e-learning among students. They found that if a programme fitted in with existing commitments and practice this was viewed as a facilitator. Similarly, Lai et al.,<sup>32</sup> who investigated why a CDSS resulted

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in limited adoption, found that barriers among clinicians included concerns relating to the potential disruption of workflow. Similar issues were raised by Ash and Bates in relation to electronic health record (EHR) implementation.<sup>33</sup> Ideally, there would therefore also be as few job changes as possible as a result of the application's introduction. This may, however, prove difficult as, when considering the introduction of the NHS CRS, the changes to work patterns are likely to be substantial.

Other important attributes are trialability and observability. Healthcare staff and patients will need the opportunity to practice how to use the application and to see how it works to improve care. This may be done individually with dummy records or in training (see below) and should be tailored to individual needs. Previous studies of eHealth adoption support the importance of these constructs.<sup>31</sup>

The potential for re-invention is another important described attribute. Healthcare staff need to be able to adapt the use of NHS CRS to their particular profession's requirements. This may be done via design features and requires active efforts of involving staff. Supporting the usefulness of this construct, Ash et al. interviewed health professionals at sites where computerised provider order entry (CPOE) was successfully implemented and identified the ability to adapt the application to local needs as a facilitator for adoption.<sup>14</sup>

Feasibility is also important, this referring to the need to communicate to adopters that introducing the new paperless application is feasible to use in their healthcare setting. This may be difficult in hospitals due to the application's high perceived implementation complexity, but can be addressed by highlighting and addressing potential barriers, such as for example lack of access to computers and potential disruptions to workflow.

Another important construct is the perceived divisibility of the programme, which is achieved by introducing an innovation slowly and in a piecemeal fashion. This has to a large extent already been addressed by introducing the different components of the Programme in phases (referred to as 'releases') beginning with the introduction of some functions and the aim of all functions being available by 2010. Equally, in the 'Early Adopter' programme,<sup>34</sup> some aspects of SCR are not available at the start, but will be available later (such as patient access through HealthSpace and the 'sealed envelopes' function). However, the fact that two different types of software, namely Cerner Millennium and Lorenzo will be used means that timings of implementation of releases (and therefore functions) vary depending on the software in question. This heterogeneous way of implementation may prove problematic.

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A potential area for concern, however, is that there is continuing negative publicity surrounding the Programme which is likely to impact on the perceptions of many end-users. The Ipsos MORI survey commissioned by NHS CFH,<sup>35</sup> for example, showed a widespread unfavourable attitude towards the Programme, especially in doctors. A perceived barrier to implementation was the lack of staff knowledge on how the Programme will affect them and the lack of staff training. Findings from the Medix Survey confirmed this negative opinion of the Programme among doctors and found that support for the NPfIT has declined markedly over the past few years.<sup>36</sup> Also, the majority of doctors thought that NPfIT was not a good use of resources and some voiced concerns about confidentiality and security of the applications. These negative perceptions are planned to be targeted through a project of identifying positive case studies by the NHS Institute for Innovation and Improvement with the aim to improve perceptions surrounding the NPfIT among doctors.<sup>37</sup> This is a step in the right direction, but there is also the need to focus on other healthcare professionals.

Conversely, patient perceptions of EHRs appear relatively positive according to a survey conducted by Health Which? and the NPfIT.<sup>38</sup> The majority of patients in the UK seem to believe that EHRs can improve care through improved communication and increased accessibility. However, some concerns were voiced about confidentiality, which has subsequently to an extent been addressed by efforts to diffuse these concerns through initiatives such as the NHS Care Record Guarantee, which is setting standards to protect confidentiality.<sup>39</sup>

#### **14.4.3 PROMOTING ADOPTION—WHICH STRATEGIES ARE LIKELY TO BE SUCCESSFUL?**

Greenhalgh et al.'s work offers some helpful strategies on how end-users may be positively influenced to adopt innovations.<sup>1</sup> A central component of these efforts should focus on tailoring techniques to the needs of different adopter groups. NHS CFH has already begun to address this with the development of the Do Once and Share Programme,<sup>40</sup> which employs so called 'action teams' in order to identify how best to tailor the design and introduction of different components of the NPfIT to the individual professions' needs. Below we outline potential approaches to influencing individual perceptions about the NHS CRS derived from the above framework.

##### *The importance of constant end-user involvement*

Constant end-user involvement is of prime importance when designing and implementing eHealth innovations.<sup>41</sup> It is again important to target all different

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adopter groups (staff at all levels) and if possible invite representatives to meetings while actively seeking opinions and divergent viewpoints.

An increased involvement of end-users is important in order to promote sense of ownership of the newly introduced application. A potential problem with the NHS CRS is, however, that its implementation is top-down and is and will often be perceived as being imposed by the Government. To promote a sense of ownership, efforts therefore will need to concentrate on improving communication, open dialogue and discussion with end-users in order to promote collective decision-making and increase individual autonomy.

Evidence for the effectiveness of constant end-user involvement in facilitating adoption also comes from several studies of eHealth implementation. For example, Bates describes a successful implementation of a CPOE application for prescribing (also known as ePrescribing) in two hospitals in the US.<sup>42</sup> He argues that the success of these may be due to the fact that these applications were home-grown. Also, Lee, who interviewed nurses regarding the use of newly introduced portable digital assistants (PDAs), found that participants showed initial resistance but constant involvement and feedback which was then incorporated to revise the application facilitated adoption.<sup>16</sup>

NHS CFH has made significant efforts of increasing end-user involvement in the NPfIT. This issue was also highlighted by the National Audit Office.<sup>5</sup> NHS CFH is, for example, asking for feedback and potential barriers to adoption on their website and an evaluation of the implementation and adoption in early adopter sites of the SCRs has also recently been commissioned.<sup>43</sup> This involves incorporating the views of key stakeholders such as GPs, nurses, patients and the public, practice managers and other clinical and administrative staff. It is hoped that the results will identify potential barriers to adoption that can be addressed before the application is rolled out nationally. The final report is expected to be finished by summer 2008.

NHS CFH is also working closely with the Salford Royal Hospitals NHS Trust, which has piloted the introduction of the EHR since 1999.<sup>44</sup> The pilot is characterised by an active involvement of doctors, nurses, pharmacists and allied health professionals. Originally, NHS CFH had divided England into five geographical clusters of implementation but since the introduction of the NPfIT Local Ownership Programme in April 2007 the original five clusters have become three “Programmes for IT”.<sup>45</sup> This is designed to increase local responsibility for implementing applications by actively involving the 10 regional Strategic Health Authorities (SHAs) and local health community programmes in implementation activities for each of the programmes (this

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also allows local NHS staff to have their say). NHS CFH has further appointed Local Service Providers (LSPs) to support the gradual roll-out of IT systems for the NHS organisations in each of the three areas.

The NLOPs and their corresponding LSPs are:

- Southern Programme for IT: Fujitsu
- London Programme for IT: British Telecom
- North, Midlands and East Programme for IT: Computer Sciences Corporation.

It is planned that LSPs in the London and Southern Programme will use Cerner Millenium Software, whilst the North, Midlands and East Programme will use Lorenzo Software. Here, for example, the Lorenzo Core Team, made up of a range of experts from a variety of health professional and managerial backgrounds, are working closely with NHS CFH and providing advice and opinions on implementing the NHS CRS.<sup>46</sup>

Efforts have also been made to increase involvement of the public. NHS CFH's Public Engagement Team is working on actively engaging patients in the development, implementation and evaluation of the NPfIT. They have, for example, engaged with patients and found several concerns regarding the NHS CRS were relatively prevalent. These included concerns about access in those that are not computer literate, issues surrounding the sharing of information and transfer as well as concerns surrounding user control.<sup>47</sup> The team is now planning to address these with the help of road shows and demonstrations of how the NHS CRS will look. Also, the NHS Care Record Guarantee published by the Department of Health (DH) setting standards to protect the confidentiality of electronic patient records has incorporated views of the public.<sup>39</sup> NHS CFH also states that high priority is given to allow patients access to their own records and that patient groups have been consulted in prioritising what they want to see included in their records, which is likely to increase a sense of ownership. For the future, NHS CFH is planning to conduct regular assessments of public attitude to the NHS CRS through workshops and discussion groups and to help patients with long-term conditions to help manage their own care through the record. It is now important that these plans are put into action.

End-user input has also been canvassed regarding the specification of the application through the development of OBS.<sup>29</sup> Involved in the development of OBS were SHAs, Electronic Record Development and Implementation Programme (ERDIP) sites, IT directors and the Academy of Medical Royal Colleges Information Group. Comments on OBS were invited and received from a variety of stakeholders and NHS organisations. However, a potential



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problem is that NHS CFH did not record which contribution was made by which stakeholder, which complicates tailoring the programme to individual needs.

What now needs to be done is to incorporate the data obtained into existing applications and maintain seeking user input throughout the development and implementation of the NHS CRS. Special consideration should also be given to possibilities of re-design and modification if the need is expressed. There is also still a lack of involvement of local NHS organisations and individuals and local input such as at the trust level has so far not been achieved (especially with regard to DCR). With regard to patients, a greater sense of ownership may be achieved through increased access to their own records. This may be addressed with the 'sealed envelope' function, but has as yet not been implemented.

### *Training*

Training adopters in how to use different components of the NHS CRS is crucial for demonstrating the application's usability. This may involve the utilising demonstrations of how to use the application through, for example, case studies. Alternatively, observations of sites where the application has already been successfully implemented and is routinely used may also be helpful. In primary care, demonstrations for patients in areas of where EHRs will be implemented are already done. But end-users that do not come from these sites have no possibility to see how the record may look.

Using dummy records may also prove a useful technique to employ during training as this will give healthcare staff the opportunity to practice using the application in a safe space (where any mistake they might make does not have adverse consequences). In addition, building on existing IT skills can facilitate adoption. It may therefore be more acceptable for staff if the introduction of the NHS CRS is built onto existing systems.

Several studies investigating the implementation of eHealth innovations in healthcare support the importance of training in facilitating adoption.<sup>14;16;48;49</sup> For example, Docherty and Sandhu's study found that it is important to give students who are not experienced eLearners the opportunity for pre-course training.<sup>31</sup> Conversely, they argue that it also needs to be recognised that some have existing skills and those will not require training which highlights the need to tailor training to individual needs. Moreover, Lai et al.,<sup>32</sup> who investigated why a CDSS resulted in limited adoption, conducted interviews with clinicians to identify barriers to CDSS use; they found that barriers included a major lack of understanding about how the application functions. Based on this insight, the



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authors therefore designed a tutorial with information about the application that clinicians could view and found that clinicians who used the tutorial reported an improved understanding and confidence of using the application. Case studies in this tutorial to illustrate were viewed as particularly beneficial. Also, Travers and Parham report the successful implementation of a 'home-grown' emergency department patient tracking application.<sup>50</sup> Here, one-to-one training tailored to individual needs (determined through needs assessment before start of training) of staff was found to facilitate implementation. Staff reported that practicing how the application worked increased their confidence in it.

NHS CFH has already established a Training and Development (ETD) programme, which provides guidance and support for NHS staff in using the new IT applications, including the NHS CRS.<sup>51</sup> NHS CFH estimates that around 850,000 NHS staff will be trained through this programme. Both National Application Service Providers (NASPs) and Local Service Providers, coordinated by the NASP Training Coordination Project, will be conducting local needs assessments and devising training plans in accordance with these. Although NHS CFH emphasises that training should start early, a detailed plan of action is not available. The ETD programme has several basic components. These include the NHS Essential IT Skills (European Computer Driving Licence) Service that was established to provide IT learning material and testing for NHS staff.<sup>52</sup> Another part is the PC Coaching Trainer Services,<sup>53</sup> which is a mobile training unit with IT experts and national eLearning material for several parts of the NPfIT (including Spine, PDS and NASP). Additional parts of the ETD include NHS CFH's 'Table-Top Challenge' (TTC) with 'Focus—the Change Game'.<sup>54</sup> This is a game designed to introduce the NPfIT to staff, explaining how components of the Programme will look and they will affect individual staff and different departments. Milton Keynes General NHS Trust is already using the game to facilitate the implementation of the NHS CRS. Moreover, a Training Messaging Service (TraMS) with a 'Like Live' training environment is planned to be introduced and will enable NHS staff to practice on dummy patients for the NHS CRS.<sup>55</sup> Plans to train staff using the NHS CRS locally through local service providers have also been voiced and NHS CFH is awarding quality marks for IT courses that meet employers' needs.<sup>56</sup> However, a detailed training plan does not exist and despite the apparent efforts, a structured approach to training staff at all levels is still lacking. It is further unclear how all these different components of the ETD programme will eventually come together and how they are tailored to the individual needs of end-users.<sup>4</sup>

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### *Utilising the influence of social networks*

Utilising informal social networking in influencing end-user perceptions of a new application is vital. These may work either horizontally (through peers) or vertically (top-down through management). Utilising horizontal networks may be more effective than top-down implementation as this will promote a sense of ownership.

Horizontal networks may operate through peer demonstration and discussion. It would therefore be useful to offer demonstrations through colleagues who are used to using the NHS CRS and offer workshops or meetings chaired by enthusiasts from the same profession. Another way to utilise horizontal networks may be to give staff details of a contact from same profession used to the application or to get key individuals from each group with knowledge of how to use the NHS CRS to speak about their positive experiences.

It has to be kept in mind, however, that a variety of social networks operate when implementing the NHS CRS. Each of these needs to be targeted separately as different groups are likely to use the application in different ways.

There has so far been an apparent lack of attention been paid to the use of social networks in promoting the successful adoption of the NHS CRS. The introduction of ESpace, which is a web-based discussion forum where healthcare staff can exchange experiences regarding the NPfIT, is a promising start.<sup>57</sup> Also, clinical leads can play an important role in this context (see below).

### *Utilising the influence of key individuals*

The need for specifically targeting key players that can help to drive developments has been touched upon above. Ideally these are influential individuals who have experience of using the NHS CRS and can persuade others of the application's usefulness. Adoption of innovations is facilitated if individuals who introduce the application are homophilous (have shared language and meanings) to the target group (ie potential adopters). For staff this means that these key individuals would therefore best come from the same professional group as potential adopters. Patients may have to be targeted separately. Ideally, these key individuals will also need to be socially and clinically competent in order to "sway" others to use the application. In line with this, Travers and Parham describe the successful implementation of an emergency department patient tracking application.<sup>50</sup> They report that key staff (doctors, nurses and clerical staff) facilitated adoption acting as champions and promoting the use of the application.

NHS CFH has already made significant efforts in utilising the influence

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of key individuals, following recommendations from the UK National Audit Office to appoint high calibre clinical leads.<sup>5</sup> Key individuals from different professions (GPs, hospital doctors, nurses and allied health professions) have been appointed in 2004 to promote the programme and to improve perceptions of the Programme among key stakeholders. This is done through conferences, presentations, communication with peers, networking and guidance. There is also an ongoing recruitment of high quality individuals, specifically with a view to promoting the NHS CRS.<sup>58</sup> However, some non-clinical staff groups have so far been neglected such as, for example, administrative staff.

### *Communicating the usefulness of the new application*

Explaining exactly how the NHS CRS can improve care and performance in a variety of different settings is another potentially crucial issue in facilitating adoption and influencing adopters' perceptions. However, there is a need to tailor information to different groups as there are likely to be differences between lay people and healthcare professionals. It has, for example, been found that health professionals especially value high quality evidence of effectiveness, while this may be less of a priority for patients. Here, the usefulness of EHRs may be best illustrated through case studies where they have prevented patient harm.

For example, Crowe and Sim performed an evaluation of the introduction of an information, picture archiving and communication system (RIS or PACS) in an Australian hospital.<sup>59</sup> They report that it was well received by clinicians due to perceived benefits in improving patient care and a reduction of time in reaching clinical decisions. Also, Keshavjee et al. evaluated the implementation of EHRs in several primary care sites in the US.<sup>60</sup> They concluded that the perceived value of EHRs is crucial for their successful implementation, as some physicians dropped out because they felt the application increased time spend on charting. Conversely, Terraz et al.,<sup>23</sup> who evaluated clinicians' perceptions of an Internet-base guideline regarding colonoscopy patients found that an important barrier to its use was the time needed for using the guideline. However, as a note of caution Pagliari warns that care should be taken not to raise end-user expectations if they cannot be fulfilled as this can be damaging to implementation and adoption.<sup>41</sup>

NHS CFH has begun to address these issues by publishing some information on its website for both staff and patients as well as by launching the NPfIT Catalogue in January 2007, an electronic file listing certain new applications and their benefits. An important role in this objective has also Mainstreaming IM&T Strategy Planning and Benefits NHS CFS's work-stream (see Chapter

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3). But there is still an urgent need to provide clinicians with quantitative data on the effectiveness of the NHS CRS (but as discussed in Chapter 6, this is no straightforward matter).<sup>4</sup> If end-users perceive the Programme as effective and can view and assess this effectiveness with quantitative evidence, a positive attitude towards the Programme and resulting adoption is likely to be engendered. This is especially necessary for facilitating adoption in healthcare staff and requires mapping out each potential user of the application in order to address their individual needs, as effectiveness is likely to be judged according to these. For patients, the NHS Care Record Guarantee has begun to address these issues.<sup>39</sup> It was first launched in 2005 and has been revised following some concerns expressed relating to clarity. NHS CFH reports positive reactions from patients.

#### *Specifically addressing end-user concerns*

Targeting individual adopter groups is also important for addressing end-user concerns. Active efforts need to be made to diffuse these and potential barriers to use need to be aired. This can be done through discussion groups giving individuals the opportunity to voice their concerns or by explaining how the NHS CRS fits into existing structures. Potential effects on other applications within the setting need to be discussed and specifically addressed.

It is further necessary to address potential concerns at each stage of implementation. These can be divided into the following three stages:

- pre-adoption
- early use
- established users

Concerns at the pre-adoption stage should be addressed before the introduction of the new application. Concerns have, in the case of EHRs for example, been voiced surrounding confidentiality, consent and cost-effectiveness of the application.<sup>61;62</sup> Furthermore, Hendy et al. recently interviewed key personnel from four NHS trusts regarding their perceptions of the NPfIT.<sup>63</sup> They found that although the Programme was generally supported, participants expressed several concerns relating to financial issues, delays in implementation and concerns surrounding communication between local structures and NHS CFH.

Work by NHS CFH's Public Engagement Team has further revealed concerns surrounding access, sharing of information and information transfer as well as concerns surrounding user control (see below).<sup>47</sup> Another likely concern at this stage is a degree of computer anxiety or, worse still, phobia among some

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potential users.<sup>64</sup> These issues are best addressed by describing how the new application will look and function, and describing in detail what impact this will have on individuals day-to-day practice. This is especially important for the introduction of eHealth innovations as these are extremely complex and disruptive to work patterns. It is also important to explain exactly what is needed in order to achieve the application's implementation in terms of time, aims and expected benefits.

NHS CFH's communication efforts have so far mainly concentrated on patients, with a relative lack of effort on eliciting and then addressing potential concerns in healthcare staff. There is thus also an urgent need to actively find out what these concerns are amongst different groups of end-users (ranging from top management to clinicians to administrative staff). With regard to patients, NHS CFH has plans to implement the Public Information Programme (before the NHS CRS is introduced) to inform members of the public and diffuse potential concerns.<sup>65</sup> Concerns regarding security and confidentiality have so far been relatively well addressed. Users, for example, will have to use a smartcard, username and password when attempting to access the application. In order to get a smartcard, they will have to register and different healthcare professionals will have different levels of access. There will also be an audit trail for recording activity. NHS CFH has further designed an opt-out consent application, so that patients do not have to have an SCR if they choose not to. There is, however, still some discussion as to whether this opt-out application should be used and there currently appear to be plans to revise it.<sup>66</sup>

Another issue is that an accurate timeline has not been disseminated to end-users, the Programme has experienced significant delays (see Table 14.1) and there are vast differences in estimation of likely costs.<sup>4</sup> A lack of knowledge as to how exactly the different components of the NHS CRS will operate further complicates matters.<sup>4</sup> The NPfIT Catalogue mentioned above is, however, a step towards addressing these issues and NHS CFH is in the process of producing more information through various other initiatives.

Concerns during early use of the application are currently only relevant in early adopter sites, but they are likely to gain importance as the NHS CRS is implemented throughout the NHS. Again, concerns during this stage are likely to vary among different adopter groups and different contexts. But these need to be addressed efficiently during the early stages of the implementation. This may be done through training on dummy records or computers in general as mentioned earlier. An important issue to consider at this stage is the need for appropriate support, which may take the form of printed manuals and or human

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support. Studies of eHealth implementation stress the importance of adequate support as a facilitator for adoption.<sup>14;31;48</sup>

How exactly NHS CFH is planning to provide support, which is especially important for the early use stage, is unclear. It is therefore important to devise and disseminate strategies on how this could be done in order to reassure end-users.

Concerns in established users are also likely to become of increasing importance as the NHS CRS is implemented nationally. Above all, the application needs to be effective. If end-users perceive it to be, for example, more time consuming than paper-based records it is less likely to be used.<sup>32</sup> Another important issue here is that end-users may want some flexibility in adapting the use of the application to fit their particular needs. This is again best done through asking those who have worked with the application and actively involving them in considering the potential for re-invention.

As this stage is as yet not imminent, NHS CFH has not made any efforts to consider potential concerns in established users. This should, however, be done as soon as the application starts to be used nationally through constant end-user involvement.

#### **14.4.4 THE IMPORTANCE OF CONTEXT**

The inner and outer context can play an important role in facilitating or inhibiting the adoption of eHealth innovations.<sup>33;67</sup> These will be discussed in turn.

##### *Inner-organisational context*

###### *Clearly setting and explaining goals*

Clearly setting and explaining goals is important in ensuring successful adoption of an innovation. This may involve giving adopters a timeline and clearly stating what exactly is expected of members of staff at every level in terms of using the new application.

There have been problems with sticking to timelines so far, as is the case with the implementation of the SCR, which is currently about two years behind schedule. A clear implementation date for the NHS CRS is still needed, as it is likely that the 2010 target will not be met. Also, due to difficulties in disseminating how exactly different components of NHS CRS will function,<sup>4</sup> efforts should concentrate on informing staff at every level prior to implementation what exactly will be expected of them. Again, usage of the new application is likely to vary in different staff groups or departments and expectations need to be tailored accordingly.



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### *Explicit and clear back-up from management*

The introduction of the NHS CRS will further need explicit and clear back-up from organisational management structures, as this can influence adoption. This will require proactive and strong leadership locally (in departments) as well as centrally supporting the introduction of the new application.<sup>68;69</sup> It will also involve a certain degree of formalisation and setting of clear standards, whilst still allowing some degree of flexibility in implementation.

In line with this, Travers and Parham report the successful implementation of a home-grown emergency department patient tracking application and found that the fact that use of application was mandatory facilitated adoption.<sup>50</sup> Similarly, Ash et al.,<sup>14</sup> who interviewed healthcare professionals at sites where CPOE was successfully implemented, have identified a strong organisational culture as a facilitator (including collaboration, teamwork, leadership, trust). Also, Lee found that a strong organisational policy back-up facilitated adoption of PDAs in nurses.<sup>16</sup> Sjogren et al. further evaluated introduction of telemedicine in Sweden.<sup>48</sup> They conducted interviews with a range of key staff and highlighted the importance of managers showing interest and commitment to the introduction of the new application.

In relation to the NHS CRS, progress has been made with regard to setting standards. NHS CFH has, for example, published the National Programme Implementation Guide,<sup>70</sup> which includes guidance designed to help trusts and programme managers with the implementation of the Programme. It includes standards and best practice guidelines as well as information about the Programme and advice on where to get help. Similarly, the NHS Care Record Guarantee and the Joint Guidance on the use of IT Equipment and Access to Patient Data set standards to protect the confidentiality of EHRs and clear guidance on what is expected of staff in this context.<sup>39;71</sup> In addition, technical and training standards have been set and discussed earlier in this chapter. Various internal initiatives to ensure clear standards and leadership have also been put into place such as, for example, the recent Informatics Review led by Matthew Swindells (the interim DH director general for information and programme integration)

With regard to leadership, NHS CFH has put in place clear management standards and structures for the NPfIT, thereby providing strong leadership capacity. NHS CFH is led by the Director General for IT in the NHS, who has been in post since 2002 (but he will leave by end of 2007) and the Chief Operating Officer (in post since 2003). Also, a clinical director for the SCR has recently been appointed and the Chief Executives of the NHS SHA are now the Senior Responsible Owner for the implementation of the Programme.

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### *Communication and networking*

Effective communication and networking between the local structures and management is also important when implementing innovations. It is therefore crucial to effectively communicate the use and implementation of the NHS CRS within the NHS and beyond. This may be problematic due to its size, but can be facilitated through targeting specific units or departments that can do this locally. In order to do this, applications will have to be developed to ensure efficient communication and networking between departments, hospitals and organisations.

In terms of networking with other organisations, NHS CFH has made significant efforts. For example, it is networking with academic institutions through the Professional Awards in Information Management and Technology (Health) and with IT organisations such as the UK Council for Health Informatics Professions and PRIMIS+. NHS CFH has also set up a Voluntary Sector National Advisory Group. In addition, NHS CFHs Public Engagement Team is already closely working with the Patient Advice and Liaison Services. However, there is still a lot to be done in terms of facilitating networking and communication between local structures such as individual hospitals as well as opening channels of communication between local structures and management. This may be achieved through increased user involvement, which has been discussed above.

### *Allocate appropriate resources*

For the implementation the allocation of appropriate resources is necessary. This will involve not only time and money, but crucially also training. In terms of time, it is important to allocate a certain period for assimilation in which the application may slow down initially. It is possibly therefore best to introduce the NHS CRS slowly and at a carefully chosen time of year (eg avoiding a busy time such as Christmas). Also, additional resources will have to be allocated for unanticipated expenses and for potential supporting infrastructure costs such as a helpline or designated staff who can help with on-the-job training. The need for giving users access to resources and help if needed is particularly important and continuing human support as well as written instructions will need to be provided.<sup>16;31;48</sup>

### *Incentives*

Introducing incentives can be a good way of facilitating the implementation of innovations. These may take the form of qualifications, promotions or

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increasing salaries if individuals can teach others how to use the application. Using incentives has been shown to be an important factor in facilitating the adoption of eHealth applications.<sup>16;48</sup> For example Benson has highlighted the issue that in general practice incentives have been used relatively efficiently promoting adoption of eHealth, while incentives for hospital doctors to do so remain elusive.<sup>72</sup>

NHS CFH has already made clear efforts in providing incentives and considerations surrounding this issue are ongoing (eg the Informatics Review mentioned above). For example, it is planning to provide incentives for local service providers to train trainers and has put in place the Professional Awards in Information Management and Technology in Health as an incentive for staff to acquire competence in IT skills. A potential issue is that many incentives are based on increased expenditure. But a more cost-effective possibility of providing incentives may lie in feeding back improvements in performance that have been made with the introduction of the new application. Efforts to introduce such and similar applications should be actively explored by NHS CFH.

*Explicitly address the role of NHS CFH*

It is further important to clearly identify the role of the external change agency. In addition, a good and stable relationship between change agency and adopters is important in facilitating implementation.

NHS CFH may be viewed as an external change agency as it will introduce the NHS CRS and has the responsibility for delivering the NPfIT. It should therefore provide both leadership and monitoring of progress of the Programme. However, although NHS CFH is now responsible for all aspects of implementation this may have to change to overall management responsibility and setting of standards as local structures are becoming more involved. In order to develop a common language and shared meanings, there may have to be increased relationship building and enhanced personal dialogue between NHS CFH and implementation sites with adopter input (ie staff and patients).

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### *Outer environmental context*

In order to successfully implement the NHS CRS, there is a need to create awareness of its existence and foster a positive attitude among end-users. This needs to be actively done through, for example, mass media campaigns with the help of the Internet, television or newspapers. In support of the importance of creating awareness, Lai et al.,<sup>32</sup> investigated why a CDSS application resulted in limited adoption. Their qualitative study of clinicians found that barriers to adoption included a lack of awareness of how the application functions.

NHS CFH has also launched a Public Information Programme,<sup>65</sup> which aims to inform members of the public in areas where the NHS CRS is implemented of the nature of the new application. This currently only applies to early adopter areas. The strategy is divided into the following three stages:<sup>5</sup>

- disseminating information about the NHS CRS to NHS employees locally via films and posters
- disseminating detailed information on how the application will benefit specific staff groups (GPs, hospital doctors, clerical workers, allied health professionals, nurses and other NHS staff), collaboration with Medical Royal Colleges
- disseminating detailed information about the NHS CRS to members of the public targeting households specifically.

NHS CFH also publishes information on the nature and progress of the NPfIT on its website and has begun a campaign to distribute over one million leaflets, DVDs and posters to explain the NHS CRS to NHS staff. However, there has been a lot of negative press surrounding the NPfIT and the lack of awareness among healthcare professionals (as indicated by the surveys described earlier in this chapter) makes success of the Public Information Campaign questionable.<sup>41</sup> Active efforts should therefore focus on improving the image of the Programme by increasing efforts of positive press coverage (eg through increased contact and relationship building with the press) and on increasing awareness especially among healthcare professionals. This should ideally be done well before the application is introduced nationally so that staff have time to become aware of and accustomed to the imminent change.

It is further important that the implementation of the NHS CRS is backed up by policies and political directives (external incentives). This has already been achieved as the NPfIT is well supported by the highest structures such as the Prime Minister, the Secretary of State for Health and the Department of Health.<sup>5</sup> The Department of Health is playing an especially strong role in backing up NHS CFH's activities. Furthermore, the NPfIT is part of a major re-structuring

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of the NHS in general including new contracts and re-configuration of several service areas, which might further help to facilitate implementation.

#### *14.4.5 Evaluation*

The importance of appropriate and programme-tailored evaluation in eHealth innovation has been repeatedly highlighted.<sup>73–75</sup> This has already been thoroughly discussed in the previous chapter and incorporated into our model of Infusion of eHealth Innovations in Health Service Organisations.

Evaluation can be difficult in a complex programme such as the NPfIT and specifically the CRS as it is likely to affect a variety of organisational and individual aspects. Nevertheless, evaluation is integral to the process of design, implementation and adoption of innovations and therefore a worthwhile endeavour. This will need to involve allocating designated staff and involve giving feedback to the public, individual staff, departments and trusts. It will also involve a deliberate effort of investigating intended and unintended outcomes as well as knock-on effects.

An evaluation of the implementation and adoption of the NHS CRS in several primary care sites participating in the early adopter programme has already been commissioned by NHS CFH.<sup>34</sup> However, there is also a pressing need to ensure that audit and feedback are in place during the national roll-out of the application. To date, there is no agreed way of assessing the progress of the NPfIT, but an evaluation of the adoption of the NHS Care Record Service in secondary care is planned to be commissioned, which is promising.<sup>37</sup>

### **14.5 WHAT ARE THE IMPLICATIONS FOR NHS CFH?**

As can be seen from the preceding discussion there are a number of areas likely to facilitate the successful implementation and adoption of the NHS CRS that have already been addressed relatively well; however, other areas such as user involvement in the design of the application have been almost completely overlooked. Based on our model, we summarise in Table 14.2 key areas of successful initiative in relation to NHS CFH's efforts to implement the NHS CRS. Of particular salience in this respect are the strong support structures, setting of standards, increasing efforts of end-user involvement, commitment to training and addressing concerns relating to confidentiality and security.

Nevertheless, there are still a number of areas that warrant additional efforts. These are summarised in Table 14.3 and include addressing the design, e.g. user-friendliness of the application (if possible through end-user involvement), clearly and explicitly stating plans and goals (targeting different adopter groups),

increasing use of horizontal networks and communication, promoting positives attitudes among end-users and efforts of evaluation.

**Table 14.2 Areas of progress in relation to NHS CFH's efforts to implement the NHS CRS**

<b>Strong ministerial and managerial support for the Programme</b>	<p>Prime Minister support</p> <p>Secretary of State for Health</p> <p>Department of Health</p>
<b>Setting standards</b>	<p>Setting standards through the National Programme Implementation Guide and the Joint Guidance on the use of IT Equipment and Access to Patient Data</p> <p>NHS CFH has put in place clear management standards and structures for the NPfIT providing strong leadership</p>
<b>Application design and access</b>	<p>Access of information tailored to staff's role</p> <p>Applications in place to authenticate the identity of users</p> <p>Setting of standards through the electronic Government Interoperability Framework and Output Based Specifications</p> <p>NHS Care Records Service Registration Authority to register users</p>
<b>Addressing concerns</b>	<p>NHS Care Record Guarantee</p> <p>Designing access applications and audit trails to ensure security and confidentiality</p> <p>Public Information Programme</p>
<b>End-user involvement and evaluation</b>	<p>Ipsos MORI survey to determine the public attitude</p> <p>Early adopter sites testing the SCR</p> <p>Pilot of EPR</p> <p>Local Ownership Programme (NLOP)</p> <p>Lorenzo Core Team</p> <p>Public Engagement Team</p> <p>Do Once and Share Programme</p>
<b>Networking and key individuals</b>	<p>ESpace</p> <p>Setting up links with academic institutions, IT organisations, voluntary and patient advice groups</p> <p>Clinical leads as key individuals promoting change</p>
<b>Training and Development (ETD) programme</b>	



### Box 14.3 Areas for improvement in relation to NHS CFH's efforts to implement the NHS CRS

Application design and access	<p>Need to increase the user-friendliness of the application (consider emergency access to information, visual appeal—this is best done through end-user involvement)</p> <p>Ensure adequate positioning of computers (consider emergencies and system failure)</p> <p>Ensure clear standards for information input</p> <p>Allow for flexibility of application and potential for re-invention</p>
Be more clear and explicit about	<p>Users of the application and how they will use it</p> <p>A detailed training plan and when it is implemented</p> <p>An accurate timeline and clear estimation of cost</p> <p>How support will be provided (early and continuous)</p> <p>Access to help and support</p>
Increasing utilisation of social networks and individuals	<p>Need for greater utilisation of horizontal networks</p> <p>Need to utilise key individuals to act as champions in all adopter groups</p>
Creating awareness and promoting positive attitudes	<p>Increased efforts to reduce the negative perception of the NPfIT especially among clinicians</p> <p>Actively seek and diffuse concerns</p> <p>Communicate the usefulness of the application with quantitative means</p>
Increased communication and user input	<p>Local structures and management</p> <p>NHS CFH as the change agency and implementation sites/adopters</p> <p>Target and inform end-users in the pre-adoption stage (as early as possible and not just before the CRS is introduced in their area as is the case in the Public Information Programme)</p>
Need for an evaluation of effectiveness of the programme and designated staff to investigate intended and unintended outcomes as well as knock-on effects	
Increased efforts exploiting the potential of cost-effective incentives	

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## 14.6 CONCLUSIONS

In conclusion, Greenhalgh et al.'s framework has been of considerable value, particularly in aiding to identify practical techniques on how perceptions of the newly introduced application among potential adopters may be most effectively targeted.<sup>1</sup> Their framework has also helped to highlight contextual (both micro and macro) factors that need to be addressed when the NHS CRS is implemented in order to facilitate successful adoption.

Although the model is generic enough to be applicable to eHealth innovations, it clearly needed some adaptation to increase its applicability in this context. This has been relatively straightforward to do by incorporating aspects surrounding the design of the innovation with end-user needs (ie human factors).<sup>17;18</sup> The adapted model has been extremely helpful in understanding the socio-techno-cultural dimensions of organisational change in the context of the NHS CRS.

Having applied the new model to the case of the NHS CRS, it is clear that NHS CFH, although having overlooked a very important step, namely user involvement in the design stage, are important in-roads in terms of the implementation or adoption strategy. Particularly promising are efforts concentrating on increased user involvement, evaluation, training, addressing issues surrounding security and confidentiality, utilising the influence of clinical leads and piloting in early adopter sites, this latter issue being especially important given the fact that end-user involvement during the design stage was overlooked. But particular on-going problems include the lack of clarity regarding the detail of CRS and impact on end-users, the lack of data on effectiveness and the lack of opportunity for clinicians to meaningfully engage and experiment with this innovation.

We strongly recommend detailed usability assessments and testing of the application during the pilot stage (ie the early adopter programme and its evaluation) and the availability of extensive real time support and tailored training before and during implementation. It will further be important to develop feedback loops in relation to future updates of the SCR and DCR and incentives to be put into place appropriately. Utilising horizontal networks and improving communication with end-users as well as management will be essential throughout this process. Greater clarity on the exact nature of SCR and DCR and revised timeline and cost estimates are additional essential steps that should be taken as soon as possible to minimise further professional or patient alienation. Increasing efforts also need to concentrate on devising appropriate means of evaluation and feedback.

Yet, despite fitting with existing evidence, the explanatory power of our model has as yet not been empirically tested. It is therefore important to keep

in mind that neither the model itself, nor our adaptation of it, will guarantee the successful implementation and adoption of the NHS CRS.

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## SECTION 4

# CONCLUSIONS, DISCUSSION AND FUTURE RESEARCH PRIORITIES

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## CHAPTER 15

### Conclusions, discussions and recommendations

#### SUMMARY

- We have in undertaking this work made four main methodological contributions to this nascent field, namely:
  - development of a very comprehensive search strategy for identifying high quality primary and secondary literature investigating the impact of eHealth on the quality and safety of healthcare
  - development of integrated conceptual maps of eHealth, quality and safety, which have, as demonstrated in this project, the ability to draw attention to the major potential benefits and risks associated with use of a variety of eHealth applications.
  - development of a tool, based on internationally agreed approaches, for critically appraising systematic and quasi-systematic reviews of eHealth applications.
  - adapted and developed existing theories relating to the diffusion of innovations to propose a model which may help identify key parameters for the successful design, implementation and ultimately adoption of eHealth innovations into complex healthcare environments.
- This project has also laid the foundations for the creation of an important international resource—*NHS Connecting for Health Database of Systematic Reviews and Randomised Controlled Trials in eHealth*—that should, we believe, once fully developed, be of international interest to all those with an interest in information technology and its impact on healthcare delivery.
- The formative work for this project and the review of technical reports and a variety of review documents clearly demonstrate that eHealth applications have the potential to dramatically improve the quality of healthcare delivery. Perhaps even more importantly, there is also considerable potential to improve the safety profile of clinical practice through the elimination of both latent and active errors and promoting

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real-time systems checks and professional support.

- The major finding from reviewing the empirical evidence—which is considerable but of very variable quality—is that there is very limited rigorous evidence demonstrating that these technologies actually improve either the quality or safety of healthcare.
- Despite these substantial gaps in the evidence-base, we are, based on the theoretical work and empirical evidence reviewed, cautiously optimistic that a number of the eHealth applications being introduced through NHS Connecting for Health’s National Programme for Information Technology are likely to result in significant medium- to long-term benefits to organisational efficiency and patient care.
- We would in particular encourage NHS Connecting for Health to prioritise the incorporating of appropriately designed ePrescribing capability, ideally with decision support functionality, in an integrated way into the NHS Care Records Service.
- Realising the benefits of this and other technological advances is, however, crucially dependant on actively facilitating end-user input throughout the commissioning, design, development and implementation process as this will maximise the chances that clinically relevant and helpful tools are developed and then appropriately used.
- Appreciating the structural, organisational and, to a lesser extent, professional challenges that need to be overcome in deployment should, however, never be overlooked. This is particularly important when complex transformative technologies such as the NHS Care Records Service are introduced. The need for training in the use of new technologies and on-the-job support also needs much greater appreciation than has hitherto been the case.
- End-user consultation and obtaining feedback should be viewed as an on-going processes which should continue after deployment to ensure that any problems are identified early, as are possible solutions, which can then be incorporated into system upgrades.

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## **15.1 INTRODUCTION**

The specific conclusions and implications of our work in relation to specific eHealth technologies and the more cross-cutting issues of interoperability human factors considerations have been summarised and reflected on in chapters in the preceding Section of this report (Chapters 5–13). In this penultimate chapter, we seek to pull together some of the key overarching developments and conclusions arising from this work, consider the strengths and limitations of the approach adopted, and reflect on some higher order policy implications arising from our findings. The following final chapter of this report will similarly seek to summarise some key overarching research implications arising from this review.

## **15.2 KEY METHODOLOGICAL DEVELOPMENTS**

The process of identifying, critically appraising, interpreting and synthesising the evidence was challenging and necessitated developmental work on four key fronts, each of which we briefly consider below.

### **15.2.1 APPROACHES TO IDENTIFYING THE EVIDENCE**

Our initial scoping of the literature revealed that much of the potentially relevant published literature was poorly indexed in medical databases. To identify this literature we therefore needed to develop a novel search strategy, which we did using several iterative cycles of extracting key terms, searching and then reflecting on the literature identified as discussed in Chapter 2. The resulting search strategy (see Appendix 1) is we believe the most comprehensive ever produced and should be of considerable benefit to academics in the field. That said, given the speed with which this field is evolving, we recommend that this search strategy be periodically updated. Based on our experiences, we have a number of recommendations regarding key words and indexing of this literature, which we plan to discuss with Medline with a view to promoting improved access to this literature.

### **15.2.2 TOOLS TO CRITICALLY APPRAISE THE LITERATURE**

Assessing quality of primary or secondary research is an elusive metric.<sup>1–4</sup> There has in recent years been a welcome proliferation of tools with which to critically review the literature.<sup>5</sup> However, our assessment of these revealed that none were appropriate for our purposes, the major problems being the lack of appreciation that systematic reviewers may be willing or consider it appropriate to incorporate a range of study designs—particularly those that are

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non-randomised controlled-based—and the lack of interpretation<sup>6</sup> or attention to describing or capturing contextual considerations, which were often of crucial importance. Our focus on safety issues,<sup>7–9</sup> delivery, organisation and implementation posed a further challenge.<sup>10–19</sup> We found our adapted Critical Appraisal Skills Programme tool (see Appendix 2) appropriate for our needs and we hope that others working in this area also find it to be useful.

### **15.2.3 INTEGRATED CONCEPTUAL MAPS OF EHEALTH, QUALITY AND SAFETY TO AID INTERPRETATION OF STUDIES**

Building on earlier conceptual mapping of the field of eHealth, we were able to characterise three key areas of application of the range of technologies which are now becoming available, namely: managing data; supporting professional decision-making; and supporting patients through telemedicine and the field of consumer informatics. Considering the inter-relationships between these applications enabled us to put boundaries around the review and also, through integrating the domains of quality and safety, to develop a helpful conceptual framework within which to reflect on potential benefits and risks, but also within which to identify possible areas of congruence and dissonance between these theoretical reflections and the actual empirical evidence-base (see Chapter 4).

### **15.2.4 ADAPTATION OF EXISTING INNOVATIONS THEORY TO DEVELOP A FRAMEWORK FOR INFUSION OF EHEALTH INNOVATIONS IN COMPLEX HEALTHCARE SETTINGS**

A key finding from the review of the human factors literature is the real risk of failure of eHealth innovations if commissioners, designers and programme managers fail to pay adequate attention to the aspirations, beliefs, perceptions and experiences of end-users.<sup>20;21</sup> Our review of the literature revealed a number of helpful socio-cultural theories within which to envision change management in a healthcare context, but none of which specifically related to the controlled introduction of (complex) eHealth innovations. Drawing on the most relevant theories we have developed a new model, which, based on our experiences of conducting the detailed case study presented in the preceding chapter, provided a useful explanatory framework within which to assess whether adequate attention is being paid to design, implementation and adoption considerations, whilst also considering factors relating to both the inner organisational context and the wider socio-political terrain (see Chapter 14). As with all such frameworks, its predictive ability remains as yet unknown; nonetheless, we hope that this *Infusion of eHealth Innovations in Health Services Model* provides a helpful



framework within which to conceptualise planned information technology (IT) interventions in complex healthcare environments.

### 15.3 KEY RESOURCE DEVELOPMENT: LAYING THE FOUNDATIONS FOR AN INTERNATIONAL DATABASE OF HIGH QUALITY EVIDENCE

This aforementioned work has enabled us to lay the foundations for a potentially very valuable resource, namely a database of high quality critically appraised, appropriately interpreted and indexed evidence. Whilst we are aware that other databases of eHealth exist, none is as comprehensive or potentially as policy or practitioner or user orientated as the one we hope to create. This would therefore, we believe, be of considerable international interest and benefit, particularly if access was made available, free of charge, through the Internet. That said, undertaking the further developmental work needed to ensure that this is ready for general use would require a considerable amount of additional work; there is in addition the need to keep this database up-to-date. Figures 15.1–3

**Figure 15.1-3 Mock-up of NHS Connecting for Health Evaluation Programme Database of Systematic Reviews and Randomised Controlled Trials.**

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**NHS Connecting for Health Evaluation Programme Database**

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**Publication Finder**

Reference:

**Keyword**

**Title**

**Author**

**Journal**

**Year**

**Study Design:**

- ☐ Randomised Controlled Trial
- ☐ Review (non-systematic)
- ☐ Systematic Review & Meta-analysis

**Evaluated Outcomes:**

- ☐ Hardware and Technical Quality
- ☐ Software Quality
- ☐ General Computer Knowledge
- ☐ Attitude towards Computers/User Satisfaction
- ☐ Usage Patterns
- ☐ Quality of Documented and Processed Information
- ☐ Technology Costs
- ☐ Organisational or Social Aspects of Patient Care
- ☐ Quality of Patient Care
  - ☐ Costs of Patient Care
  - ☐ Efficiency of Work Processes
  - ☐ Appropriateness of Patient Care
  - ☐ Medical Error

**Setting:**

- ☐ Hospital/inpatient
  - ☐ Tertiary Care
  - ☐ Intensive Care
  - ☐ Surgical Care
- ☐ Outpatient/ambulatory
  - ☐ Secondary Care
  - ☐ Primary Care
- ☐ Accident & Emergency
- ☐ Integrated Delivery Network (IDN)
- ☐ Nursing home
- ☐ Pediatrics
- ☐ Pharmacy
- ☐ Radiology
- ☐ Laboratory
- ☐ Pathology

**Technology:**

- ☐ Computerised Provider Order Entry
- ☐ Electronic Health Record
- ☐ Electronic Patient Record
- ☐ Results Reporting/Viewing Systems (Laboratory, Pathology)
- ☐ Intensive Care Information and Documentation Systems
- ☐ Surgical Care Information and Documentation Systems
  - ☐ Anesthesia Information and Documentation Systems
- ☐ Nursing Information and Documentation Systems
- ☐ Radiology Information Systems
  - ☐ PACS
- ☐ Pharmacy Information Systems

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### Publication Finder - Search Results

Number of records found: 96 << < 1 of 10 > >>

<b>Title:</b>	Computer-assisted care improves outcomes in people with diabetes		
<b>Authors:</b>			
<b>Journal:</b>	Evidence-based Healthcare & Public Health	<b>Year:</b>	2004
<b>Title:</b>	[The evidence base of clinical practice guidelines, health technology assessments and patient information as a basis for clinical decision-making]. [German]		
<b>Authors:</b>	Antes, G. and Antes, Gerd		
<b>Journal:</b>	Zeitschrift für Ärztliche Fortbildung und Qualitätssicherung	<b>Year:</b>	
<b>Title:</b>	A Web-based diabetes care management support system		
<b>Authors:</b>	Baker, A. M., Lafata, J. E., Ward, R. E., Whitehouse, F., Divine, G., Baker, A. M., Lafata, J. E., Ward, R. E., Whitehouse, F., and Divine, G.		
<b>Journal:</b>	Joint Commission Journal on Quality Improvement	<b>Year:</b>	2001
<b>Title:</b>	Impact of a clinical decision support system on the management of patients with hypercholesterolemia in the primary healthcare setting		
<b>Authors:</b>	Bassa, A., Del, Val M., Cobos, A., Torremade, E., on, S., Crespo, C., Brosa, M., io, S., and Espinosa, C.		
<b>Journal:</b>	Disease Management & Health Outcomes	<b>Year:</b>	2005

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### Publication Finder - Publication

<b>Ref Type:</b>	Journal
<b>Ref ID:</b>	6470
<b>Title:</b>	Assessment of decision support for blood test ordering in primary care. a randomized trial
<b>Authors:</b>	van Wijk, M.A.; van der, Lei J.; Mosseveld, M.; Bohnen, A.M.; van Bommel, J.H.; van Wijk, M.A.; van der Lei, J.; Mosseveld, M.; Bohnen, A.M.; van Bommel, J.H.;
<b>Pub Date:</b>	2001/2/20
<b>Notes:</b>	11182837Annals of internal medicine0372351, 5a6AIM, IMClinical Trial. Comparative Study. Journal Article. Randomized Controlled Trial. Research Support, Non-U.S. Gov'tEnglish
<b>Keywords:</b>	Behavior; Clinical; Computerized; Controlled; Decision Support Systems; Decision Support Techniques; Faculty; Family Practice; Female; Forms and Records Control; General; Group; Group Practice; Guideline Adherence; Guidelines; Health; Hematologic Tests/ut [Utilization]; Humans; Internal; Internal Medicine; Laboratory; Male; Medical; Medical Informatics; Medical Records Systems; Medicine; Methods; Netherlands; Nonparametric; Physician's Practice Patterns; Poisson Distribution; Practice; Practice Guidelines; Records; Reducing; Regression Analysis; Research; Research Support; Science; Software; Statistics; Universities; University;
<b>Reprint:</b>	Not in File
<b>Journal:</b>	Annals of Internal Medicine
<b>Volume:</b>	134
<b>Issue:</b>	4
<b>Start Page:</b>	274
<b>End Page:</b>	281
<b>Pub Place:</b>	United States
<b>Abstract:</b>	BACKGROUND: Different methods for changing blood test-ordering behavior in primary care have been proven effective. However, randomized trials comparing these methods are lacking. OBJECTIVE: To compare the effect of two versions of BloodLink, a computer-based clinical decision support system, on blood test ordering among general practitioners. DESIGN: Randomized trial. SETTING: 44 practices of general practitioners in the region of Delft, the Netherlands. PARTICIPANTS: 60 general practitioners in 44 practices who used computer-based patient records in their practices. INTERVENTION: After stratification by solo practices and group practices, practices were randomly assigned to use BloodLink-Restricted, which

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provide a mock-up for a possible front-end of such a database, which we have tentatively called the *NHS Connecting for Health Database of Systematic Reviews and Randomised Controlled Trials in eHealth*.

## **15.4 MAIN OVERARCHING FINDINGS**

### **15.4.1 A RIPE ENVIRONMENT FOR INFORMATION TECHNOLOGY IN HEALTHCARE**

Given the serious financial and resource implications of ageing populations, improved survival from a range of acute and long-term disorders, and the ever-increasing array of treatment options now available, health services need to find new, more cost-effective ways of delivering care.<sup>22;23</sup> Also of relevance here are rising public expectations for accessible,<sup>24</sup> timely<sup>25–27</sup> and high quality care, and the associated epidemiological and health services work demonstrating considerable and at times very worrying variations in quality of care between healthcare providers, and threats to patient safety.<sup>28</sup> In parallel with these demographic transitions and concerns about the future funding of state-run health services, there have been dramatic advances in both hardware and software capabilities, such that technology now plays an integral part of the lives of most people in economically developed societies and this is increasingly also true with respect to those living in the less economically developed world also (witness the spread of mobile phones,<sup>29</sup> or personal computers for example).<sup>30</sup>

It is the coming together of this need to find novel personalised cost-effective solutions and the development of technological capabilities that have created an environment in which the development of IT applications in relation to healthcare have been able to proliferate.<sup>31–33</sup> Given that these trends are, for the foreseeable future at least, set to continue and the considerable commercial interest associated with these developments,<sup>34</sup> we anticipate that the number of IT solutions being developed and the range of conditions or indeed behavioural factors for which they may have a role and the speed with which they become available will continue to increase rapidly. At present Europe has a competitive advantage in the ‘eHealth industry’ with an opportunity for this to become one of the largest in the health sector with a turnover of €11 billion or 5 per cent of the total health budget by 2010.<sup>34–39</sup>

### **15.4.2 A VAST AND RAPIDLY EXPANDING BODY OF LITERATURE THAT IS POORLY INDEXED, APPRAISED AND ORDERED**

In many ways, it is encouraging—given the relatively nascent fields of eHealth, quality and safety—that there is now such a large body of academic work at the intersection between these relatively immature fields of enquiry. As noted above,

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this reflects the real sense of opportunity that these technological innovations can positively impact on care provision, patient outcomes and cost.<sup>39;40</sup> As is also noted above, however, the relative infancy of these fields did (and to an extent continues to) pose a number of difficulties for researchers and those wishing to interpret this evidence.<sup>41–44</sup> The inter-relatedness of many of the technologies being developed and the different contexts in which these have been developed and deployed adds to the complexity of producing meaningful taxonomic frameworks and assessing likely effectiveness and generalisability.

#### **15.4.3 EVIDENCE OF VARIABLE QUALITY THAT IS DIFFICULT TO INTERPRET**

Our formal assessment of the quality of empirical evidence has demonstrated that the field of eHealth research is plagued with research of varying quality (see Appendix 5). Another point of concern relates to the outcome measures that have been used in eHealth research. Relatively few studies reported on safety outcomes<sup>18;45</sup> when evaluating new technologies, whilst others sometimes failed to assess the most salient dimensions of quality.<sup>34;46–49</sup> Cost-effectiveness was furthermore rarely formally studied,<sup>49</sup> even though new eHealth applications are frequently promoted as being ‘cost-saving’.<sup>39</sup>

It is important to note that many of the studies revealing the clearest evidence of benefits emanate from academic clinical centres where developers of new applications have also been directly associated with the evaluation of these technologies.<sup>50–53</sup> This double role of developer and evaluator or researcher (and in some cases also being a user) of an application represents a noteworthy conflict of interest and leads to the potential for appreciable information bias. But perhaps more importantly, it may influence the findings of studies through dynamics that are not monitored or accounted for, such as the degree of motivation or computer literacy of end-users of these applications and the extent to which they contribute to design and re-design of an application that is under evaluation. These so-called home-grown applications are the ones that have invariably demonstrated evidence of greatest benefits. It is however unclear how effective these applications would be if employed in other environments.

#### **15.4.4 VAST GAP BETWEEN THEORETICAL AND EMPIRICALLY DEMONSTRATED BENEFITS**

Our synthesis of evidence on the impact of IT on quality and safety of healthcare has demonstrated a vast gap between the theoretical and empirically demonstrated benefits. Although seminal reports on quality and safety of healthcare<sup>54</sup> invariably recognise IT as one of the main vehicles for making

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radical improvements in delivery of healthcare, our work shows that realising these will require substantial effort and time. Most of the technologies are at present supported only with either face validity and or modest or weak empirical evidence. There is thus the need for much more evaluation of promising technologies, which unless adequately academically studied, may not “mature” to the extent that is needed for these to realise fully their potential when deployed in every-day clinical settings.<sup>55;56</sup>

The paradox is that whilst the number of IT applications in healthcare and software programmes is growing (high dissemination), we still have insufficient understanding of how, why, and under what conditions, such interventions might work (low evaluation). Healthcare needs IT solutions that are both theoretically- and empirically-based.

#### **15.4.5 INADEQUATE ATTENTION BEING PAID TO SOCIO-TECHNO-CULTURAL CONSIDERATIONS**

A contributing factor to this gap between theoretical and empirical factors is that many of the applications developed are not fit-for-purpose. Flagging of drug interactions, for example, is potentially a very important benefit given the frequency with which medication errors occur. Studies however repeatedly show that most prompts about drug-interactions are ignored by doctors as they are perceived as clinically irrelevant.<sup>57;58</sup> Greater attention to the design considerations such that they provide grades of advice and support, offer alternatives, and for the most serious issues prevent overriding for example, could greatly enhance the usefulness of such professional support tools and increase the likelihood of these achieving their intended outcomes. This is however dependant on these human factors being accorded at least as much priority as the more technical developments, which is where the majority of attention and resources continue to be devoted.

### **15.5 MAIN STRENGTHS AND LIMITATIONS OF THIS OVERVIEW**

#### **15.5.1 STRENGTHS**

We have reviewed, synthesised and attempted, with the help of a novel conceptual framework for understanding the inter-relationships between eHealth, quality and safety, to interpret a very large body of disparate knowledge of varying methodological quality. In so doing, we have, through using a comprehensive strategy for searching the major medical databases, sought to identify work of high quality and then, through subsequent searching of references and the grey literature, snowballed to incorporate the broader theoretical, technical,



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socio-technical and change management literature, where appropriate. Recognising the potential importance of this work to the future development and roll-out of the policy and research agenda of NHS Connecting for Health (NHS CFH), we have furthermore wherever possible, tried to consider the policy and research implications of our findings. The result is, we believe, a comprehensive overview of the relevant theoretical and empirical literature in relation to the impact of key dimensions of eHealth, namely approaches for the storage and management of patient records and professional support tools, and ways in ensuring that these are designed, developed and deployed in such a way that they are likely to prove acceptable to end-users and, ultimately, effective when implemented in routine care.

#### **15.4.2 LIMITATIONS**

There are, however, a number of limitations that need to be borne in mind when considering the findings from this review, many of which are common to umbrella reviews of this kind. The main issue is that in focusing on systematic and quasi-systematic reviews, we were to a large extent dependant on the quality of and reporting of data in these reviews, which was on the whole quite variable. This in turn, somewhat reflects the underlying problems with the primary literature, which we needed to turn to on several occasions to obtain further clarity on issues. Ideally, we would have undertaken this more frequently but given the initial developmental work that needed to be undertaken and furthermore the volume of potentially relevant evidence identified, time constraints made this difficult. There is therefore the possibility that we may have overlooked some key findings not picked up by reviewers and or that we may have misinterpreted some evidence. We are also at risk of overlooking studies that may in turn have been missed by authors of individual reviews.

Our review has focused primarily on the relevant quantitative literature, but given the importance of contextual factors in interpreting the findings from these studies, it is important that the broader descriptive and qualitative literature is also considered. This was achieved to an extent because many of the systematic reviews included in this overview incorporated a far broader array of designs than is commonly included in, for example, effectiveness reviews which include only randomised controlled trials. Our snowballing approach to the identification of studies also helped to identify some of this work but we cannot in any way claim that we have been comprehensive in our identification, retrieval or review of this literature, which is, given the very poor indexing of this literature, a very time consuming and labour intensive process.



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There are thus some important potential limitations, however, despite these potential limitations, we are confident that this work has produced a reliable summary of a highly rich, complex, rapidly evolving but crucially important field of enquiry, which we hope will prove useful to policy-makers, practitioners and members of the public alike.

## **15.6 RECOMMENDATIONS FOR POLICY**

Based on our synthesis of the evidence described above and wider trends within the IT sector, we consider below some key policy considerations.

### **15.6.1 INTEROPERABILITY**

The critical importance of ensuring interoperability between the increasingly numerous and diverse applications now commonly used in healthcare settings is widely recognised.<sup>58</sup> Currently, most IT applications in the NHS are not interoperable; that is to say that they cannot exchange information electronically. NHS Connecting for Health is now active (on a global scale) in developing and ensuring interoperability and such efforts need to be sustained at both a national and international level. It is particularly important that agreed standards are enforced across all applications used by the NHS, including those already in use but particularly in relation to procurement of new technologies to avoid potentially serious problems with information saved in different formats or standards.<sup>54</sup>

### **15.6.2 DATA QUALITY**

Far greater attention needs to be given to the quality of data being recorded by healthcare professionals as this will be crucial to maximising the potential benefits of the introduction of the NHS Care Records Service. Correctness and completeness of data is of utmost importance not just for current clinical care but even more for future care when many computerised decision support systems (CDSSs) and other applications will critically depend on the quality of the recorded data; inaccurate information may lead to wrong and potentially dangerous recommendations. Accurate data recording of clinical information is also required to ensure effective secondary uses of the data, including applications for paying for episodes of healthcare (such as Payment by Results), needs assessment and public health monitoring, quality measurement, and research.

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### **15.6.3 COMMITMENT TO EVALUATION**

As eHealth is with us to stay and is furthermore very likely to continually expand its role in aiding the management and provision of healthcare, it is vital that we take every opportunity to learn from the largest IT commissioning and deployment project in healthcare in the world. The National Programme for Information Technology (NPfIT) offers an unparalleled opportunity not just for introducing improvement into NHS but also to learn how to implement IT into healthcare and how to further improve it once introduced. The Programme could also have far-reaching implications, not just for England but also for many other countries as they introduce electronic health records and other eHealth applications. Linked to this is the potential for economic benefits: as well as the eHealth market in the UK, opportunities may exist to export much of the knowledge and technology developed in the UK.

Due to the continually evolving nature of IT, it is inevitable that many of the applications currently being introduced will be due for major upgrade, improvement or replacement within the next few years. Developing the at-present very weak evidence-base in relation to how to facilitate implementation and adoption is therefore likely to result in significant long-term benefits. Bearing this in mind, we strongly recommend that, wherever possible, implementation proceeds within the context of carefully considered evaluation (see Chapter 16).

### **15.6.4 COMPARATIVE STUDIES TO GUIDE PROCUREMENT DECISIONS**

There is an urgent need for comparative head-to-head studies in relation to IT applications that healthcare systems are considering procuring. It is somewhat paradoxical that head-to-head rigorously conducted trials are the “gold standard” for evaluation of other health technologies (eg new medicines or surgical interventions), but not eHealth applications. While we realise that these may be in some cases difficult as the interventions may be multiple and their pathways to impact complex or subject to effect modification, alternative rigorous methodologies for evaluation can nonetheless be considered. Simple satisfaction surveys and face-validity should not be taken as constituting sufficient evidence.

Commercial and home-grown applications procured by NHS CFH for the NHS should undergo the same rigorous evaluation as would be expected for new medicines as they may have comparable effects—positive and negative—on patients’ health, the safety of healthcare, costs, and on the overall quality of care. In line with the above recommendation, a European regulatory body comparable to European Medicines Agency could help ensure that rigorous

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standards for the quality and safety of IT applications (such as ePrescribing applications) are met. Such a body could in collaboration with the European Medicines Agency proactively engage in research on ePrescribing, for example, and compile a list of all important medication interactions and create a priority list for implementation for software developers and then support evaluation.

#### **15.6.5 DEVELOPING HOME-GROWN APPLICATIONS**

Given the repeated emphasis on the importance of contextual factors it is important to appreciate that evidence from the US is, given the very different healthcare systems in operation, often unlikely to be generalisable to a UK context in any simplistic way. Furthermore, given the strength of evidence that home-grown applications produce the best outcomes, NHS CFH should consider supporting development and rigorous evaluation of selected home grown NHS applications over commercial off-the-shelf applications. As there are currently over 5,000 different applications in use in the NHS—many home-grown—a mechanism could be developed to try to learn from and support further development of the best of these so that they meet standards expected for use on a larger perhaps national scale.

#### **15.6.7 STAFF TRAINING AND DEVELOPMENT**

The NHS is Europe's largest employer with a workforce of over one million people, approximately half of whom operate in clinical roles. Information technology already impacts on many workers' day-to-day role and it will in the months and years to come set to impact on more-and-more of this workforce in an increasingly profound way. Given the acknowledged training needs of this workforce, it is particularly important that every opportunity is taken to promote the relevant knowledge, skills and competencies, for example beginning in medical and nursing schools but extending throughout staff's working careers.

#### **15.6.6 INTERNATIONAL COLLABORATIONS**

Information technology in healthcare is now a top priority in the European Union, US and most Organisation for Economic Co-operation and Development (OECD) countries. This mutual interest provides a strong basis for promoting collaborative endeavours such as in relation to the development and enforcement of standards and the mutual sharing of lessons and experiences from attempts at IT-based healthcare reform. Such learning is at present suboptimal and evaluation efforts are in some areas duplicated whilst in other areas large gaps

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remain. International collaborations can help in the development of high quality eHealth applications and also in the evaluation of eHealth applications by making such evaluations less environment-specific and more generalisable.

## **15.7 CONCLUSIONS**

The key overarching conclusions to emerge from this work relate to the substantial potential that eHealth applications offer in transforming, personalising and improving the accessibility of care but that, perhaps unsurprisingly, given the relative infancy of this field of enquiry, it remains largely unclear to what extent this potential will be realised. Factors contributing to this uncertainty include the fact that, unlike in many other areas of medicine, interventions often continue to be implemented based on the simplistic assumption that the benefit associated with their introduction is self-evident, but also that given the importance of end-user acceptance and engagement with the technology, realising the benefits of this technology is highly context dependence.

What has also not helped is that in some, or possibly many, cases technology has been introduced without adequate attention to the needs of end-users (ie the innovation has been technologically rather than clinically driven), with the result that interventions are introduced which have very little clinical applicability and if anything make delivery of high quality care harder to achieve than was previously the case.

Integration and interoperability are extremely important considerations in ensuring that these technologies actually embed with existing working patterns and it is therefore crucial that national standards are agreed, communicated to technology developers and then applied. The NHS Connecting for Health's sign up with Continua Health Alliance is an important development in this respect.

Given the widespread gulf identified between the theoretically described potential benefits and the actual empirically demonstrated benefits and risks, it is imperative, particularly given the levels of investment currently taking place in eHealth to strategically begin to prioritise future research in this field. This is, however, dependant on a clear appreciation of the likely benefits and risks, the ways of identifying and appraising relevant literature and also an awareness of the current body of world knowledge, all of which this review has made important progress in addressing. This now needs to be taken forward initially by expanding this review in relation to other key areas of eHealth, such as consumer informatics, telecare and eLearning, and then synthesising this with the current body of work. There is also clearly the need to keep this review

up-to-date to ensure that eHealth implementation strategies remain based on the best currently available evidence.

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## CHAPTER 16

### Future research priorities

#### SUMMARY

- Whilst the theoretical benefits of introducing eHealth applications are potentially endless, there exists a wide divide between what has been theorised and what has been empirically demonstrated.
- Contributing to this deficit of evidence is both a relative lack of research in relation to the number of eHealth applications being deployed and the relatively poor quality of primary and secondary work that characterises much of this field of enquiry.
- Given the continuing likely investments in technological solutions, it is important that strategic higher order research considerations are prioritised whilst at the same time also commissioning evaluations in relation to specific technologies.
- Key strategic considerations for improving the quality of research include the need for research that will generate greater conceptual clarity and consensus about the nature of the discipline, an agreed taxonomic framework for considering the increasing number of eHealth applications that are now emerging and methodological advances in relation to enabling their rapid but nonetheless rigorous evaluation.
- Research toolkits for academics, commissioners of research and journal editors are needed, both in relation to primary research and systematic review techniques.
- There is also the need to increase research capacity in this area and we recommend creation of junior and senior fellowship opportunities, and the creation of interdisciplinary research networks to facilitate methodological advances and also application specific understanding.
- Also contributing to the lack of evidence of beneficial impact of eHealth applications is our as yet immature understanding of how effectively to design, implement and facilitate successful adoption of these new technologies; research into these socio-techno-cultural considerations needs in particular to be prioritised.

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## 16.1 INTRODUCTION

eHealth applications have many theoretical benefits and offer the potential to radically transform the delivery, safety and quality of healthcare. However, as highlighted by this systematic overview of the literature, there is an enormous gulf between these potential benefits and the actual evidence-base in support of eHealth applications. In part, this reflects the relatively few evaluations taking place compared to the number of deployments of technology in healthcare. This in turn reflects the commonly held belief that the benefits of eHealth applications are so self-evident that no formal evaluation of many such interventions is actually needed. As Auerbach et al. note in their recent thoughtful contribution, ‘... contrary to the principles of evidence-based healthcare, many novel quality and safety improvement strategies are rapidly disseminated without strong evidence to support their wider uptake’.<sup>1</sup> That said, and as highlighted by this report, there have now clearly been a number of evaluations reported and furthermore academics are increasingly trying to synthesise these in a transparent manner. The standards of much of this evidence has, however, been found wanting, this reflecting a number of underlying systemic failings and barriers.<sup>2</sup>

Building on previous chapters, in which we highlight specific examples of areas in which the evidence-base needs strengthening with regards to particular applications (Chapters 6–11) and cross-cutting themes (Chapters 5, and 12–14), we here focus on higher level conceptual, methodological and policy considerations which, if addressed, could greatly contribute to improving the evidence-base in the emerging field of eHealth.

## 16.2 HIGH LEVEL AREAS FOR FURTHER RESEARCH

Although a review of evaluation studies of eHealth applications between 1982 and 2005 found a slight increase in methodological quality over this time period, the authors concluded that the quality of published eHealth evaluation studies was still inadequate to produce reliable evidence for clinicians and policy-makers.<sup>3</sup> Our experience of engaging with the more contemporaneous literature suggests that little has changed.

### 16.2.1 FURTHER THEORETICAL WORK

We have, as reported in Chapters 4 and 14, needed to undertake conceptual work, firstly to try and organise and aid interpretation of the vast body of work uncovered and, secondly, to help think through the issues of potential importance that need to be considered in relation to successful deployment of eHealth applications. This developmental work, whilst useful does, however, need to be further

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refined and, importantly, with respect to our *Infusion of eHealth Innovations in Health Services Organisations Model* this needs to be prospectively evaluated to assess the practical utility of this framework. Additional developmental work on the integrated conceptual maps of eHealth, quality and safety to assess if these are practically useful for policy-makers and academics working in this area and furthermore whether these remain fit-for-purpose as the number of eHealth applications continues to burgeon are also needed.

### **16.2.2 MATURATION OF METHODOLOGY IN PRIMARY RESEARCH**

Although our focus in this overview was on reviewing evidence from secondary sources, it is clear that there are a number of limitations with much of the primary evidence in this field. Issues relating to the selection of the most appropriate study design,<sup>4</sup> selection<sup>5</sup> and definition of outcomes to be studied,<sup>6</sup> statistical analysis,<sup>7</sup> transparency<sup>8</sup> and poor reporting<sup>9</sup> have all contributed to a mismatch between the volume of research that has been conducted and what can be reliably concluded about the likely impact of these technologies. A common conclusion of systematic reviews of eHealth applications is thus, perhaps unsurprisingly, a call for more rigorously conducted studies. This is usually an explicit call for more randomised controlled trials; what is however needed is not just simply more trials, but ones that are more appropriately designed to answer the types of questions that are particularly relevant in this area. For example, one potentially highly applicable version is the stepped wedge randomised trial design which Brown and Lilford describe as involving:<sup>10</sup>

‘... sequential roll-out of an intervention to participants (individuals or clusters) over a number of time periods. By the end of the study, all participants will have received the intervention, although the order in which participants receive the intervention is determined at random. The design is particularly relevant where it is predicted that the intervention will do more good than harm (making a parallel design, in which certain participants do not receive the intervention unethical) and or where, for logistical, practical or financial reasons, it is impossible to deliver the intervention simultaneously to all participants. Stepped wedge designs offer a number of opportunities for data analysis, particularly for modelling the effect of time on the effectiveness of an intervention.’

Primary eHealth research has consistently lacked high quality economic analyses. This limitation of previous research is particularly worrying given the very high cost of investment on eHealth applications and the belief that such investment will be highly cost-effective. In 1995, van der Loo et al. commented

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on the low rate at which negative consequences and costs of eHealth applications were assessed.<sup>11</sup> Unfortunately, the quantity and quality of economic analyses has not improved substantially since van der Loo et al. published their review in 1995. In a recent systematic review of eHealth, Chaudhry et al. concluded that empirically measured cost data in eHealth evaluations were limited and inconclusive. Studies typically used hybrid methods—frequently mixing primary data collection with secondary data collection plus expert opinion and assumptions—to make quantitative estimates for data that had otherwise not been empirically measured.<sup>12</sup> In a similar vein, in a review of health information technology evaluation studies published between 1982 and 2002, the authors found that whilst the volume and range of economic evaluations had increased, investigators routinely omitted key details about cost or effectiveness from their study designs, resulting in publications with incomplete, and potentially biased, economic findings. Of the studies that reported economic findings, 23 per cent did not report any economic data, 40 per cent failed to include any effectiveness measures, and more than 50 per cent used a case study or pre-test–post-test design. Hence, during a period when health economic evaluation methods in other areas of healthcare have developed significantly, there is little evidence of similar progress in the economic evaluation and assessment of eHealth applications.<sup>13</sup>

We also believe that it is important for primary work to explicitly consider evaluations of organisational impact (eg impact on workflow, processes of care, the overall efficiency of care as well and also psycho-social and socio-techno-cultural considerations) of eHealth interventions. This type of holistic evaluation has however been uncommon; this most likely stems from the tendency amongst researchers to focus on the clinical impact as the single most important motive for implementing eHealth applications and from a failure to think of these as complex interventions. Evaluating organisational impact is important as this complements the findings from clinical and economic evaluations. Much of the research employing the more traditional study designs used to evaluate clinical impact has thus failed to explain why the technological interventions have been successful or not.<sup>14</sup> There is now, however, increasing recognition that organisational issues are at least as important as technical considerations in relation to eHealth applications and the evaluation of these parameters is thus imperative (see Chapter 13).

Related to this are issues concerning the timeliness and time-period over which these evaluations are conducted. With respect to the former issue, as technology advances and applications evolve, previous research may rapidly



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become out-of-date and is thus of limited value if researchers have only focused on narrow end-points. Broader assessments of organisational impact, if theoretically grounded and well conducted, are however of more general interest and are less time-bound in their conclusions. With respect to the latter consideration, our review suggest that many benefits and risks are only detectable and fully understood after a reasonable length of deployment; these may therefore easily be overlooked in the short-term evaluations that are often the norm in this field.

In sum we suggest development (maturation) of the clinical, economic and organisational impact of eHealth to make future findings more practically useful. As Clamp and Keen, in the context of commenting on the effectiveness and cost-effectiveness of electronic health records note, ‘... the literature has, to-date, largely failed to deliver usable findings’.<sup>15</sup>

### **16.2.3 INNOVATIVE METHODOLOGY IN PRIMARY RESEARCH**

As noted above, there is still in general a lack of appreciation of the importance of studying and describing contextual factors when conducting eHealth evaluations. This unfortunately appears to remain the case despite repeated and long-standing calls in the literature for the formal incorporation of qualitative work into quantitative research studies. Quantitative findings need to be understood in the context in which eHealth applications are implemented and evaluated; a major potential gain from these mixed methods approaches is the opportunity simultaneously to study questions of effectiveness and the processes through which these effects are mediated. Consequently the use of pluralistic approaches to evaluation has been called for such as those employed for the evaluation of complex interventions.<sup>16;17</sup> The Medical Research Council (MRC) has produced guidance on conducting evaluations of complex interventions and Holbrook et al. are currently seeking to build on the combine current principles of health technology assessment and complex intervention research to suggest a methodologic framework that will assist in evaluations of the clinical impact of eHealth applications.<sup>18</sup>

There has thus far been a lack of truly innovative work. Innovation and creativity may very well be fostered by multi-disciplinary research. Barber et al., for example, argue that a key benefit of evaluating eHealth applications using multi-disciplinary methods is a ‘... more comprehensive understanding of the overall achievement from eHealth applications; and one that can usefully serve the wider community of policy-makers, healthcare managers, researchers, practitioners and patients.’<sup>19</sup> Future tenders in the field should

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therefore demonstrate a clear appreciation of the importance of conducting multi-disciplinary research. The regular use of multi-disciplinary research in eHealth will we believe engender interdisciplinary expertise. Recent work commissioned by NHS Connecting for Health Evaluation's Programme has in many ways being exemplary in this respect in explicitly encouraging researchers to recognise the importance of studying the broader impact of the eHealth innovation under study.<sup>20</sup>

#### **16.2.4 INNOVATION AND MATURATION OF METHODOLOGY IN SECONDARY RESEARCH**

In light of the methodological immaturity of primary research, it is perhaps unsurprising that many of the attempts at secondary research have also proved inconclusive. Systematic reviews are considered to be the highest level of evidence in healthcare and have repeatedly been conducted in eHealth. After amassing an omnibus of systematic reviews and health technology assessments (see Appendix 5), we found few that demonstrated sensitivity to the idiosyncrasies of conducting primary research in eHealth and as a result many were often unaware of their own limitations. Whilst innovation in conducting secondary research in healthcare has been demonstrated by the development of the realist review<sup>21</sup> and narrative synthesis,<sup>22</sup> both of which are highly suited to secondary research in eHealth; such approaches have, however, rarely been employed by researchers. We suggest the need for innovative methodology in secondary research that is based on a clear understanding of the relevant theoretical considerations. This developmental work is important as systematic reviews and high quality syntheses of the evidence remain very useful in this field of enquiry, especially if primary research becomes more rigorous and useful.

#### **16.2.5 TOOLKITS, COMPETENCE AND CAPACITY**

The above aspirations to improve the quality, relevance and volume of both primary and secondary research are however unlikely to be realised without the development of appropriate toolkits to support researchers, training opportunities for researchers wishing to specialise in this field and the broader more fundamental issue of increasing research capacity.

There are a full range of methodological approaches that are available to and should appropriately be selected from by researchers in eHealth, this choice fundamentally being guided by the nature of the question being asked and the available timeframe and resources. Brender, for example, describes nearly 40 different relevant methodologies, most of which are under-used, this possibly

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reflecting amongst researchers a lack of awareness of their existence and limited methodological competencies.<sup>23</sup> Employing the most appropriate design is one of the most important and also at the same time one of the most difficult decisions to make when embarking on an evaluation.

Not only must researchers employ the appropriate evaluative methodology, but they must also plan and conduct the study correctly. Guidelines could help researchers, particularly those who are novices, to think through some of these considerations. Such guidelines have, for example, been published in relation to the validation of telematics applications in medicine (VATAM).<sup>24</sup> It is thus encouraging to learn that preparation of a set of good practice guidelines for evaluation in health informatics (GEP-HI) are currently in progress and it is therefore important to wait for the results of this exercise before undertaking further work in this respect.<sup>25</sup> Nonetheless, based on previous experiences, it is clear that prospective employment of the guidelines will undoubtedly help with their future refinement, hopefully contributing to higher quality future evaluations and facilitating comparative and secondary research.

Also of note in this respect is that consensus guidelines for robust reporting in eHealth have recently been published (STARE-HI).<sup>25</sup> Evaluators should consider and, where appropriate, make use of such standards and editors of peer-reviewed journals should similarly be encouraged to ensure that evaluations of eHealth applications conform to such standards.

Our research necessitated conducting quality appraisal of reviews of the literature. Our experiences showed that existing critical appraisal tools such as the Critical Appraisal Skills Programme (CASP) for systematic reviews were not sensitive to the full range of issues of potential interest and relevance. To ensure that our own work did not suffer from these same deficiencies highlighted above, we found it necessary to adapt existing instruments in order to appraise systematic reviews. We took an internationally agreed standard, the CASP and modified it to reflect sensitivity to relevant methodological and contextual considerations (see Appendix 2 for the adapted tool). Whilst we found it useful, it is important to establish whether other review teams also find it useful and also whether it remains fit-for-purpose as overviews extend into other areas of eHealth applications not covered in this review.

Additionally, the robustness of eHealth evaluations should improve through the development of research competence and capacity. This should include MSc and PhD studentships to train junior researchers considering specialising in this area, but also post-doctoral fellowships, and senior fellowships. Research capacity could also be expanded through the creation of research networks; for

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example, an eHealth specialty network could be established as part of the UK Clinical Research Network (UKCRN) initiative.

## **16.3 SOME PRIORITY AREAS FOR FURTHER RESEARCH AND DEVELOPMENT**

### **16.3.1 DESIGN, DEVELOPMENT AND DEPLOYMENT**

Lack of methodological rigour and narrow use of research methodologies coupled with lack of competence and capacity in research presented may in part explain the lack of evidence of benefit of many of these technologies. Likely too though, is a genuine lack of realisation of envisaged benefits due to a variety of factors, these including:

- implementation of valid applications that are not fit-for-use and this lack of use consequently translates into a lack of benefit—this is due fundamentally to a lack of end-user involvement in design and development phases
- implementation of usable applications, but which lack clinical relevance—this typically reflects a lack of clinical expertise and or involvement in the design and development phases
- a poorly conceived and highly disruptive implementation strategy that results in abandonment of the project.

The above scenarios all point to further research into human factors research during the design and development of eHealth applications, and the importance of organisational issues during implementation. We suggest further development of human factors and organisational issues research frameworks and methodologies, encouraging the research community to evaluate these processes to enhance our understanding of one of the most vital elements of any eHealth project or programme.

### **16.3.2 SPECIFIC AREAS FOR FURTHER RESEARCH**

We have commented in detail on application specific areas for further research in earlier chapters (Chapters 5–11). There are, however, some additional key areas which we would here like to draw attention to as research and development could have an immediate and major impact of patient safety and quality in healthcare. We suggest these areas as they are fundamental to maximising the realisation of envisaged benefits of eHealth applications and in particular clinical information systems, which form the technical infrastructure of any “networked” health service delivery organisation.

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### *Use of information technology to improve clinical coding in primary and secondary care*

Clinical codes are the language of health information technology and are used extensively in the delivery and management of health services. For example, computerised decision support systems (CDSSs) for clinicians, tools for measuring quality of care such as the Quality Management and Analysis System (QMAS), and payment systems such as Payment by Results all require clinical codes to function. Hence, accurate clinical coding is essential if we are to capitalise on the advantages that clinical information systems bring to areas such as clinical management, audit, quality improvement, health service planning, and research. Previous studies and systematic reviews suggest there are major deficiencies in clinical coding in the NHS and these could have a significant impact on patient safety and quality of care.<sup>26–28</sup> A review of the barriers to clinical coding in primary care points to the limitations of coding systems and terminologies in use; the skill gap in their use; poor fit with (time-consuming and distracting); lack of motivation of primary care professionals; and the lack of priority within the organisation.<sup>29</sup> These problems will only be exacerbated in secondary and tertiary care in the UK as clinical information systems are implemented by NHS Connecting for Health (NHS CFH) as part of their National Programme for Information Technology (NPfIT). Key areas for development therefore include the training of clinicians and other NHS staff in the use of clinical coding systems; making clinicians aware of why clinical code are important; the use of IT to improve the accuracy of clinical coding, for example, through the use of computational techniques to make use of clinical information in textual data; and the development of methods and standards for measuring the quality of clinical coding.

### *Use of information technology to improve the recording and detection of threats to patient safety*

Adverse events are common in healthcare and pose a significant hazard to patient safety and public health.<sup>30–32</sup> Current research suggests that there is considerable under-recording of adverse events; for example, of adverse drug reactions. With the computerisation of healthcare, new methods for detecting adverse events will become possible, using data mining and machine learning computational methods that are common in other areas but not yet in healthcare settings. A recently conducted systematic review examined studies that used pharmacy and laboratory data retrospectively to detect adverse drug reactions in amongst hospitalised adult patients. The review found that such data could

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help identify patients who had suffered adverse events.<sup>33</sup>

Similar methods could also be applied to detect adverse events prospectively. To again use the example of adverse drug reactions, patients on specific drugs, such as newly launched agents, could have their health status monitored prospectively to detect possible serious but currently unknown side-effects of drugs. A second example could be in the use of similar techniques to identify patients at high risk of suffering complications from medical care or at high risk of death or emergency medical admission, and who would benefit from intensive review and management.

#### *Education and training of frontline clinicians in use of information technology*

Currently there is a lack of general IT and health informatics skills amongst NHS staff.<sup>34</sup> Although major professional bodies have all acknowledged the importance of these skills in the face of an increasingly technologically sophisticated healthcare system, it is uncertain to what degree education and training of clinical practitioners has incorporated the necessary skills. Frontline clinicians all need to be competent in the use of information technology, from the use of standard desktop packages such as word processors and spreadsheets through to the use of specialised eHealth applications. This programme of education could begin with an update of the RHIED report (ICT/136 DoH)—research into the extent to which *Learning to Manage Health Information* has been incorporated into medical, nursing, allied health professionals and healthcare management pre- and post-registration education, training and development curricula.<sup>34</sup>

## **16.4 CONCLUSIONS**

Following the completion of our systematic overview of the literature and after reviewing reports about the successes, failures and limitations of previous projects implementing the use of IT in healthcare, some important issues emerge. One key issue is that to incorporate IT into routine clinical practice and health services this should, wherever possible, proceed on the basis of rigorous evidence about the benefits and costs of implementation. A second key issue is that all phases of implementation, from early pilots to full-scale assimilation, should undergo evaluation to ensure that the expected benefits are being realised and unforeseen problems are identified and, where possible, rectified. Thirdly, given that we know so little about how to successfully integrate IT innovations into routine models of care, it is important that experiences of introducing innovations, whether positive or negative, are shared both internally within



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the organisation and externally, so as to help thinking in this field to continue to evolve.

At present, previous evaluations of eHealth applications have had many limitations. There is an urgent need to address these limitations through increased research capacity, training of eHealth researchers, and the continuous rating of research quality and evidence synthesis. This review shows that eHealth has the potential to radically transform the delivery of healthcare, and dramatically improve patient safety and quality. However, eHealth implementation should be based on the rigorous assessment of research evidence if the full clinical and economic benefits of this technology are to be realised.

In England, the Government currently funds health related research through two main routes, the MRC and the National Institute for Health Research (NIHR). A new office was recently established, the Office for Strategic Coordination of Health Research (OSCHR) that will take an overview of the budgetary division and research strategy of both the MRC and NIHR. One of the areas of focus for the OSCHR will be eHealth. When coupled with the implementation of the Programme being delivered by NHS CFH, there is we believe enormous potential to conduct innovative and methodologically rigorous research.

This is an area of research and development where the UK can be a world leader, with the associated benefits for patient safety, quality of care and public health; and for the national economy and wealth of the nation.

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  26. Hogan WR, Wagner MM. Accuracy of data in computer-based patient records. *J Am Med Inform Assoc* 1997;4:342–355.
  27. Jordan K, Porcheret M, Croft P. Quality of morbidity coding in general practice computerized medical records: a systematic review. *Fam Pract* 2004;21:396–412.
  28. Thiru K, Hassey A, Sullivan F. Systematic review of scope and quality of electronic patient record data in primary care. *BMJ* 2003;326:1070.
  29. de Lusignan S. The barriers to clinical coding in general practice: a literature review. *Med Inform Internet Med* 2005;30:89–97.
  30. Institute of Medicine. *To Err Is Human: Building a Safer Health System*. 2000. Washington, DC, National Academy Press.
  31. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. 2001. Washington, D.C., National Academy Press.
  32. Institute of Medicine. *Patient Safety: Achieving a New Standard for Care*. 2003. Washington, D.C., National Academy Press.
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## SECTION 5

# APPENDICES & GLOSSARY

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## APPENDIX 1:

### Search strategy and methodology filters

Complete search string for OVID (MEDLINE and EMBASE)

#### SEARCH STRATEGY:

(IT MeSH & free text terms ‘AND’ patient safety and quality, organisational and implementation issues MeSH & free text terms)

(Man-Machine Systems/ OR Office Automation/ OR Information Management/ OR Data Collection/ OR Automation/ OR Autoanalysis/ OR Technology, Radiologic/ OR Technology, Pharmaceutical/ OR Technology, Medical/ OR Point-of-Care Systems/ OR Patient Identification Systems/ OR Medication Systems, Hospital/ OR Hospital Communication Systems/ OR Adverse Drug Reaction Reporting Systems/ OR Biomedical Engineering/ OR Biomedical Technology/ OR Electronic Mail/ OR Emergency Medical Service Communication Systems/ OR Computing Methodologies/ OR pattern recognition, automated/ OR drug information services/ OR user-computer interface/ OR speech recognition software/ OR software/ OR numerical analysis, computer-assisted/ OR decision support techniques/ OR mathematical computing/ OR computer simulation/ OR Artificial intelligence/ OR Algorithms/ OR Feedback/ OR medical informatics/ OR Medical informatics applications/ OR Decision making, computer-assisted/ OR diagnosis, computer-assisted/ OR image interpretation, computer-assisted/ OR radiographic image interpretation, computer-assisted/ OR therapy, computer-assisted/ OR drug therapy, computer-assisted/ OR “information storage and retrieval”/ OR information systems/ OR clinical laboratory information systems/ OR decision support systems, clinical/ OR hospital information systems/ OR medical order entry systems/ OR integrated advanced information management systems/ OR management information systems/ OR ambulatory care information systems/ OR clinical pharmacy information systems/ OR database management systems/ OR decision support systems, management/ OR operating room information systems/ OR “personnel staffing and scheduling information systems”/ OR radiology information systems/ OR medical records systems, computerized/ OR reminder systems/ OR medical informatics computing/ OR informatics/ OR Automatic Data Processing/ OR Public Health Informatics/ OR Nursing Informatics/ OR

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Patient Identification Systems/ OR Natural Language Processing/ OR Fuzzy Logic/ OR Expert Systems/ OR Knowledge Bases/ OR Medical History Taking/ OR “Neural Networks (Computer)”/ OR Programming, Linear/ OR Computers, Handheld/ OR “Appointments and Schedules”/ OR “Referral and Consultation”/ OR Information Services/

OR

(Clinical decision support OR Electronic outpatient booking OR Electronic refer\$ OR electronic hospital refer\$ OR Electronic discharg\$ OR electronic patient discharg\$ OR electronic health record\$ OR computerized patient record\$ OR computerised patient record\$ OR personal health record\$ OR Computerised intervention\$ OR Computerized intervention\$ OR IHCA OR Decision support technique\$ OR Interactive Health Communications Application\$ OR CDSS OR computer aid\$ OR computer assisted OR Computer\$ reminder\$ OR Computerized Physician Order Entry OR CPOE OR data mining OR data repository OR e health OR eHealth OR e prescribing OR Electronic patient record OR electronic prescribing OR e-mail OR Electronic mail OR health informat\$ OR health technology OR intranet OR PDA OR personal digital assistant OR information system\$ OR Computerized laboratory results OR GP to GP OR GP 2 GP OR GP2GP OR GPtoGP OR Electronic laboratory results OR Clinical Laboratory information system OR Laboratory information system\$ OR LIS OR Laboratory Information Management System OR Medical information systems OR Web based refer\$ OR Internet-based refer\$ OR e-Booking OR “Choose and book” OR Electronic prescri\$ OR Electronic Transmission of Prescriptions OR Care Records Service OR “Picture Archiving and Communication System\$” OR PACS OR QMAS OR “Quality Management and Analysis System\$” OR bar cod\$ OR (CAD and (computer-assisted OR computer-aid\$))).tw.)

**AND**

(Diffusion of Innovation/ OR Efficiency, Organizational/ OR Models, Organizational/ OR “Organization and Administration”/ OR Organizational Culture/ OR Organizational Innovation/ OR Organizational Objectives/ OR Technology Transfer/ OR Attitude to Computers/ OR Computer Literacy/ OR Computer User Training/ OR Cost Savings/ OR Cost-Benefit Analysis/

OR

(usability OR sustain\$ OR spread OR socio-technical OR sociotechnical OR implement\$ OR evalaut\$ OR computer anxiety OR change management OR change agent\$ OR barrier\$ OR agent of change OR adopt\$).tw.



OR

(device approval/ OR equipment failure/ OR equipment failure analysis/ OR equipment safety/ OR exp health services misuse/ OR iatrogenic disease/ OR quality assurance, health-care/ OR quality control/ OR quality indicators, health-care/ OR quality of health-care/ OR risk reduction behavior/ OR software validation/ OR equipment design/ OR guideline adherence/ OR software design/ OR program evaluation/ OR total quality management/ OR (exp medical errors/ not exp observer variation/) OR (exp risk management/ not exp risk sharing, financial/) OR exp accident prevention/ OR exp “outcome and process assessment (health-care)”/ OR “Maintenance and Engineering, Hospital”/ OR “Forms and Records Control”/ OR “Facility regulation and control”/

OR

(wrong site surgery OR workaround OR underuse OR time out OR slip\$ OR side effect\$ OR sentinel event OR safety OR safe practice\$ OR root cause OR red rule OR read back OR quality OR proximate cause OR production pressure OR product recall\$ OR procedural deviation OR overriding alerts OR negligence OR near miss OR misuse OR mistake\$ OR misdiagnosis OR medication reconciliation OR medical complication\$ OR leapfrog OR adverse drug event\$ OR adverse event\$ OR adverse occurrence\$ OR adverse reaction\$ OR complication\$ OR hazard\$ OR failure\$ OR incident\$ OR improv\$ OR error\$ OR lapse OR information overload OR inappropriate OR human factors research OR human factors engineering OR human factors design OR human factors OR heuristic OR harm OR face validity OR Equipment failure OR delayed diagnosis OR defective product OR cost utility analysis OR cost benefit analysis OR contributing factor\$ OR confirmation bias OR close call OR clinical governance OR availability bias OR appropriate treatment OR appropriate care OR alert fatigue OR adverse drug interaction OR iatrogenic OR swiss cheese model).tw.))

**Table 1. Number of hits from 1st January 1997 to 30th April 2007 on OVID MEDLINE and EMBASE**

	MEDLINE (Ovid) (1950 to April Week 3 2007)	EMBASE (Ovid) (1980 to 2007 Week 17)
without filter form 1997 to 2007	110 745	223 107
with SR filter form 1997 to 2007	1 660	5 227
with RCT filter form 1997 to 2007	8 830	21 048

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#### **SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK (SIGN) METHODOLOGY FILTERS**

SIGN methodology filter for systematic reviews on OVID MEDLINE (SR filter)

1. Meta-Analysis/
2. meta analy\$.tw.
3. metaanaly\$.tw.
4. meta analysis.pt.
5. (systematic adj (review\$1 or overview\$1)).tw.
6. exp Review Literature/
7. or/1-6
8. cochrane.ab.
9. embase.ab.
10. (psychlit or psyclit).ab.
11. (psychinfo or psycinfo).ab.
12. (cinahl or cinhal).ab.
13. science citation index.ab.
14. bids.ab.
15. cancerlit.ab.
16. or/8-15
17. reference list\$.ab.
18. bibliograph\$.ab.
19. hand-search\$.ab.
20. relevant journals.ab.
21. manual search\$.ab.
22. or/17-21
23. selection criteria.ab.
24. data extraction.ab.
25. 23 or 24
26. review.pt.
27. 25 and 26
28. comment.pt.
29. letter.pt.
30. editorial.pt.
31. animal/
32. human/
33. 31 not (31 and 32)
34. or/28-30,33
35. 7 or 16 or 22 or 27

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36. 35 not 34

SIGN methodology filter for systematic reviews on OVID EMBASE (SR filter)

1. exp Meta Analysis/
2. ((meta adj analy\$) or metaanalys\$).tw.
3. (systematic adj (review\$1 or overview\$1)).tw.
4. or/1-3
5. cancerlit.ab.
6. cochrane.ab.
7. embase.ab.
8. (psychlit or psyclit).ab.
9. (psychinfo or psycinfo).ab.
10. (cinahl or cinhal).ab.
11. science citation index.ab.
12. bids.ab.
13. or/5-12
14. reference lists.ab.
15. bibliograph\$.ab.
16. hand-search\$.ab.
17. manual search\$.ab.
18. relevant journals.ab.
19. or/14-18
20. data extraction.ab.
21. selection criteria.ab.
22. 20 or 21
23. review.pt.
24. 22 and 23
25. letter.pt.
26. editorial.pt.
27. animal/
28. human/
29. 27 not (27 and 28)
30. or/25-26,29
31. 4 or 13 or 19 or 24
32. 31 not 30

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SIGN methodology filter for randomised controlled trials on OVID MEDLINE  
(RCT filter)

1. Randomized controlled trials/
2. Randomized controlled trial.pt.
3. Random allocation/
4. Double blind method/
5. Single blind method/
6. Clinical trial.pt.
7. Exp clinical trials/
8. Or/1-7
9. (clinic\$ adj trial\$1).tw.
10. ((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).tw.
11. Placebos/
12. Placebo\$.tw.
13. Randomly allocated.tw.
14. (allocated adj2 random).tw.
15. Or/9-14
16. 8 or 15
17. Case report.tw.
18. Letter.pt.
19. Historical article.pt.
20. Review of reported cases.pt.
21. Review, multicase.pt.
22. Or/17-21
23. 16 not 22

SIGN methodology filter for randomised controlled trials on OVID EMBASE  
(RCT filter)

1. Clinical trial/
2. Randomized controlled trial/
3. Randomization/
4. Single blind procedure/
5. Double blind procedure/
6. Crossover procedure/
7. Placebo/
8. Randomi?ed controlled trial\$.tw.
9. Rct.tw.
10. Random allocation.tw.

- 
11. Randomly allocated.tw.
  12. Allocated randomly.tw.
  13. (allocated adj2 random).tw.
  14. Single blind\$.tw.
  15. Double blind\$.tw.
  16. ((treble or triple) adj (blind\$).tw.
  17. Placebo\$.tw.
  18. Prospective study/
  19. Or/1-18
  20. Case study/
  21. Case report.tw.
  22. Abstract report/ or letter/
  23. Or/20-22
  24. 19 not 23

## APPENDIX 2:

### Quality assessment form (CASP)

#### CRITICAL APPRAISAL CHECKLIST FOR A SYSTEMATIC REVIEW OF HEALTH INFORMATICS EVALUATIONS

Adapted from:

Critical Appraisal Skills Programme (CASP), Public Health Resource Unit, Institute of Health Science, Oxford. Oxman AD, Cook DJ, Guyatt GH. Users' guides to the medical literature. VI. How to use an overview. *JAMA* 1994; 272:1367–1371.

REVIEW FOCUS			
	Yes (+2)	Somewhat (+1)	No or can't tell (0)
1. Did the review address a clearly focussed issue? Was there enough information on <ul style="list-style-type: none"><li>• The population studied (patients and end-users)</li><li>• The outcomes considered (how defined, measured etc.)</li></ul>			
2. Did the review assess a clearly focussed technology? Was the technology <ul style="list-style-type: none"><li>• Clearly defined or described</li><li>• If more than one technology is assessed, were the technologies and there relationship to the other technologies clearly delineated</li></ul>			
3. Did the authors look for the appropriate sort of papers? The 'best sort of studies' would <ul style="list-style-type: none"><li>• Address the review's question</li><li>• Have an appropriate study design</li></ul>			



## VALIDITY OF REVIEW RESULTS

	Yes (+2)	Somewhat (+1)	No or can't tell (0)
<p>4. Do you think the important, relevant studies were included?</p> <p>Look for</p> <ul style="list-style-type: none"> <li>• Which bibliographic databases were used</li> <li>• Follow up from reference lists</li> <li>• Personal contact with experts</li> <li>• Search for unpublished as well as published studies</li> <li>• Search for non-English language studies</li> <li>• Comprehensive search string demonstrating awareness of the myriad of MeSH terms available</li> </ul>			
<p>5. Did the review's authors do enough to assess the quality of the included studies?</p> <p>The authors need to consider the rigour of the studies they have identified. Lack of rigour may affect the studies results. Particular attention should be paid to methodological issues surrounding evaluations of health informatics such as unit of analysis and allocation discrepancies, measurement of variables, contamination, transparency of results, etc.</p>			
<p>6. Were the studies accurately described?</p> <p>Such as the functional capacity of the technology(ies), the way in which the end-user interacted with the technology(ies) and degree of compliance, organisational setting and degree of computerisation etc.? When and where the study was conducted and why technology was implemented. Individual study results related back to those elements?</p>			
<p>7. Are the results of individual studies reported in a clear and meaningful way or just listed with no real flow?</p> <p>Consider whether studies with similar characteristics such as organisational setting, outcomes measured and functional capacity of technology(ies) were grouped together</p>			

## VALIDITY OF REVIEW RESULTS

	Yes (+2)	Somewhat (+1)	No or can't tell (0)
<p>8. If the results of included have been combined, was it reasonable to do so? (overall result presented from more than one study or meta-analysis) Consider whether</p> <ul style="list-style-type: none"> <li>• The technologies were similar in functionality, integratedness, how output was presented, end-user training, level of compliance, etc</li> <li>• The results were similar from study to study, ie how measured and defined</li> <li>• The results of all the included studies are clearly displayed</li> <li>• The results of the different studies are similar</li> <li>• The reasons for any variations are discussed</li> </ul>			
<p>9. Did the review demonstrate awareness of its own limitations? Consider whether the review</p> <ul style="list-style-type: none"> <li>• Quality, quantity and consistency of included studies</li> <li>• Presented its findings in light of other similar reviews</li> <li>• Future research indicated?</li> </ul>			

## RESULTS

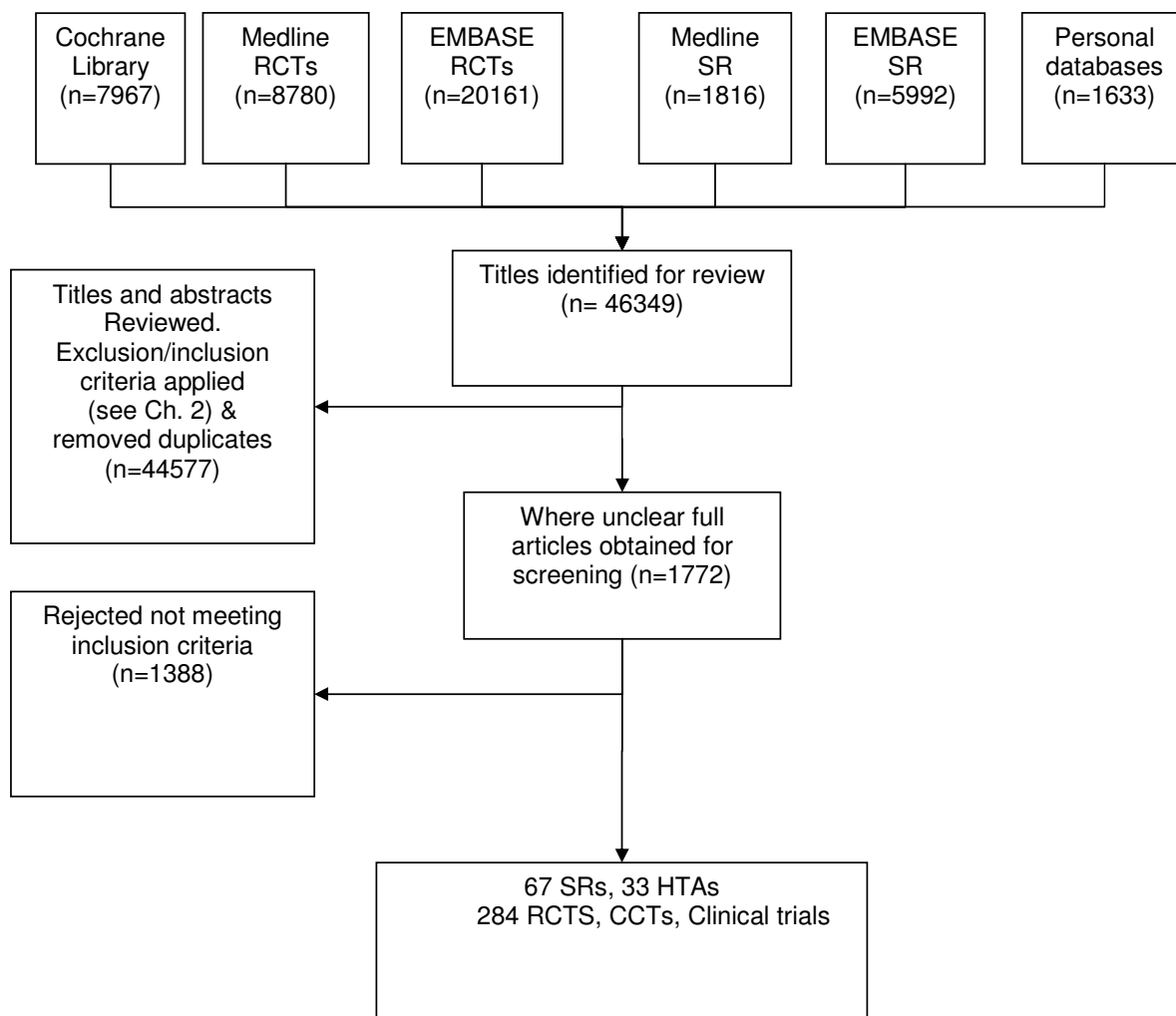
	Yes (+2)	Somewhat (+1)	No or can't tell (0)
<p>10. Does the review present an overall result? Consider</p> <ul style="list-style-type: none"> <li>• If you are clear about the reviews 'bottom line' results, ie is an answer to study question(s) is ascertainable</li> <li>• What these are (numerically or verbally if appropriate)</li> <li>• How were the results expressed (NNT, OR, etc.)</li> </ul>			
<p>11. How precise are the results? Are the results presented with confidence intervals if expressed numerically? What words are used to describe effect size? Consistency of findings?</p>			

## APPLICABILITY

	Yes (+2)	Somewhat (+1)	No or can't tell (0)
12. Implications for policy makers and or those considering implementing such technologies? Appropriate based on findings?			
13. Are the results generalisable beyond the confines of the setting in which the work was originally conducted? Consider whether <ul style="list-style-type: none"> <li>• The patients covered by the review could be sufficiently different from your population to cause concern</li> <li>• Your local setting is likely to differ much from that of the review in terms of degree of computerisation and end-user skills, etc</li> <li>• Similar functionality will be employed</li> </ul>			
14. Were all important outcomes considered? Such as workflow, patient outcomes, practitioner performance, economic and negative outcomes.			
15. Are you able to assess the benefit versus harm and costs? Even if this is not addressed by the review, what do you think? This is important as A. studies concerning cost-benefit are rarely performed in HI, B. negative outcomes are rarely assessed in studies of HI. Dependent on #14!			

## APPENDIX 3:

### PRISMA flow diagram



## APPENDIX 4:

### Data extraction and critical appraisal scores of systematic reviews (n=67)

REFERENCE	Abbod MF, Catto JW, Linkens DA, Hamdy FC. Application of artificial intelligence to the management of urological cancer. <i>J Urol</i> 2007;8(4 Pt 1):1150–6
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	6
Objective/Questions Addressed in the Review	To review basic concepts behind artificial intelligence techniques and explore the applications in various aspects of urological cancer management.
No of Studies Included in the Review	25
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, INSPEC
Search Strategy	NS
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	AI in urological cancer management
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	In general, most investigators have used ANN reporting improved diagnostic accuracy over non-AI methods.
Conclusions, considerations for implementation, adoption or system design and development.	When correctly used, AI models can be superior to standard statistical methods and allow more thorough and flexible interrogation of data with reliable prediction of disease outcomes. Most current AI models are limited by the requirement for operator refinement, preventing widespread commercial uptake, although some are cited in this survey.

Further research	No explicit further research is noted. However, the authors argue that it is likely that the accuracy and role of AI will increase with the discovery of novel biomarkers and the use of electronic medical records.
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REFERENCE	Abulafia O, Sherer DM. Automated cervical cytology: Meta-analyses of the performance of the PAPNET system. <i>Obstet Gynecolog Surv</i> 1999;54(4.)
How does it meet inclusion criteria?	meta-analysis of all studies published on the AutoPap 300 QC automated cervical cytology system
CASP Total Score	15.5
Objective/Questions Addressed in the Review	To review current knowledge regarding the performance of the AutoPap 300 QC System NeoPath Inc., Redmond, WA) for automated cervical cytology screening.
No of Studies Included in the Review	14
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE through October 1998
Search Strategy	No search terms were provided by the authors, additional sources were identified through cross-referencing in the English language that language.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	AutoPap 300 QC System as a primary screening modality
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	In summary, limited studies addressing the performance of the AutoPap 300 QC System suggest that as a primary screening modality, this system has sensitivity rates of between 85 and 100 per cent in identifying abnormal slides, and as a quality control modality, sensitivity rates of between 30 and 40 per cent.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations were made concerning implementation were made neither was a discussion on adoption or organizational factors.



Further research	The authors note that most of the studies included in their review were from a core group of researchers and furthermore, independent studies are required to confirm these findings.
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REFERENCE	Austin SM, Balas EA, Mitchell JA, Ewigman BG. Effect of physician reminders on preventive care: meta-analysis of randomized clinical trials. <i>Proc Annu Symp Comput Appl Med Care</i> 1994;121–124.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria with meta-analysis
CASP Total Score	19.5
Objective/Questions Addressed in the Review	To assess the clinical value of the physician reminder in increasing compliance for selected preventive healthcare measures.
No of Studies Included in the Review	4
No of Participants Studied in Total	NS
Databases and Years Searched	Columbia Registry
Search Strategy	NS
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	physicians
Intervention(s) and Comparisons	reminders, an information intervention that arrives at the time of decision-making for cervical cancer screening and tetanus immunisation with no similar assistance in the control group
Setting	family, internal medicine
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	For cervical cancer screening, the overall odds ration 1.180, 95% CI 1.020–1.339 with a tolerance of 0.794 and were non-significant for heterogeneity. For tetanus immunisation, the overall odds ratio was found to be 2.819, 95% CI 2.664–2.975 with a tolerance of 105.220 and were non-significant for homogeneity.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation made and no discussion of adoption issues or technical logistics made.

Further research	Further evaluation for tetanus immunisation would be unethical, but cervical cancer screening warrants further RCTs.
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REFERENCE	Balas EA, Austin SM, Mitchell JA, Ewigman BG, Bopp KD, Brown GD. The clinical value of computerized information services. A review of 98 randomized clinical trials. <i>Arch Fam Med</i> 1996;5(5):271–278.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria with quality assessment
CASP Total Score	18.5
Objective/Questions Addressed in the Review	To review all randomised clinical trials addressing the efficacy of clinical information systems and to determine the clinical settings, types of interventions, and effects studied.
No of Studies Included in the Review	100 trials included in this study, as reported in 98 articles
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, Proceedings of the meetings of the American, International and European Medical Informatics Associations
Search Strategy	The following medical subject heading (MeSH) terms and textwords were combined in the searches (:l ) clinical trials, cohort studies, and medical informatics (MeSH, explode);( 2) prospective, trial, or group (textwords); (3) random\$, comput\$, or microcomput\$ (truncated words) and (4) clinical trial (publication type). Manual searches of numerous books and monographs were performed in the area of medical informatics (eg <i>Lecture Notes in Medical Informatics</i> , International Federation of information Processing–International Medical Informatics Association monographs). The reference lists of retrieved reports and reviews of computer applications were also reviewed. After the initial set of trial reports was compiled, specific information interventions were identified, and additional search strategies were developed using the appropriate descriptive terms. Finally, trials were located by contacting by mail or telephone experts in the areas of medical informatics, primary health care, and health science management Experts abroad were reached primarily by E-mail (eg Brazilian Medical Informatics list, researchers in Australia, Japan, and European countries).
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	NS
Intervention(s) and Comparisons	computerised information intervention with no similar computer assistance in the control group

Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	effect measured on the process or outcome of care
Range of Observations or Period of Follow Up	NS
Findings or results	Computerised physician reminders about preventative care and computerised treatment planners, eg computer algorithms to assist decision-making concerning drug dosages, were successful (significant at $p \leq .05$ ).
Conclusions, considerations for implementation, adoption or system design and development.	With regards to implementation, buyers should specify the inclusion of successful information services in technical specification and developers should include them in future medical computer systems.
Further research	Improved research methodology is necessary and research should be undertaken within the inpatient setting and patient outcomes should also be studied.

REFERENCE	Balas EA, Krishna S, Kretschmer RA, Cheek TR, Lobach DF, Boren SA. Computerized knowledge management in diabetes care. <i>Med Care</i> 2004;42(6):610–21.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria with quality assessment
CASP Total Score	22
Objective/Questions Addressed in the Review	To identify the impact automated information interventions of on diabetes care and patient outcomes and to enable this knowledge to be incorporated into diabetes care practice.
No of Studies Included in the Review	9
No of Participants Studied in Total	over 4000
Databases and Years Searched	MEDLINE, HealthSTAR, CINAHL, Compendex, Dissertation Abstracts, ABI/Inform, EBM Reviews–Best Evidence and the Cochrane Database of Systematic Reviews, ERIC, INSPEC, and PsycINFO
Search Strategy	Extensive electronic literature searches were performed plus manual searches of review articles and bibliographies of potentially relevant RCTs
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	NS
Intervention(s) and Comparisons	computerised prompting of diabetes care with no such computer assistance in the control group
Setting	NS

Patients Reviewed	patients with diabetes mellitus
Pre-defined outcomes	effect was measured in the process or outcome of diabetes care
Range of Observations or Period of Follow Up	NS
Findings or results	Compliance with diabetes care guidelines was also significantly better (P 0.05) among the intervention group physicians than in the control group—yet, there were also particular outcomes for which there was not a significant difference between the intervention and the control group: HgbA1c assessment compliance; foot examination compliance; ophthalmologic examination compliance; HgbA1c compliance;
fasting blood sugar compliance; self-measurement of blood glucose compliance; and referral to dietary clinic	
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation are made.
Further research	Further research is needed as healthcare executives and policy-makers would probably like to obtain additional information about costs and more meticulous long-term data on patient acceptance and clinical utilisation of the systems, because they are likely to be considering a purchase. Future studies should also include cost calculations of computerised interventions in diabetes care. More research also is needed regarding the effect of computer literacy on access to quality diabetes care by disadvantaged patients.

REFERENCE	Bates DW, Evans RS, Murff H, Stetson PD, Pizziferri L, Hripcsak G. Detecting adverse events using information technology. <i>J Am Med Inform Assoc</i> 2003;10(2):115–128.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria with quality assessment
CASP Total Score	19
Objective/Questions Addressed in the Review	To review methodologies of detecting adverse events using information technology, reports of studies that used these techniques to detect adverse events, and study results for specific types of adverse events.
No of Studies Included in the Review	25, 7 with gold standard

No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE 1966–2001
Search Strategy	Electronic search used two Medical Subject Headings (MeSH), Iatrogenic Disease and Adverse Drug Reporting Systems; with the MeSH Entry Term, Nosocomial Infection; and with key words (adverse event, adverse drug event, fall, and computerized detection). English language studies only.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	computerised methods to detect nosocomial infections, adverse drug events, adverse drug reactions, adverse events or falls
Setting	inpatient
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Tools such as event monitoring and natural language processing can inexpensively detect certain types of adverse events in clinical databases. These approaches already work well for some types of adverse events, including adverse drug events and nosocomial infections.
Conclusions, considerations for implementation, adoption or system design and development.	With regards to implementation, the authors note that computerised techniques for identifying adverse drug events and nosocomial infections are sufficiently developed for broad use. They are much more accurate than spontaneous reporting and more timely and cost-effective than manual chart review.
Further research	The authors postulate that research will probably allow development of techniques that use tools such as natural language processing to mine electronic medical records for other types of adverse events. The authors believe that a key benefit of electronic medical records will be that they can be used to detect the frequency of adverse events and to develop methods to reduce the number of such events.

REFERENCE	Bennett JW, Glasziou PP. Computerised reminders and feedback in medication management: a systematic review of randomised controlled trials. <i>Med J Aust</i> 2003;178(5):217–222.
How does it meet inclusion criteria?	says it's a systematic review

CASP Total Score	21.5
Objective/Questions Addressed in the Review	To systematically review randomised controlled trials (RCTs) of computer-generated medication reminders or feedback directed to healthcare providers or patients.
No of Studies Included in the Review	24
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE between June 1998 and April 2002, the Cochrane Controlled Trials Register (1996–2001), CINAHL (1982–2001), Current Contents (1997–2001), COMPENDEX (1987–2001) MEDINFO (1980–1992) and SCAMC/AMIA Annual Fall Symposium (1984–1991)
Search Strategy	MEDLINE searches used combinations of medical subject headings (MeSH) terms (randomized controlled trial, reminder systems, drug therapy, medical informatics [exploded]) and free text (random*, medication* OR drug*, adheren* OR complian*). Similar techniques were used for the other databases. The reference lists of retrieved articles were scanned for references to further trials. English language only.
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	NS
Intervention(s) and Comparisons	CDSS for reminders or feedback in medication management
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Computerised DSSs providing reminders and feedback to healthcare providers and patients can make modest improvements in medication management. They have successfully changed the class of medication prescribed, increased generic prescribing, improved activities related to medication management (eg diagnostic testing), and enhanced patient adherence to medication regimens. It appears that reminders are more effective than feedback. More specifically, reminders from CDSSs to providers generally improved medication management in the outpatient setting, with relative rates from 1.0 to 42. Physician feedback systems in outpatient settings generally had smaller effects on clinician behaviour than reminder systems, relative rates were from 1.0 to 2.5.



Conclusions, considerations for implementation, adoption or system design and development.	With regards to implementation, the authors conclude that the current evidence should encourage wider use of CDSS for medication management, based on careful consideration of local factors though.
Further research	Further research should focus on what features of DSSs—such as multiple rather than single options, “help” and explanation functions, or speed—might enhance the effects seen.

REFERENCE	Charvet-Protat S, Thorat F. Economic and organizational evaluation of an imaging network. <i>J Radiol</i> 1998;79(12): 1453–9
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	12
Objective/Questions Addressed in the Review	To evaluate the cost and efficacy of PACS compared to film-based or traditional archiving and communication systems.
No of Studies Included in the Review	10 papers evaluating 8 different PACS for the economic analysis, 7 papers for the benefit analysis
No of Participants Studied in Total	NS
Databases and Years Searched	NS but from 1990 and 1996
Search Strategy	The literature between 1990 and 1996 was screened.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	PACS which the authors note are designed as follows: <ul style="list-style-type: none"> <li>• variable source of images, qualitatively and quantitatively;</li> <li>• an archiving system including a server (juke-box) and storage devices (optical disks);</li> <li>• a communication network allowing data (image) transfers;</li> <li>• workstations allowing image viewing and post-processing in the radiology department and viewing only for consultants outside the radiology department.</li> </ul>
The economical evaluation was to be based on a comparison between film-based systems and PACS.	
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	all associated costs related to the resources used
Range of Observations or Period of Follow Up	NS

Findings or results	The reality of the organisational benefit has yet to be demonstrated. The economical evaluation comparing PACS and film-based systems shows an increased in cost for PACS. Savings related to PACS (films, archive space, staff) are currently insufficient to off-set the cost of the initial investment and service contracts. It would appear that 5–6 years are needed before the savings generated by PACS even-out the initial investment.
Conclusions, considerations for implementation, adoption or system design and development.	<p>This has lead the ANAES to issue the following recommendations:</p> <ul style="list-style-type: none"> <li>• Due to the required investment, the decision to implant PACS in the private and public sectors should be preceded by an evaluation performed with the collaboration of the Agences Regionales de l'Hospitalisation and take into account the role of the hospital within the regional context. Evaluation sites should provide evidence of real benefits, especially regarding productivity gains, data transfers, and hospital stay.</li> <li>• The goals of PACS should be clearly defined for any given hospital. Activity objectives should be assessed, such as the expected number of examinations per imaging modality. Objectives for improved archival should also be established. Finally, all personnel should be involved in the project since it may significantly affect the organisation of work.</li> <li>• The configuration of each network should be consistent. PACS should be using international standards: DICOM, security, homogeneity of hospital and radiology information systems (HIS and RIS). This will facilitate intra- and inter-hospital interface capabilities.</li> </ul> <p>The next step is teleradiology, or image transfer from one imaging center to another. This aspect was not discussed here and would be the subject of a separate evaluation. Indeed, teleradiology, and eventually telemedicine, are very broad subjects and further research is needed.</p>
Further research	Available studies suffer from methodological limitations underscoring the need to develop new evaluation tools.

REFERENCE	Chatellier G, Colombet I, Degoulet P. An overview of the effect of computer-assisted management of anticoagulant therapy on the quality of anticoagulation. <i>Int J Med Inform</i> 1998;49(3):311–320.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria and meta-analysis
CASP Total Score	21
Objective/Questions Addressed in the Review	To assess the overall effectiveness of computer-assisted prescription systems on the quality of anticoagulation.

No of Studies Included in the Review	7
No of Participants Studied in Total	1336*
Databases and Years Searched	MEDLINE
Search Strategy	Systematic MEDLINE search using Knowledge Finder software using the following MeSH key-words: Computer systems, Decision-Making, computer-assisted; drug therapy, computer-assisted; Evaluation studies; and Randomized controlled trials. These key-words were searched in the title, the summary, and the index headings of MEDLINE. Language restrictions not noted.
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	NS
Intervention(s) and Comparisons	computer-assisted decision-making with regards to anticoagulation treatment
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	A global odds ratio of 1.25 [95% CI 1.08–1.48] or a 25% increase in the proportion of visits where patients were within therapeutic INR range with a non-significant heterogeneity test
Conclusions, considerations for implementation, adoption or system design and development.	No outright recommendations for implementation are made although the authors conclude that CDSSs for adjustment of anticoagulant dose are effective at control of treatment.
Further research	Further research on patient outcomes and clinical- and cost-effectiveness is warranted.

REFERENCE	Chrischilles EA, Fulda TR, Byrns PJ, Winckler SC, Rupp MT, Chui MA. The role of pharmacy computer systems in preventing medication errors. <i>J Am Pharm Assoc</i> 2002; 42(3):439–48.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	15
Objective/Questions Addressed in the Review	To describe the controversies and review the evidence about computer-aided prospective drug utilisation review.

No of Studies Included in the Review	5
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE
Search Strategy	NS
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	focused on pharmacists
Intervention(s) and Comparisons	computer-aided prospective drug utilisation review defined as systems that generate alerts for prescriptions that violate a pre-established criterion for appropriate drug use
Setting	Focused on pharmacy
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Only limited evidence supports the effectiveness in preventing and resolving drug therapy problems.
Conclusions, considerations for implementation, adoption or system design and development.	The authors discuss possible determinants of effectiveness such as sensitivity, specificity, operational definitions and data sources, accessibility of ancillary information.
Further research	The authors recommend three types of studies required to create an evidence-base on which policy and pragmatic recommendations could be made. RCTs assessing overall effectiveness of PDUR systems; Simulation studies examining potential determinants of PDUR system effectiveness to be followed by RCTs if warranted; a combination of epidemiological and experimental designs to study pharmacist effectiveness in responding to alerts.

<b>REFERENCE</b>	<b>Clamp S, Keen J. The value of Electronic Health Records. 2006</b>
How does it meet inclusion criteria?	realist review, application of inclusion/exclusion criteria with quality assessment
CASP Total Score	24.5
Objective/Questions Addressed in the Review	To summarise what is known, and what is not yet known, about the value of EHR in healthcare.
No of Studies Included in the Review	NS

No of Participants Studied in Total	NS
Databases and Years Searched	NS
Search Strategy	NS
Study Designs Eligible for Inclusion	studies which used a range of different research methods
Practitioner Targeted	NS
Intervention(s) and Comparisons	EHR defined broadly to include clinical images and non-health data, such as data that would typically be held by social services in many countries. EHR; CPOE; and PACS
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	impact of EHR on clinical or management processes, costs and benefits (including patient outcomes) of any observed process changes
Range of Observations or Period of Follow Up	NS
Findings or results	<p>In many papers the evidence was not decisive. There is, for example, evidence of clinician dissatisfaction with EHR, and also evidence that little of the available functionality is used. There is no compelling evidence that EHR reduce the incidence of adverse drug events (ADEs), or that the introduction of EHR increases—or decreases—consultation time. Hospital clinical imaging: reasonable evidence of positive work processes changes in radiology and other departments; no evidence that PACS increases running costs; weak evidence that PACS reduces radiation dosage; and weak positive evidence that PACS increases diagnostic accuracy. CPOE: strong evidence that CPOE reduces medical error rate; reasonable evidence that CPOE standardises care whilst engaging clinicians and realising benefits; reasonable evidence that CPOE reduces turnaround times and inaccurate orders allowing pharmacists to perform more clinical and problem solving activities; weak evidence for the reduction in preventable ADE rate; and weak evidence for cost-savings—dependent on size, existing systems and functional capacity of CPOE systems under implementation. EHR: strong evidence that EHRs result in re-distribution of time costs between doctors, nurses and administrative staff; reasonable evidence that EHRs changes patterns in service delivery; weak evidence for cost-savings or increased costs and patient outcomes. The authors found very little solid economic evidence, and even the better studies that presented cost data did not employ health economists. It is for all practical purposes true to say that the authors found no technically sound evidence .</p>

	about cost changes associated with EHR, bar one paper on PACS. Similarly, limited evidence about the impact of EHR on patient experiences and outcomes was found. Finally the authors have found no evidence at all about 'network effects'
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation or considerations for system design/development made.
Further research	A focus on macro effects rather than micro is warranted in future studies. The authors note that 1. there were no studies which actually sought to capture all of the costs and benefits associated with an EHR at the level of a process, or within a single hospital setting, and 2. none of the published studies provided adequate contextual information to evaluate the evidence presented properly.

REFERENCE	Delpierre C, Cuzin L, Fillaux J, Alvarez M, Massip P, Lang T. A systematic review of computer-based patient record systems and quality of care: more randomized clinical trials or a broader approach? <i>Int J Qual Health Care</i> 2004;16(5):407–16.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	17.5
Objective/Questions Addressed in the Review	To analyse the impact of computer-based patient record systems (CBPRS) on medical practice, quality of care, and user and patient satisfaction.
No of Studies Included in the Review	26
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, Cochrane Library and EMBASE 01/2000–03/2003
Search Strategy	Electronic search used the following keywords: electronic record, informatic record, electronic medical record, electronic patient record, patient order entry, computer-based patient system, clinical decision support systems, and evaluation.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	CBPRS defined as computer software designed to be used by clinicians as a direct aid in clinical decision-making. To be included, the systems should have recorded patient characteristics and offered online advice, or information or reminders specific to clinicians during the consultation
Setting	NS



Patients Reviewed	NS
Pre-defined outcomes	medical practice, quality of care, and user and or patient satisfaction
Range of Observations or Period of Follow Up	NS
Findings or results	A clear positive impact of CBPRS on preventive care was noted. This finding is consistent with other systematic reviews. Improvements in medical practice and the adoption of guidelines was less certain. Positive experiences were as frequent as experiences showing no benefit. In studies of arterial hypertension and major depression , there was no improvement in medical practice and compliance with guidelines, most studies were inconclusive concerning prescription error. Only six studies analysed the impact of the use of CBPRS on patient outcomes and did not show any benefit of CBPRS.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation made. .
Further research	Further research is needed as most of the studies did not include qualitative factors such as characteristics of the disease and the tool, the ward in which it is developed, and the relationship between various healthcare professionals, which can impact upon the use of CBPRS. A broad review including all the factors that could influence the success or failure of the use of CBPRS in medical practice is indicated in the future.

REFERENCE	Dorr D, Bonner LM, Cohen AN, Shoai RS, Perrin R, Chaney E et al. Informatics systems to promote improved care for chronic illness: a literature review. <i>J Am Med Inform Assoc</i> 2007;14(2):156–163.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	21
Objective/Questions Addressed in the Review	To understand information systems components important in supporting team-based care of chronic illness.
No of Studies Included in the Review	109 articles were reviewed involving 112 information system descriptions
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, PreMEDLINE, Business Source Premier, ABI, and the Cochrane Library for January 1, 1996–February 28, 2005

Search Strategy	Searches using search concepts (with appropriate synonyms): 1) informatics/information systems; 2) patient care management/collaborative care; and 3) chronic illness. This strategy was supplemented by articles identified as key in the reference sections of the studies received and from experts in the field.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	information systems used in the chronic illness care
Setting	NS
Patients Reviewed	patients with chronic illness
Pre-defined outcomes	process, quality outcomes, and healthcare costs
Range of Observations or Period of Follow Up	NS
Findings or results	<p>Process of care: Guideline adherence (for example, screening for target disorders, conducting lab tests on a recommended schedule) was the most frequently evaluated process outcome; it was assessed in 19 studies with 79% (15) positive and 21% (4) neutral assessments.</p> <p>Change in visit frequency (eg decrease in emergency visits) was assessed in ten studies with 50% in the positive direction and 50% neutral. Documentation (eg provider documentation of diagnostic criteria for specified disorders) was assessed in six studies with 83% (five) positive and 17% (one) neutral assessment. Treatment adherence (primarily adherence to medications) was assessed in three studies with 67% (two) positive and 33% (one) neutral assessment. Change in referral rate was assessed in two studies; both had neutral results. Screening and testing was assessed in two studies; both had positive results. Eleven studies assessed cost (typically involving some analysis of informatics system costs and savings to the organisation) with 91% (ten) positive and 9% (one) neutral outcomes.</p> <p>Clinical outcomes: Changes in laboratory values were assessed in ten studies with 50% positive and 50% neutral outcomes. Changes in scores on standardised instruments were assessed in ten studies with 30% positive, 60% neutral and 10% negative outcomes. Number of hospitalisations was assessed in seven studies with 43% (three) positive and 57% (four) neutral outcomes. Quality of life was assessed four times with 75% (three) positive and 25% (one) neutral outcome. Disease complications were assessed in only two studies with one positive and one neutral outcome.</p>

Relationship between informatics system components and outcomes: One subcomponent of Health Information and Data, the ability to exchange data with an electronic medical record, was positively related to improvements in process outcomes ( $r$  0.28,  $p$  0.05). Decision support was moderately helpful in the form of computerised prompts ( $r$  0.20,  $p$  0.08), but were related to failure when only electronic access to guidelines were provided through the system ( $r$  0.37,  $p$  0.02). Population management in general ( $r$  0.25,  $p$  0.06) and especially features such as generating reports of traditional (disease state, adherence) and non-traditional (unfinished care plan elements, telephone calls) measures ( $r$  0.32,  $p$  0.02) and auditing/providing feedback to providers ( $r$  0.31,  $p$  0.02) were positively associated with process and outcomes improvement. Advanced, specialised Order Entry systems, such as those including disease specific checks and corollary orders templates, those facilitating ordering of care plan elements like referral to a specialist or nurse care manager, and those wherein team members other than the primary care provider can create role-specific orders, were also related to improvements in process outcomes ( $r$  0.41,  $p$  0.02). Patient Support/Patient Portals were modestly associated with success ( $r$  0.20,  $p$  0.10). Electronic scheduling (an Administrative task) was associated with success ( $r$  .19,  $p$  0.08).

Multivariate analysis: Due to the small number of experimental studies, the authors could not create a comprehensive mathematical model of the relationship between informatics components and clinical or care process outcomes. A multivariable logistic regression demonstrated strong concordance with the above results, especially the combination of advanced Order Entry features (for instance, information about drug interactions) with Decision Support (like care plan elements reminders) and key Population Management and Administrative Processes features (such as follow-up of care plan, scheduling, and referrals) ( $c$  0.86; Hosmer-Lemeshow  $p$  0.28). Access to Population Management and Health Information and Data features remained strongly identified with positive results but insufficient variation existed to determine the strength of the association in the multivariate models.

Sociotechnical Assessment: Thirty studies described some usability assessment, using methodologies such as user interviews, surveys, number of encounters with system, etc. Of these studies, 80% (24) had mostly positive assessments of informatics system usability; 13% (four) were neutral and 7% (two) were negative. Most were not formal usability studies, making comparisons difficult. Accuracy was assessed

	<p>in only four studies using methods such as comparison of informatics-generated advice to expert clinician advice; all four studies found positive results. In addition, fifty-one studies included qualitative descriptions of implementation issues, usability suggestions, and recommended content. Suggestions for success in implementing HIT systems included involving end-users in the development process, responsiveness to end-user feedback, and thorough training. Having a physician buy-in to teach peers about the software was helpful.</p> <p>Barriers to adoption of HIT systems included concerns about the impact of HIT use on the clinical encounter, security issues, and concerns about resources. Failure to consider increased time to use the system (performance usability) or alteration in workflow were also barriers. Barriers to building informatics systems included resource-related challenges, technological difficulties, security concerns, and social barriers related to the availability of particular technologies in some areas. Usability recommendations ranged from concrete details of the user interface to more global suggestions about workflow (designating one person to handle all on-line messages, enabling real-time data entry for synchronous decision support). Improvements to decision support tools were the most frequently requested content modifications; specifically requested were support for medication and dosage decisions and additional features to support adherence to guidelines. Reported unintended outcomes were mostly positive and included improved communication and more efficient workflow.</p>
Conclusions, considerations for implementation, adoption or system design and development.	With regards to implementation the authors conclude that for information systems to be successful, an appropriate non-IT system of care must be in place, and the use of specialised IT components must fit with systems of care. Usability is essential to successful implementation of a software system. Learning from previously implemented systems supports efforts to leverage current knowledge into optimal improvement.
Further research	The authors note that formal usability assessment was rare.

REFERENCE	Eslami S, Abu-Hanna A, de Keizer NF. Evaluation of outpatient computerized physician medication order entry systems: a systematic review. <i>J Am Med Inform Assoc</i> 2007;14(4):400–6.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	17

Objective/Questions Addressed in the Review	To identify and summarise published studies of outpatient CPOE systems that evaluated one of six aspects: safety; cost and efficiency; adherence to guidelines; alerts; time; and satisfaction, usage, and usability.
No of Studies Included in the Review	30
No of Participants Studied in Total	NS
Databases and Years Searched	Ovid MEDLINE® (1950 to March 31, 2006) Ovid MEDLINE In-Process®, and EMBASE® (1980 to March 31, 2006)
Search Strategy	In the first part, the authors applied keywords without quotes and MeSH terms pertaining to electronic prescription. These terms cover old and new ways to refer to CPOE systems. In the second part, the authors searched for medication related terms to identify studies that address prescribing. In the third part, the authors searched for terms related to outpatient care. The results of these three parts were combined using the Boolean operator "and." Searching was supplemented by scanning bibliographies from identified articles. The final literature search was performed on March 31, 2006.
Study Designs Eligible for Inclusion	primary data reported with evaluative focus
Practitioner Targeted	NS
Intervention(s) and Comparisons	CPOE system for medication ordering and/or a CDSS used during the medication ordering
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	safety; cost and efficiency; adherence to guidelines; alerts; time; and satisfaction, usage, and usability
Range of Observations or Period of Follow Up	NS
Findings or results	Most studies (3 of 4) did not show significant reduction in the number of ADEs; studies on alerts show that alerts were largely ignored by physicians; there is some indication, although only from two studies with non-RCT design, that advice on equally effective but cheaper drugs and evidence-based messages are more effective at reducing costs than simply displaying a list of drugs with their prices; and finally there is more evidence on the ability of CPOE systems to increase adherence to guidelines in outpatient settings.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation were made.

Further research	Further research into patient outcomes, and research using non-traditional methods is warranted. Standards for CPOE system requirements and functionality, such as those pertaining to providing alerts, merit more attention as they could facilitate the design and implementation of such systems in the future.
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REFERENCE	Eslami S, de Keizer NF, Abu-Hanna A. The impact of computerized physician medication order entry in hospitalized patients-A systematic review. <i>Int J Med Inform</i> 2007 [Epub ahead of print]
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	16
Objective/Questions Addressed in the Review	To identify, uniformly characterise, and assess the reported CPOE impact in all published studies evaluating any aspect, safety and otherwise, associated with the use of a CPOE system in the inpatient setting.
No of Studies Included in the Review	67
No of Participants Studied in Total	NS
Databases and Years Searched	Ovid MEDLINE® & MEDLINE® in-process (1966 to August 2006), EMBASE® (1980 to August 2006), and the Cochrane library
Search Strategy	In strategy 1, keywords and MeSH terms that are currently in use for referring to a CPOE system (part A) are combined with terms related to inpatient care (part B). In strategy 2, computer (C) and medication (D) related terms are combined to identify studies that address prescribing with computerised systems in an inpatient setting (B), for especially uncovering older studies. The results of these two strategies are combined by using the Boolean operator “or”. Searching was supplemented by scanning bibliographies from identified review articles. The literature search was performed in August 2006.
Study Designs Eligible for Inclusion	Primary data reported with evaluative focus
Practitioner Targeted	NS
Intervention(s) and Comparisons	CPOE for medication ordering
Setting	inpatient
Patients Reviewed	NS
Pre-defined outcomes	NS



Range of Observations or Period of Follow Up	NS
Findings or results	Almost all studies in our review that evaluated the effect of CPOE systems on adherence to guidelines showed a positive effect; the review showed that the rates of the proximal outcomes, medication errors, fell due to CPOE introduction although the effect on ADEs, which is amore relevant clinical outcome, did not merit enough attention; there is some evidence about the positive effects of CPOE on hospital and pharmacy costs; all three articles concerning the acceptance of alerts showed that physicians did not accept most of the alerts; all three studies which consider ordering time as an outcome measure, from 1993 until the most recent one in 2001, showed that CPOE increased ordering time for physicians; almost all studies which evaluated the effect of CPOE on user satisfaction and usability were observational studies and showed positive results; the following medical facets were mainly missing: knowledge-base completeness and accuracy; the extent of adverse drug reaction reporting and consistency with dealing with different medication trade names
Conclusions, considerations for implementation, adoption or system design and development.	The authors note that implementing information technology applications such as CPOE is a socio-technical activity, which often depends more on organisational context than on a specific technology.
Further research	The authors note that one could perhaps argue for more RCT studies in the evaluation of CPOEs but they do have prohibitive costs. One fruitful way to proceed with is the use of controlled trials focusing on CPOE systems with more decision support for specific patient groups, high risk drugs, typical ADEs, using more powerful designs like interrupted time series. Another fruitful direction is to recognise that while the standard RCT methodology is excellent for studying system or clinical performance, it is not well suited to answering questions concerning whether systems will be used or how they will be used. This calls upon a complementary evaluation methodology that considers the social context in which CPOE systems operate.

REFERENCE	Fischer S, Stewart TE, Mehta S, Wax R, Lapinsky SE. Handheld computing in medicine. <i>J Am Med Inform Assoc</i> 2003;10(2):139–149.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	14
Objective/Questions Addressed in the Review	To summarise the current literature covering the use of handheld devices in medicine.

No of Studies Included in the Review	NS
No of Participants Studied in Total	NS
Databases and Years Searched	OVID, MEDLINE between 1998 and October 2001 and PreMEDLINE up to June 2002
Search Strategy	Searches applying the text words "personal digital assistant," "PDA," "microcomputer," "palm," "handheld," "wireless," and a combination of these search terms were used. Other search strategies included the review of reference lists and bibliographies of published work as well as internet-based reports found by using standard internet search engines.
Study Designs Eligible for Inclusion	subjective as well as objective descriptions
Practitioner Targeted	NS
Intervention(s) and Comparisons	handheld devices in medicine
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	No overall statement on findings per se but the authors conclude that handheld computers have significant potential to improve medical practice beyond serving as an address-book or calendar. The increasing implementation of this technology is impressive, but handheld devices have not yet become a standard medical tool.
Conclusions, considerations for implementation, adoption or system design and development.	The authors conclude that there are three components for successful system implementation: the technology, the software, and the people who need to use it. If any of these three points is not optimised, the system will be established but not used. Although hardware and software are available, they may not be optimised for the medical environment. Furthermore, the consumer's interest may be the limiting factor to a successful system implementation.
Further research	Although this technology appears attractive, further studies are necessary to prove benefits in terms of costs, patient outcome, and clinician satisfaction.

REFERENCE	Fitzmaurice DA, Hobbs FD, Delaney BC, Wilson S, McManus R. Review of computerized decision support systems for oral anticoagulation management. <i>Br J Haematol</i> 1998;102(4):907–909.
How does it meet inclusion criteria?	subset of another broader systematic review
CASP Total Score	14.5
Objective/Questions Addressed in the Review	To report the findings relating to CDSS for oral anticoagulation management of a primary-care-based systematic review which largely focused on near-patient testing.
No of Studies Included in the Review	7
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, Bath ISI Data Service, Science Citation Index, Index to Scientific and Technical Proceedings, Department of Health, EMBASE, General Practitioner Lit Data Base, Royal College of General Practitioners, CINAHL between 1986–1995
Search Strategy	Searches using computerized decision support, expert systems, electronic data interchange, and computer communication networks; in combination with: family practice, primary (health) care, physicians (sic) office and general practice. A comprehensive examination of the bibliographies from all publications identified by the computer searches was carried out in order to ensure that all relevant publications were included in the systematic review. These searches were supplemented by hand-searching citations and specialist journals, and questioning experts in the field.
Study Designs Eligible for Inclusion	methodology criteria alluded to but not explained
Practitioner Targeted	NS
Intervention(s) and Comparisons	CDSSs for anticoagulation
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Evidence from one study that CDSS for anticoagulation can achieve improved therapeutic control in terms of INR when compared to human performance.

Conclusions, considerations for implementation, adoption or system design and development.	The authors note that it remains important for any new CDSS to undergo full performance evaluation.
Further research	Reductions in medical and secretarial time as well as audit facilities have not been subject to evaluation according to authors. Evaluations should occur in the field in which they will be implemented.

REFERENCE	Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. <i>JAMA</i> 2005; 293(10):1223-38.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	25
Objective/Questions Addressed in the Review	To review controlled trials assessing the effects of computerised clinical decision support systems (CDSSs) and to identify study characteristics predicting benefit. The primary questions of this review were (1) Do CDSSs improve practitioner performance or patient outcomes? and (2) Which CDSS and study level factors are associated with effective CDSSs?
No of Studies Included in the Review	100
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, EMBASE, Evidence-Based Reviews databases (Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, and Cochrane Central Register of Controlled Trials), and INSPEC bibliographic databases from 1998 through September 2004
Search Strategy	The final strategies used the terms computer-assisted decision making, computer-assisted diagnosis, computer-assisted therapy, decision support systems, reminder systems, hospital information systems, randomized controlled trial, and cohort studies (complete strategies available from the authors)
Study Designs Eligible for Inclusion	randomised and non-randomised trials with a contemporaneous control group
Practitioner Targeted	NS
Intervention(s) and Comparisons	CDSSs, comparison of patient care with a CDSS to routine care without a CDSS
Setting	NS

Patients Reviewed	NS
Pre-defined outcomes	clinical performance (ie a measure of process of care) or a patient outcomes
Range of Observations or Period of Follow Up	NS
Findings or results	<p>There were 10 trials evaluating diagnostic systems. All studies measured practitioner performance, and the CDSS was beneficial in 4 studies (40%). There were 21 trials evaluating reminder systems for prevention. All trials measured practitioner performance, and the CDSS was beneficial in 16 studies (76%). There were 40 studies of CDSSs for active health conditions. These CDSSs improved practitioner performance in 23 (62%) of 37 studies evaluating this outcome. Of the 27 trials measuring patient outcomes, 5 (18%) demonstrated improvements. There were 29 trials of drug dosing and prescribing. Single-drug dosing improved practitioner performance in 15 (62%) of 24 studies, and 2 of the 18 systems assessing patient outcomes reported an improvement. Another 5 systems used computer order entry for multi-drug prescribing. Four of these systems improved practitioner performance, but none improved patient outcomes. Studies in which users were automatically prompted to use the system described better performance compared with studies in which users had to actively initiate the system [success in 44/60 studies [73%] vs 17/36 studies [47%]; <math>P=0.02</math>; unadjusted OR, 2.8; 95% CI, 1.2–6.6; OR adjusted for methodological quality, 3.0; 95% CI, 1.2–7.1]. Similarly, studies in which the authors also created the CDSS reported better performance compared with those in which the trialists were independent of the CDSS development process [success in 51/69 studies [74%] vs 5/18 studies [28%]; <math>P=0.001</math>; unadjusted OR, 6.7; 95% CI, 1.7–25.3; OR adjusted for methodological quality, 6.6; 95% CI, 1.7–26.7].</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>With regards to implementation, the decision to adopt a CDSS for local patient care is complex and is influenced by many considerations. Those responsible for CDSS implementation are typically administrators, information technology managers, and clinicians, all of whom are increasingly pushed by technology and guided by government regulations. Important issues include CDSS user acceptance, workflow integration, compatibility with legacy applications, system maturity, and upgrade availability. Some are concerned about increased practitioner dependence on CDSSs, with eroded capacity for independent decision-making. Finally, cheaper, non-computerised alternatives may be equally or more effective in improving care and reducing medical errors.</p>

<p>Conclusions, considerations for implementation, adoption or system design and development.</p>	<p>One of the primary considerations in adopting a CDSS is its clinical effectiveness: To what extent should it be proven beneficial before mass deployment? Clearly, some testing is required, as a CDSS can have unanticipated effects when used in patient care. Some highlight the need for multi-centre cluster randomised controlled trials demonstrating improvements in important patient outcomes. Using such a standard, this review suggests that the majority of available systems are not yet ready for mainstream use. Most trials were unable to enrol enough clusters or patients for adequate statistical power to detect improvements in patient outcomes. Unfortunately, this situation is unlikely to change soon, given the substantial time and resources needed to conduct such trials, particularly in the area of preventive health. Furthermore, CDSSs are limited by the cumulative knowledge used to program their recommendations. It would be unrealistic to require repeat CDSS testing every time advances in the knowledge-base become available. Thus, for initial consideration, it may be reasonable to require proof of CDSS effectiveness only on practitioner performance, particularly if such outcomes represent current accepted standards in care. In our review, many systems met this requirement. However, this does not preclude the need for subsequent trials or in-practice assessment to confirm system performance in improving patient health. Institutions need to measure effects on local outcomes and be prepared to iteratively modify their system in response to practice-based knowledge. While some perceive that CDSSs improve efficiency and reduce costs, the current supporting evidence is limited. Although some studies have assessed the costs when outcomes were improved, the cost-effectiveness of these systems remains unknown. Many studies suggested the CDSS was inefficient, requiring more time and effort from the user compared with paper-based methods. Finally, most CDSSs used research funding to facilitate implementation. As highlighted in this review, up to 21% of trials used staff paid by research funds for data entry or CDSS recommendation delivery. When investing in a commercially available system, funding for support personnel is an additional cost to be considered. There is currently widespread enthusiasm for introducing electronic medical records, computerised physician order entry systems, and CDSSs into hospitals and outpatient settings. In other commercial, industrial, and scientific spheres of activity, computers have become ubiquitous and have improved safety, productivity, and timeliness. Given this progress, computerisation of the healthcare environment should offer tremendous benefits. However, uptake has been slow, and multiple challenges have arisen at every phase of software development, testing, and implementation. The progress of</p>
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	CDSSs has mirrored these trends. Systems are proliferating, their technical performance and usability are improving, and the number and quality of evaluations is increasing. These evaluations have shown that many CDSSs improve practitioner performance.
Further research	Further research is needed to elucidate the effects of such systems on patient health.

REFERENCE	Georgiou A, Williamson M, Westbrook JI, Ray S. The impact of computerised physician order entry systems on pathology services: a systematic review. <i>Int J Med Inform</i> 2007;76(7):514–29.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	19
Objective/Questions Addressed in the Review	To review current evidence of the impact of CPOE on hospital pathology services and to identify the indicators, which have been used to measure impact.
No of Studies Included in the Review	19
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, CINAHL, EMBASE, SocScience Index and Cochrane Database of Systematic Reviews between 1990 and August 2004
Search Strategy	Database searches for Concept 1: order entry: Order entry (T), order management (T), electronic health records (T), medical records systems, computerized (aSH), clinical laboratory information systems (SH), laboratory information systems Concept 2: decision support: Database management systems (T, SH), computer-assisted decision support (T), decision making, computer assisted (aSH), clinical decision support systems (T), decision support systems, clinical (SH), decision support techniques (T, SH), expert systems (T, SH) Concept 3: electronic or computerised :Computer (T), electronic (T), microcomputer (T, SH) Concept 4: pathology/laboratory: Laboratory (Ta, SH), Pathology (Ta, SH) T denotes text, SH denotes a subject heading. a SH denotes subject heading exploded. Web-based searches using Google and hand searches of international health informatics journals were completed. The reference lists from relevant articles and additional articles by key authors were also reviewed.
Study Designs Eligible for Inclusion	experimental or quasi-experimental including before and after studies and times series studies
Practitioner Targeted	NS

Intervention(s) and Comparisons	CPOE
Setting	hospital
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Of the eleven studies of the impact of CPOE on test volumes, seven reported a significant decrease in test volume, three showed no change and one reported an increase in tests ordered. Five studies measured laboratory related test costs, of which four showed significant reductions and one showed no change. Four studies found that CPOE systems with computerised decision support improved compliance with guideline advice. Most studies reported no significant impact on length of stay. There are data suggesting that CPOE systems are beneficial for clinical and laboratory work process. Few data however are available regarding the impact of CPOE on patient outcomes
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation given. The authors note that there exists a broad assumption that CPOE will virtually eliminate errors that are traditionally associated with the transcription of information on to paper orders (eg missing patient identifiers, illegible information, missing signatures). However, CPOE will not eliminate the physician making an inappropriate test choice (although decision support features may ameliorate this to some degree) and may generate its own class of errors by selecting the wrong test from unclear or ambiguous computer-generated pick lists.
Further research	There remains a strong need for further research to provide robust evidence of the impact of CPOE systems on clinical and laboratory work processes. None of the studies focused on the impact of CPOE on pathology work processes, even though CPOE systems often involve a significant change in work patterns of pathology staff, which may indeed impact on the quality and efficacy of pathology processes. This remains an important area for future research, which would benefit greatly from collaboration between clinicians, pathology laboratory scientists and researchers.

#### REFERENCE

Handler SM, Altman RL, Perera S, Hanlon JT, Studenski SA, Bost JE et al. A Systematic Review of the Performance Characteristics of Clinical Event Monitor Signals Used to Detect Adverse Drug Events in the Hospital Setting. *J Am Med Inform Assoc* 2007;14(4):451–458.

How does it meet inclusion criteria?	systematic review in title
CASP Total Score	22.5
Objective/Questions Addressed in the Review	To analyse individual pharmacy and laboratory signals that are currently used by clinical event monitors to detect ADEs in the adult hospital setting.
No of Studies Included in the Review	NS
No of Participants Studied in Total	NS
Databases and Years Searched	OVID MEDLINE, OVID CINHAL and EMBASE between January 1, 1985 and July 1, 2006
Search Strategy	In OVID, the authors searched for the following medical subject headings (MeSH) keywords, and text words: adverse drug event, adverse drug reaction, adverse drug reaction reporting systems, clinical event monitor, clinical decisions support systems, clinical laboratory information systems, clinical pharmacy information system, computer generated signals, decision support system, drug monitoring, medication errors, and physiologic monitoring. In EMBASE, the authors searched for the above terms plus the following Emtree keywords: computer assisted drug therapy and drug surveillance program. The authors supplemented the computerised search by reviewing the reference lists of all articles selected for inclusion.
Study Designs Eligible for Inclusion	Peer-reviewed studies
Practitioner Targeted	NS
Intervention(s) and Comparisons	clinical event monitoring system to detect ADEs in an adult hospital setting describing laboratory or pharmacy ADE signals
Setting	hospital
Patients Reviewed	NS
Pre-defined outcomes	PPVs or information to allow the calculation of PPVs for individual ADE signals
Range of Observations or Period of Follow Up	NS
Findings or results	Various PPVs are given:

Conclusions, considerations for implementation, adoption or system design and development.	With regards to implementation, the fact that many of the signals to detect ADEs have relatively low PPVs should not impede the adoption of clinical event monitors. In many respects, the monitors can be treated as a type of screening test that allows for early ADE identification and intervention, and thereby reduces morbidity and mortality rates. The findings from the review should aid hospitals in prioritising event monitors.
Further research	Additional studies are needed to improve the performance characteristics of individual ADE signals and CDS systems, apply these systems to other clinical environments, develop interoperable systems, and perform economic analyses of these systems. Studies have suggested that ADE detection rates can be improved by combining multiple data sources and having a better understanding of the context of the data as they relate to patients' underlying medical conditions. Investigators have begun to use clinical decision support systems to detect ADEs in other clinical care settings, such as ambulatory care clinics and nursing homes. These systems may be particularly useful in the nursing home setting where patients are frail, have multiple co-morbid medical conditions, and take more medications per patient than in any other clinical setting. Since most systems lack standardised methods to export or share ADE algorithms, additional studies are required to develop interoperable systems. Additional cost-benefit and cost-effectiveness studies are needed not only to determine the rational selection, optimal use, and potential success of systems used to detect ADEs, but also to determine the costs of developing and maintaining the systems and of responding to true-positive and false-positive alerts.

REFERENCE	Hayrinen K, Saranto K, Nykanen P. Definition, structure, content, use and impacts of electronic health records: A review of the research literature. <i>Int J Med Inform</i> 2007 [Epub ahead of print]
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	15.5
Objective/Questions Addressed in the Review	To answer the following questions: (1) how is the EHR defined in earlier research, (2) how is the structure of EHRs described, (3) in which contexts is the EHR used, (4) who has access to EHRs, (5) what data components of the record system are used by end-users and studied, (6) what is the purpose of these studies, (7) what methods of data collection are used in the studies and (8) what are the results of these studies.
No of Studies Included in the Review	NS

No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE (PubMed), CINAHL, Inventory of Evaluation Publications (University for Health Informatics and Technology, Tirol Research Group Assessment of Health Information Systems) and the Cochrane Library (The Cochrane Collaboration)
Search Strategy	<p>For CINAHL, the search was performed using thesaurus terms and free text words, combining them in an appropriate way. The terms used were: content analysis, content validity, evaluation research, computerized patient record, documentation, validation, utilization, classification, nomenclature, vocabulary, controlled and nursing classification. In addition, free text words were ANDed with the appropriate thesaurus terms and ORed with other search statements. The search was then restricted to journal articles. As it was expected that much of the research literature within the scope of the review would not be indexed, no time limits were applied. For PubMed/MEDLINE, the search was carried out in a similar way by using both the MeSH terms and free text words. The terms used were medical records systems, computerized, content, assess and evaluate, classification, vocabulary, controlled, coding and nursing classification. For Cochrane, the search was carried out using the same terms as on MEDLINE (PubMed). On the Inventory of Health Information Evaluation Studies 1982–2002 database (evaldb), the search was based on the criteria that are used to classify studies. In this study the search was performed using two criteria of the database classification: the focus of the evaluation study and the type of information system. The focus of evaluation study criterion is classified further; one criterion is the quality of the documented and processed information, ie completeness and correctness of documentation. The other database criterion is the type of information system. Information systems are present study: CIS (general or unspecified clinical information or documentation system) OR ANAEST (anaesthesia information and documentation system) OR CPOE (physician order entry system) OR GP (GP information system) OR LAB (laboratory management system) OR NURSE (nursing information and documentation system) OR OP (operation unit planning and management system) OR PACS (picture archiving and communication system) OR PDMS (patient data management system) OR PHARM (pharmacy information system) OR PIS (patient information systems) OR RIS (radiological information system). Publications were limited to English and articles electronically retrievable as full texts or available locally.</p>
Study Designs Eligible for Inclusion	NS

Practitioner Targeted	NS
Intervention(s) and Comparisons	EHRs
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	There was no evidence that an information system can help to save time, or that documentations take more time. Less time was spent on documentation when information systems were used. Many studies indicated that the use of an information system was conducive to more complete documentation by healthcare professionals, although no changes have been observed in clinical work patterns.
Conclusions, considerations for implementation, adoption or system design and development.	The authors made no recommendations for implementation but did denote important considerations for system design and development. EHRs are used by many different healthcare professionals, and the needs and requirements of all these professionals must be taken into account in the development of the information systems. EHR systems in multi-professional use are precisely the information systems in such departments as intensive care unit or emergency department where the work by nature involves closer teamwork. On the wards, nurses and doctors record patient data in their own separate information systems, and the use of the other's documentation is difficult, which might also have an effect on patient care. Almost half of the papers concerned research into medical data components. However, nursing documentation, or documentation by other healthcare professionals such as physiotherapists, is an important part of the EHR and must not be excluded from medical documentation. Different kinds of standardised instruments are also an integral part of EHRs.
Further research	On the basis of this review, it is obvious that studies focusing on the content of EHR are needed, especially studies of nursing documentation or patient self-documentation. Comparison of the documentation of different healthcare professionals with the core information of EHRs as determined in national health projects is one possible focus of future research. The challenge for ongoing national health record projects around the world is to take into account all the different types of EHRs and the needs and requirements of different healthcare professionals and consumers in the development of EHRs. A further challenge is the use of international terminologies in order to achieve semantic interoperability.



REFERENCE	Hender K. How effective are computer assisted decision support systems (CADSS) in improving clinical outcomes of patients?
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	15.5
Objective/Questions Addressed in the Review	To assess how effective are computer assisted decision support systems (CADSS) in improving clinical outcomes of patients.
No of Studies Included in the Review	10
No of Participants Studied in Total	NS
Databases and Years Searched	Χοχηρανε Λιβραρψ ΧΔ-POM, 2000, Ισσυε 3; ΟςΙΑ Βεστ Επιδενχε, 1995 Μαρχει/Απριλ 2000; ΟςΙΑ Μεδλινε, 1995 Οχτοβερ Ωεεκ 3 2000; ΟςΙΑ ΧΙΝΑΗΛ, 1995 θυλψ 2000; Οπιδ Χυρρεντ Χοντεντσ, 1995 Ωεεκ 26 το 2000 Ωεεκ 37; Πρε-Μεδλινε• September 1, 2000; SUM search• September 4, 2000; Effective Health Care Bulletins• 19 September, 2000; Effectiveness Matters• 19 September, 2000; Aggressive Research Intelligence Facility (ARIF); Turning Research into Practice (TRIP)
Search Strategy	"CADSS"-related Decision support systems clinical, decision making computer assisted, reminder systems, computer, clinical decision making, clinical algorithm
"RCT"-related Randomized controlled trial, meta analysis, controlled clinical trial, clinical trial/s, random/ly/ised/ized, double or single blind, crossover/ studies	
Study Designs Eligible for Inclusion	First a search for systematic reviews, evidence-based clinical practice guidelines, or health technology assessments, and randomised controlled trials. If sound, relevant material of this type is identified, the search stops. Otherwise, the search strategy broadens to include studies that are more prone to bias, less generalisable, or have other methodologic difficulties. Included are case-control and longitudinal cohort studies in the critical appraisal reports. While observational and case series studies, and narrative reviews and consensus statements are cited, they are not critically appraised. Some studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.
Practitioner Targeted	NS

Intervention(s) and Comparisons	CDSS
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	practitioner performance and or patient outcomes
Range of Observations or Period of Follow Up	NS
Findings or results	Table of summarised included studies, with some comments made by the author
Conclusions, considerations for implementation, adoption or system design and development.	The authors made no recommendations for implementation.
Further research	NS

REFERENCE	Hider P. Electronic prescribing: a critical appraisal of the literature. 2002
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	24.5
Objective/Questions Addressed in the Review	To systematically review the effectiveness of electronic prescribing to improve practitioner performance and patient-oriented outcomes.
No of Studies Included in the Review	52
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, EMBASE, Current Contents, CINAHL, Healthstar, Science Citation Index, International Pharmaceutical Abstracts, Cochrane
Controlled Trials Register, Index New Zealand between 1990 – May 2001	
Search Strategy	No search terms or strategies were given. A range of other library and Internet-based catalogues was also examined along with references listed in publications obtained during the review though.
Study Designs Eligible for Inclusion	any intervention study with a comparison group and data from before and after the intervention
Practitioner Targeted	any health professional
Intervention(s) and Comparisons	computerised assistance with prescribing medication limited to ordering and transcribing
Setting	NS

Patients Reviewed	NS
Pre-defined outcomes	changes in surrogate outcomes, prescriber performance or patient outcome
Range of Observations or Period of Follow Up	NS
Findings or results	<p>Computerised support for general prescribing</p> <p>Electronic prescribing can improve physician performance especially with respect to prescribing potentially toxic drugs with narrow therapeutic ranges where drug monitoring is commonly conducted (Level I evidence). Relatively few studies have assessed patient outcomes. The effect of electronic prescribing on patient outcomes is not clear although there is some evidence that it can reduce the frequency of adverse drug reactions and shorten length of hospital stay (Level I evidence).</p> <p>Physician Order Entry</p> <p>Physician Order Entry (POE) is a computer application that enables health professionals (usually doctors) to order diagnostic and treatment services electronically. POE can effectively improve physician prescribing habits and reduce medication errors (Level III-3 evidence). However, the effect of POE on health outcomes, especially adverse drug events (ADEs), has not yet been well established (Level III-3 evidence). POE increased the time required by doctors to order medication (Level III-3 evidence). There is inconsistent evidence about whether consultations were lengthened (Level II evidence). POE has been able to reduce patient charges even though their length of stay was not changed (Level II evidence). Sometimes doctors were not satisfied with the introduction of POE (Level II evidence). Corollary orders reduced medication errors but not patient length of stay or charges (Level II evidence). Most evaluations have been conducted in a small number of specialised hospital settings (eg Harvard) where unique and sophisticated computer systems allow access to clinical notes and other laboratory data as well as administrative information.</p> <p>The provision of electronic alerts after prescribing</p> <p>Computerised reviews of prescriptions and the electronic submission of alerts to prescribers about drug interactions have been introduced into large healthcare organisations with sophisticated computer systems that incorporate clinical and administrative information. Computerised checks and electronic alerts can reduce the incidence of dangerous drug interactions and the time before the drugs are changed in hospitals with large, sophisticated computer systems (Level III-3 evidence).</p>

The intervention can improve prescribing by physicians but a small proportion of doctors appear to ignore repeated warnings (Level III-3 evidence). Prescribing alerts can reduce ADEs and improve other patient health outcomes such as the risk of renal impairment (Level III-3 evidence). Current evidence suggests that alerts do not reduce length of hospital stay or inpatient costs (Level III-3 evidence). Similarly, alerts have failed to reduce the risk of exposure to drug interactions among the general population of a health maintenance organisation (Level III-3 evidence).

Primary care-based evaluations of electronic prescribing

Computers can improve documentation and administration in the primary care setting (Level I evidence). Various computerised tools such as reminders or feedback and recommendations for treatment based on guidelines can improve physician prescribing (Level I and III-1 evidence). Computerised risk charts not closely linked to the prescribing process are ineffective (Level II evidence). Evidence that computerised prescribing improves health outcomes compared to physician-based treatment in primary care is very limited (Level IV evidence).

Computerised prescribing for specific treatments (anticoagulation, infection, hypertension, hyperlipidaemia, diabetes, asthma, childbirth and anaesthesia) Computerised prescribing does improve therapeutic control with anticoagulation therapy. Overall, the proportion of tests in the therapeutic range is higher among patients treated with computerised dosing than physician-led therapy (Level I evidence). Computers have consistently generated a higher proportion of blood concentrations within the therapeutic level compared to physicians during the initiation and maintenance of heparin treatment in hospitals (Level III-3 evidence). Although the results from the larger number of studies that have considered computerised prescribing of warfarin are

#### ELECTRONIC PRESCRIBING

less consistent (Level III-3 evidence), there is evidence that computers can out-perform experienced staff working in specialised outpatient clinics (Level II evidence). No study has examined patient outcomes or costs related to computerised anticoagulation therapy. Computer support can improve the accuracy of documentation and the completeness of prescribing records for patients receiving ongoing care for chronic conditions such as hypertension (Level 1 evidence) and lipid disorders (Level III-3 evidence). Electronic support can improve physician prescribing behaviour in relation to their management of a number of medical conditions (hypertension, infection, hyperlipidaemia, the induction of labour and anaesthesia) (Level II evidence).

	<p>Electronic prescribing systems that attempt to analyse biochemical data and provide clinical predictions or suggestions about patient management have been associated with inconsistent effects on surrogate outcomes. Beneficial effects on lipid levels (Level III-3 evidence) and blood pressure recording during surgery (Level III-1 evidence) contrast with an absence of improvement in BP recordings</p> <p>(Level II evidence), blood glucose readings (Level II evidence), and HbA1c levels (Level II evidence). Results from newer decision support programmes, which include Bayesian logic, have been inconsistent, although they have usually been no worse than physicians at maintaining the serum concentrations of various medications within a therapeutic range (Level III-1 evidence). Electronic prescribing may be more effective than its human counterpart in circumstances where medication must be given in special doses or at critical times, particularly when the regimen is complicated (Level II evidence). The impact of electronic prescribing for specific medical conditions on health outcomes is unclear. Evaluations of the effect of programmes on patient outcomes have been infrequent. However, the limited evidence available suggests that electronic prescribing can reduce the frequency of ADEs related to the use of antibiotics (Level III-3 evidence). A range of other patient outcomes from electronic prescribing, although not improved were still comparable with physician-based care in the management of diabetes (frequency of hypoglycaemic events), infection (mortality), asthma (length of stay) and the induction of labour (rates of caesarean section and other maternal/foetal outcomes) (Level II evidence). Electronic tools that did not provide personalised information and specific management advice, such as drug dose and treatment recommendations, were not effective at improving health outcomes (Level II evidence).</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>Computers should be introduced when it is important that asynchronous pieces of data need to be communicated together and where the results from complex or repetitive evaluations need to be presented to health professionals rapidly. Key characteristics of situations where electronic prescribing systems have worked well include: organisations where there has been significant collaboration and leadership from senior clinicians and management, the use of fast, reliable systems that are uniform throughout the organisation and interface well with their operators, easy and direct access to machines (fixed or mobile) that are available where the clinical work is undertaken, and the provision of adequate resources including staff training and information technology backup. Designers of computer software for use in healthcare settings should take more account of how other patient data</p>

	<p>can be used particularly in primary care where a substantial amount of information (eg medical history, tests results) is now available electronically. Decision support should be introduced judiciously. POE should be implemented within organisations with sophisticated, computerised patient information systems. Consideration should be given to the introduction of corollary orders in conjunction with POE. Computerised alerts and warnings should be provided as backup where computerised information systems exist because electronic systems can be bypassed or not kept up-to-date. New systems should be developed that can communicate with each other. International standards should be developed for these systems and their data. Given the rapid rate of development of computerised prescribing, the inconsistencies in results and the limited range of clinical settings in which they have been trialled, it is important that the provision of an electronic prescribing system should always be evaluated using a well designed method that incorporates patient outcomes. This is especially true if the system has not been previously tested, if the clinical setting differs from that of previously tested sites or if specially trained staff were included in the previous evaluation.</p>
Further research	<p>There is a pressing need for rigorous evaluations of:</p> <p>The acceptability of electronic prescribing to health professionals that:</p> <ul style="list-style-type: none"> <li>• determine aspects of decision support that are most helpful and acceptable to prescribers</li> <li>• explore the acceptability of alerts and warnings</li> <li>• investigate how these warnings could be made more useful to prescribers</li> <li>• consider the acceptability of different types of POE to prescribers.</li> </ul> <p>Economic evaluations that:</p> <ul style="list-style-type: none"> <li>• Describe costs and health outcomes associated with integrated computer systems that incorporate pharmacy, laboratory and administrative data</li> <li>• define costs and health outcomes related to POE</li> <li>• explore the marginal costs and effectiveness of decision support with and without POE</li> <li>• evaluate the marginal costs and effectiveness of decision support with and without evidence-based guidelines</li> <li>• determine whether decision support enables other professional groups to effectively and safely assume roles (prescribing, diagnosing, patient information provision etc) previously occupied by physicians.</li> </ul> <p>Patient outcomes related to electronic prescribing that:</p> <ul style="list-style-type: none"> <li>• determine the effects of all types of electronic prescribing on health outcomes</li> </ul>



	<ul style="list-style-type: none"> <li>• describe the costs and health outcomes related to the provision of specialised dosing programmes for medications with a narrow safety profile for which blood concentrations can accurately, reliably and quickly be determined and that utilise a Bayesian approach to pharmacokinetics</li> <li>• undertake evaluations of the safety features of electronic prescribing systems and their ability to appropriately cope with patient emergencies or detect and respond to their own electrical and mechanical problems</li> <li>• ascertain the health outcomes and the cost-effectiveness of computer-generated anticoagulation therapy for both the initiation and maintenance of heparin or warfarin treatment in hospital or outpatient settings.</li> </ul> <p>Relative effectiveness of different types of electronic advice for different types of prescribers in a variety of settings that:</p> <ul style="list-style-type: none"> <li>• undertake comparisons of the use of warnings at the time of prescribing versus the provision of alerts after the prescription has been completed</li> <li>• explore the use of critiquing systems that check for alerts after prescriptions have been completed for audit and quality improvement purposes</li> <li>• determine the effects of decision support on junior doctors who subsequently work in paper-based organisations</li> <li>• evaluate the use of electronic prescribing in primary care</li> </ul> <p>ELECTRONIC PRESCRIBING</p> <ul style="list-style-type: none"> <li>• consider whether decision support is more beneficial for doctors with different characteristics</li> <li>• address what decision support material should be presented simultaneously with prescribing or what should be available by an additional step</li> <li>• examine electronic prescribing interventions in New Zealand</li> <li>• elucidate reliable indicators of the risk of an ADE</li> <li>• examine the effectiveness of the provision of additional clinical information with the prescribing information that is electronically checked by the warning system</li> <li>• consider the relative or additional benefits of POE relative to other interventions (such as unit dosing, bar coding and automated dispensing systems) that aim to reduce medication errors.</li> </ul>
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REFERENCE	Hogan WR, Wagner MM. Accuracy of data in computer-based patient records. <i>J Am Med Inform Assoc</i> 1997;4(5):342-355.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria with quality assessment

CASP Total Score	16
Objective/Questions Addressed in the Review	First, to determine the quality of the literature on data accuracy in CPRs. Second, to form a synthesis of the results reported by this literature to answer the following open questions about data accuracy in CPRs: How accurate are data contained in CPRs? What are the causes of inaccurate data? Which CPR characteristics influence data accuracy, and does direct clinician entry of data into the CPR result in higher rates of correctness and completeness than entry of data by third parties? How can data accuracy in CPRs be improved? Is the accuracy of CPR data higher than the accuracy of data in paper-based records? Third, to provide methodological guidelines for researchers, quality improvement teams, and users of CPR data who are interested in performing and critiquing future studies of data accuracy.
No of Studies Included in the Review	20 articles reporting the results of 26 studies
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE and CURRENT CONTENTS, conference proceedings, a citation index (SCISEARCH)
Search Strategy	A text word search that retrieved citations containing at least one of the following words related to the concept of accuracy: accuracy, accurate, inaccuracy, inaccuracies, inaccurate, reliability, reliable, unreliability, unreliable, valid, validity, invalid, invalidity, correct, correctness, incorrect, incorrectness, complete, completeness, incomplete, incompleteness, error, erroneous, quality was performed. This list of words was generated iteratively by performing a search, adding words that the authors found in citations, then repeating the search. It was also required that articles be indexed under the MeSH term INFORMATION SYSTEMS. A second MEDLINE strategy to retrieve articles not indexed under INFORMATION SYSTEMS was employed. This search retrieved articles containing at least one of the following phrases: data accuracy, accuracy data, data inaccuracy, inaccuracy data, inaccuracies data, data quality, quality data, data error, data errors, and erroneous data. CURRENT CONTENTS was also searched from October 1995 to February 1996 to identify articles not yet indexed by MEDLINE. The first MEDLINE strategy without the INFORMATION SYSTEMS restriction was used. Finally, a citation search using SCISEARCH to identify articles that referenced an early review of the accuracy of medical data was performed. The tables of contents of all Proceedings of the Annual Symposium on Computer Applications in Medical Care (1977–1995) and the American Association for Medical Systems and Informatics Congress (1982–1989) were also reviewed.

Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	CPRs defined as a computer-based system that contains primary patient records, defined by the Institute of Medicine (IOM) as records used by healthcare professionals while providing patient care services to review patient data or document their own observations
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	correctness or completeness, or data from which the authors could compute at least one of them was reported for at least one type of data
Range of Observations or Period of Follow Up	NS
Findings or results	Based on examination of rates of accuracy from the 7 studies scoring 12 points or higher, is that data accuracy in CPRs is fair to good. With the exception of a few data types such as specific diagnoses (eg anaemia in children) and occupational history, the majority of rates of correctness and completeness from these studies are 80% and higher for the types of data studied
Conclusions, considerations for implementation, adoption or system design and development.	How to improve data accuracy requires further study.
Further research	Recommendations to researchers are as follows. Researchers should (1) report numerical measures of both correctness and completeness, (2) use an unbiased sampling technique to select patient records for inclusion in the study, (3) select a gold standard with the intention of approximating the true state of the patient as closely as possible, and (4) blind the members of the research team who are responsible for the determination of the gold standard to both the purpose of the study and the CPR data when appropriate. Ideally, studies should provide a thorough description of the CPR, including its name, hardware components, and software versions (especially if the CPR is commercially or otherwise available for implementation at other sites), what types of data it contains, how long it has been in place, its scope, and a description of its methods for data capture.

REFERENCE	Holbrook AM, Sullivan S, Keshavjee K, Hunt DL. Predictors of Success in Electronic Decision Support for Prescribing. <i>Can J Clin Pharmacol</i> 2000;7:61.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	9
Objective/Questions Addressed in the Review	To examine key predictors of success versus failure for CDSS aimed at influencing prescribing towards best evidence.
No of Studies Included in the Review	20 studies of level 1a evidence
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, EMBASE and the Cochrane Library were searched from 1976 to 1999
Search Strategy	database searches used terms related to therapy, computers and decisions
Study Designs Eligible for Inclusion	Evidence level 1a
Practitioner Targeted	NS
Intervention(s) and Comparisons	ePrescribing
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	reported barriers to or predictors of success
Range of Observations or Period of Follow Up	NS
Findings or results	Level 1A evidence, meaning that based on empiric, quantitative data, favoured: a) active, real-time decision support based on patient-specific data; b) display of costs of tests and therapies to clinicians, c) availability of guidelines, general drug information and patient education materials. Evidence to date suggests the main principles are point-of-care advice well integrated into clinical workflow with easy access to more information as needed.
Conclusions, considerations for implementation, adoption or system design and development.	Regarding adoption the authors concluded that clinicians needed flexible, fast interfaces, convenient access to computers and organised charting forms.
Further research	Future trials of CDSS should evaluate predictors of success/failure of the system

REFERENCE	Holbrook A, Xu S, Banting J. What factors determine the success of clinical decision support systems? <i>AMIA Annu Symp Proc</i> 2003;862.
How does it meet inclusion criteria?	update of a previous systematic review
CASP Total Score	6.5
Objective/Questions Addressed in the Review	To update previous review on predictors of successful CDSS
No of Studies Included in the Review	5 systematic review, 9 study reports
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, EMBASE since January 1999
Search Strategy	Database search terms included "decision support systems, clinical" combined with "computers"; or "expert systems" or "computer assisted decision making" or "computer assisted diagnosis" or "computer assisted therapy" or "computer assisted drug therapy" or "artificial intelligence" or "computerised medical records"
Study Designs Eligible for Inclusion	Systematic overviews of trials on CDSS were also reviewed. Although the target was randomised trials where predictors of success or failure were specifically measured, the authors also accepted empirical prospective studies
Practitioner Targeted	NS
Intervention(s) and Comparisons	CDSS
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	clinical outcomes and quantitatively analysed factors related to CDSS success or failure
Range of Observations or Period of Follow Up	NS
Findings or results	Seven of the 9 studies reported negative results. The 2 positive trials addressed relatively simple interventions.
Conclusions, considerations for implementation, adoption or system design and development.	Most authors expressed opinions regarding the lack of success of their CDSS, which included information coming too late to be useful, failure to remember computer passwords, too little time to use computer, the CDSS was too difficult to understand, inadequate integration of CDSS into clinical workflow, preference not to use computers, inadequate integration of CDSS with electronic medical record and failure to select a high need area of care.

Further research	Well done trials of point-of-care CDSS continue to produce mixed results, perhaps because factors that would predict successful CDSS still have not been adequately identified.
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REFERENCE	Hunt DL, Haynes RB, Hanna SE, Smith K. Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review. <i>JAMA</i> 1998; 280(15):1339-46.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	22
Objective/Questions Addressed in the Review	To systematically review controlled clinical trials assessing the effects of computer-based clinical decision support systems (CDSSs) on physician performance and patient outcomes.
No of Studies Included in the Review	28 from the previous review and 40 new
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, EMBASE, INSPEC, SCISEARCH from February 1992 to March 1998
Search Strategy	The MEDLINE search strategy included the Medical Subject Heading (MeSH) terms computer-assisted decision making, artificial intelligence, computer-assisted diagnosis, computer-assisted therapy, and hospital information systems. The complete MEDLINE, EMBASE, and INSPEC search strategies are available on request. The authors searched SCISEARCH for references to the primary studies from the previous reviews and also searched the Cochrane Library <sup>6</sup> (search strategy available on request) for potentially relevant citations. Reference lists from all relevant articles were examined and authors of relevant studies were contacted and asked if they were aware of any additional published or unpublished studies that the authors had not identified. Conference proceedings and reference lists of relevant articles were also reviewed and authors were contacted.
Study Designs Eligible for Inclusion	Studies that prospectively collected data, with a contemporaneous control group
Practitioner Targeted	health professionals in clinical practice or postgraduate training
Intervention(s) and Comparisons	CDSS defined as any software designed to directly aid in clinical decision-making in which characteristics of individual patients are matched to a computerised knowledge-base for the purpose of generating patient-specific assessments or recommendations that are then presented to clinicians for consideration, patient care with CDSS compared to that without

Setting	clinical
Patients Reviewed	NS
Pre-defined outcomes	clinician performance (a measure of the process of care) or patient outcomes (including any aspect of patient well being)
Range of Observations or Period of Follow Up	NS
Findings or results	<p>Fifteen studies assessed systems designed to assist with drug dosing with 11 of these coming from the update. Eight studies addressed the dosing of intravenous medications and 6 found improvements with the use of a CDSS. The systems that were tested were designed to assist with achieving or maintaining therapeutic theophylline or lidocaine hydrochloride levels or achieving improved anticoagulation control with heparin. Four of these trials also evaluated patient outcomes and only 1 found a significant benefit compared with usual clinical practice. The remaining 7 studies evaluated the role of CDSSs in warfarin dosing using a number of different end points. The time to reach a therapeutic international normalized ratio (INR) or prothrombin time (PT) when initiating warfarin therapy was assessed by 3 trials—the findings were inconsistent. 3 of 4 studies found that using a CDSS did not improve the anticoagulation control with regards to maintenance therapy. 4 out of 5 studies for diagnostics did not find a benefit for practitioner performance. With the update, the number of studies of CDSSs providing preventive care reminders increased from 6 to 19. All of the studies evaluated clinician performance and 14 (74%) found a benefit for at least one of the processes of care measured. 19 (73%) of 26 studies found a benefit for the heading of Other Medical Care.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>With regards to implementation, ambulatory care services and clinics should consider opportunities to acquire preventive care reminder systems—a conclusion reached in another recent review. For the time being CDSSs for diagnostics should only be deployed in settings in which they are being properly evaluated. The authors suggest that it would now be reasonable to consider using a CDSS for medication dosing in certain circumstances but do not elaborate which ones. The authors argue that it is important for healthcare centres to include some form of in-house evaluation when incorporating CDSSs but note that market forces may drive deployment of such systems before adequate evaluation.</p>
Further research	<p>The authors note a lack of studies evaluating patient outcomes positing that trials capable of assessing this will soon be warranted.</p>



REFERENCE	Jerant AF, Hill DB. Does the use of electronic medical records improve surrogate patient outcomes in outpatient settings? <i>J Fam Pract</i> 2000;49(4):349–357.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	23
Objective/Questions Addressed in the Review	To answer the following question: In the outpatient primary care setting, can the use of electronic medical records lead to improved surrogate patient care outcomes?
No of Studies Included in the Review	16
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE (1966 through 1999)
Search Strategy	Medical Subject Headings (MeSH), key words, and publication type restrictions, in all possible combinations, were used to conduct the literature search.
Study Designs Eligible for Inclusion	prospective studies with a control group
Practitioner Targeted	physicians
Intervention(s) and Comparisons	Hybrid or complete EMR systems: A hybrid EMR was defined as a system that includes integrated access to all of the following resources: clinical laboratory and radiology data; master problem lists; inpatient and outpatient encounter diagnoses and dates; prescriptions; and billing information. Physician notes are not included in such systems; they are kept in traditional paper format. A complete EMR was defined as a system that includes all of these resources, plus full outpatient encounter progress notes, histories and physicals, and consultation notes.
Setting	Outpatient/primary care
Patients Reviewed	NS
Pre-defined outcomes	Surrogate patient outcomes, morbidity and mortality
Range of Observations or Period of Follow Up	NS
Findings or results	It is not possible to draw firm conclusions from the results of these trials because they were of varying quality, conducted in dissimilar centres, and employed a variety of EMRs. However, it is apparent that EMR systems offer great potential for improving rates of patient completion of health maintenance and screening manoeuvres. While all the EMR-based reminder methods in these studies were superior to

	<p>no method at all, EMR-generated patient reminder letters and EMR-prompted nurse reminder phone calls have been associated with screening rates superior to those resulting from EMR-prompted physician reminders to patients during clinical encounters. When physicians are relied on to make reminders to patients, success appears more likely if they are supplied with patient-specific, printed or on-screen point-of-encounter prompts rather than delayed feedback letters that are not linked to an encounter. It also appears that the ability of EMR-based reminder systems to increase the rates of screening manoeuvres is greater for those interventions that can be quickly completed (eg serum cholesterol level) than for those that require a second appointment and more inconvenience (eg Papanicolaou test).</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>The use of either hybrid or complete EMRs in the outpatient primary care setting can be cautiously supported on the basis of their ability to improve provider and patient compliance with screening interventions, as well as to improve prophylactic and active problem treatment rates. However, only a small range of clinical problems has been studied, and a great deal more evidence is required before firm recommendations can be made regarding the relative merits of these systems or specific products. At this time there is no direct evidence that the use of EMRs is associated with reduced patient morbidity and mortality in the outpatient primary care setting. However, there is also no evidence to suggest that their use is harmful to patients or reduces patient satisfaction with care. Therefore, other potential benefits of EMRs, such as improved work flow, more consistent availability of records, and greater legibility of information, may be evaluated without concern for adverse impact on patient care.</p>
Further research	<p>Studies of EMRs that employ current technologies, examine their impact on patient morbidity and mortality, and are conceptualised to investigate the most likely advantages of electronic systems are urgently needed. Finally, rigorous cost-effectiveness analyses should accompany these studies to help family physicians determine the feasibility of implementing EMRs in their practices. Because of the rapid pace of technology, some of the EMRs discussed in our paper are legacy systems and do not accurately reflect those that are currently on the market. To prevent this data lag phenomenon in the future, efforts must be made to report findings generated from EMR implementation projects as quickly as possible. This goal is likely to be realised if academic health centres make EMR research and implementation a high priority. Another crucial research issue concerns the relative merits of EMR components. Carefully designed comparative trials demonstrating tangible advantages of complete systems compared with hybrid systems will be required.</p>

REFERENCE	Jimbo M, Nease DE, Jr., Ruffin MT, Rana GK. Information technology and cancer prevention. <i>CA Cancer J Clin</i> 2006;56(1):26–36.
How does it meet inclusion criteria?	says it's a systematic review
CASP Total Score	17.5
Objective/Questions Addressed in the Review	To examine the literature on information technology impacts on the delivery of cancer preventive services in primary care offices.
No of Studies Included in the Review	30
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE (1980 to April 2005), CINAHL (1982 to April 2005); EMBASE (1988 to April 2005), Cochrane Central Register of Controlled Trials (CCRCT, second quarter, 2005), and Science Citation Index (SCI; 1980 to April 2005)
Search Strategy	The MEDLINE, CINAHL, EMBASE, and CCRCT searches were conducted via the Ovid interface. The majority of the topical search retrieval was obtained via MEDLINE using medical subject headings including: mass screening; medical informatics applications; neoplasms; reminder systems; physician's practice patterns; and medical record systems, computerized. In addition, limited text word searching was utilised. Due to the large volume of literature and the variability of subject indexing among the databases, and for the purpose of organisation, six discrete searches were selectively conducted in MEDLINE, CINAHL, and EMBASE. These searches focused on: screening of all information systems in office-based practice and primary care; broad/general search on screening and information systems; prevention and health promotion of cancer; use of the electronic health record and cancer screening/prevention; cancer prevention and physician practice patterns; and cancer screening and reminder systems. Corresponding key word searches with Boolean syntax were conducted in CCRCT and SCI.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	patients and providers
Intervention(s) and Comparisons	information technology not defined
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	NS

Range of Observations or Period of Follow Up	6 mos–5 yrs
Findings or results	The effectiveness of the information technology on increasing cancer screening was modest at best.
Conclusions, considerations for implementation, adoption or system design and development.	<p>Information technology interventions in primary care should be viewed contextually and not just in isolation. Several groups have used the “tools, teamwork, and tenacity” terms to emphasise that successful intervention in busy practices requires more than just tools. Busy primary care practices need to have functioning communication processes that allow them to prioritise preventive services and incorporate new approaches into their routine operational flow. Without the ability to reflectively incorporate new innovations and adapt them to their needs, practice innovations frequently result in a temporary change with rapid return to the practice’s previous way of doing things. For practices to be able to effectively implement and sustain technology-based interventions to enhance colorectal cancer screening, they must either already have developed their own functional reflective processes or be assisted in developing these processes. The research on information technology and cancer prevention offers very little guidance at this time. There are a few pearls of wisdom from the literature reviewed. Requiring providers to respond to computer-generated reminders improves their compliance with preventive care protocols, especially for elderly patients, who had the lowest control physician compliance. Therefore, having the computer just generate a reminder is not sufficient. The reasons for not responding to the reminder include “not applicable” (test done elsewhere, patient too ill, no uterus), “next visit” (physician too busy, patient too ill), and “patient refuses” (test not necessary or too costly, patient too busy or fears result). Gathering this information can guide further evaluation of the practice and enhancements of the system. As with most technology, the ability to expand and be flexible will allow the system to better meet the physician’s needs. If a physician’s expectation is to buy a system with a single upfront investment and turn it on, he/she will be wasting their time and effort. To obtain any return on their investment or impact on their practice, a physician has to take a broader, more inclusive approach to group change and not just a single individual’s change. If a physician’s practice is more than 10 years old and has more than three providers, then look back in some of the thicker paper charts. A physician will see various efforts to alter practice patterns. Various flow sheets or paper reminder forms will represent these efforts. They were used by a few individuals within the practice and did not have widespread use or impact. The same could happen to computers if the effort to change does not involve the entire</p>

	<p>group from the front door to the back door. There will also be significant learning curves, which will cost time, money, and patience. These learning curves will keep reoccurring as new changes and updates are made. A physician has to be committed to career-long adaptation and changes. Many health systems and hospitals are developing, purchasing, and implementing various information technologies to improve practice. It remains to be determined how much effort primary care providers have put into participating in the decision-making process. If the leaders of the process only hear from the subspecialty, hospital-based providers, then the technology will never meet the needs of primary care providers.</p>
Further research	<p>The authors argue that there is no need for yet another study of reminder systems unless the investigation examines the impact in community-based offices followed for longer than a year. Future research should thus incorporate the following: 1) To address generalisability, strong consideration should be made to perform the studies in heterogeneous community practice settings, utilising practice-based research networks. 2) More emphasis should be placed on assessing the process outcomes, particularly the organizational structure (eg workflow and personnel role changes) and the nature of the clinical encounters (eg patient-physician communication, duration of the encounter, type of encounter such as periodic versus opportunistic, and issues addressed during the encounter) affected by the implementation of the interventions. 3) Long-term effectiveness and viability should be addressed, including cost-effectiveness and cost-benefit analyses. 4) Approaches other than prompts and reminders should be evaluated. Examples would include tying technology with behavioural interventions, such as tailored messages and decision aids that positively affect informed and shared decision-making. The intervention should be founded on a strong theoretical framework. 5) Various communication channels should be utilised, such as using practice Web sites (which may be personalised for each patient) and e-mails to enhance communication before and after the clinical encounters, computer kiosks in the waiting room, and the utilisation of non-clinician staff to perform technology-assisted and enhanced interventions within or outside of the clinical encounters. 6) The effect of intervention on the process of the screening practice itself should be evaluated. Examples would include gravitation to a particular screening modality (eg increased incorporation of faecal occult blood tests compared with other colorectal cancer screening modalities) and follow up of abnormal screening results.</p>

REFERENCE	Johnson KB. Barriers that impede the adoption of pediatric information technology. <i>Arch Pediatr Adolesc Med</i> 2001;155(12):1374–1379.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	12.5
Objective/Questions Addressed in the Review	To review the literature to better elucidate barriers that are likely to affect the adoption of IT by paediatric professionals.
No of Studies Included in the Review	
No of Participants Studied in Total	
Databases and Years Searched	MEDLINE
Search Strategy	MEDLINE search combined the terms medicine, information systems, and technology transfer. The resulting references were included in this article if they discussed barriers to the use of technology. The author also obtained references cited by relevant articles and explored the Internet using <a href="http://www.google.com">http://www.google.com</a> and <a href="http://www.northernlight.com">ttp://www.northernlight.com</a> and categorised the included references according to the framework above.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	paediatric healthcare professionals
Intervention(s) and Comparisons	information technology not defined
Setting	paediatrics
Patients Reviewed	children
Pre-defined outcomes	barriers or factors affecting the adoption of IT
Range of Observations or Period of Follow Up	NS
Findings or results	A variety of barriers exist that affect the adoption of useful technologies. Situational barriers include challenges imposed by the current national health environment, financial and legal risks associated with technology purchasing and use, and access to technology. The most significant barrier is that paediatric healthcare practitioners may lack the knowledge or training to use IT effectively.

Conclusions, considerations for implementation, adoption or system design and development.	<p>Although some barriers exist that may be challenging to overcome, other barriers, such as the lack of knowledge about the uses of IT, are imminently solvable. Efforts to overcome these barriers should begin in earnest and should include educating stakeholders in the care of children and adolescents, as well as improving the knowledge about various technologies available to support paediatric and adolescent healthcare.</p>
Further research	<p>A possible reason for the shortage of publications in paediatrics is the dearth of informatics researchers within the paediatric community. Given the unique needs of paediatric patients, it is most likely that only PHCPs will conduct evaluative or observational studies of IT implementation projects that will provide our specialty with generalisable results.</p> <p>Researchers should address the following questions:</p> <p>What are the knowledge, attitudes, and behaviours of PHCPs with respect to IT?</p> <p>What are the perceived barriers to the adoption of IT by PHCPs in both academic medical centres and private practice? Is the lack of time, lack of money, or lack of knowledge the key barrier to overcome?</p> <p>How prepared are today's IT tools for use by PHCPs, and what future changes are needed in these tools?</p> <p>How should the curriculum of paediatric residencies be modified to improve knowledge about IT and its role in children's health?</p> <p>What is the current state of adoption of IT by PHCPs in both academic medical centres and private practice?</p> <p>What are the benefits and costs of using IT in academic or private care facilities?</p> <p>Academic PHCPs must be encouraged to evaluate IT in paediatric settings. Of course, to carry out this research, funding needs to be available, or funding agencies need to focus on the area of medical informatics. One of the biggest challenges facing any researcher is how to garner financial support for important projects. In addition to consulting the National Institutes of Health guide <a href="http://grants.nih.gov/grants/guide/">http://grants.nih.gov/grants/guide/</a>), PHCPs interested in conducting technology research should consult pharmaceutical, laboratory, and IT vendors—all of whom may be able to provide support for</p>



	<p>focused efforts. Managed care companies typically operate with a lower capital reserve, and may be less likely to fund research unless it directly affects their revenue recovery or results in obvious cost-savings. Philanthropic organisations that have an interest in children's health may be wonderful allies, but it is important to understand the goals of the organisation by reading their annual report, reviewing their Web pages, and sending a letter of inquiry to the organisation before seeking funding in most cases. Finally, commercial organisations that cater to children may have limited funds for projects. Nintendo Inc represents one such organisation. Many other sources of funding may be found by searching the Internet.</p> <p>Occasionally, as has been the case for many Third World medical projects, support of this kind funds not only a research question but also enhancements to the infrastructure of participants. These sites can then become models for other projects. People who work in these sites can become knowledgeable about technology—furthering the educational mission while conducting important research projects.</p>
	<p>Groups such as our national paediatric practice-based research network (PROS [Pediatric Research in Office Settings]) represent a marvellous untapped resource for IT research. The PROS practitioners are highly motivated, though extremely busy paediatricians. Furthermore, they have an identified need for IT, both to improve communication with research investigators, and to facilitate the projects themselves. They are uniquely positioned to conduct research designed to improve the usability and adoption of computer technology in ambulatory settings.</p>

REFERENCE	Johnston ME, Langton KB, Haynes RB, Mathieu A. Effects of computer-based clinical decision support systems on clinician performance and patient outcome. A critical appraisal of research. <i>Ann Intern Med</i> 1994;120(2):135–142.
How does it meet inclusion criteria?	systematic search of the literature and application of inclusion/exclusion criteria with quality assessment
CASP Total Score	13
Objective/Questions Addressed in the Review	To review the evidence from controlled trials of the effects of computer-based clinical decision support systems (CDSSs) on clinician performance and patient outcomes.
No of Studies Included in the Review	27
No of Participants Studied in Total	NS

Databases and Years Searched	MEDLINE from January 1983 through February 1992 (reviews), MEDLINE search of articles published from 1974 to February 1992 (original studies), EMBASE search for the same time period; INSPEC (International Information Service for the Physics and Engineering Communities)
Search Strategy	Reviews were also found through a manual search of textbooks and conference proceedings in the areas of artificial intelligence and computer applications in medicine, original studies were also identified through an update of a previous review on computer-aided quality assurance, through review of citations in the articles from electronic searches and a search forward on three citations one each from the areas of dose determination, diagnosis, and quality assurance, using SCISEARCH; through articles on related topics collected by the Health Information Research Unit of McMaster University, including a regularly updated bibliography of studies of continuing education; and by scanning the Proceedings of the Symposium on Computer Applications in Medical Care, 1989 through 1991. After a set of relevant publications was selected for inclusion in the overview, a list of their titles was sent to
	corresponding authors and experts in medical informatics with a request for information about any additional published or unpublished studies.
Study Designs Eligible for Inclusion	prospective studies with a contemporaneous control group where patient care with a CDSS was compared with patient care without one, crossover studies were included
Practitioner Targeted	clinicians in practice and training
Intervention(s) and Comparisons	CDSS defined as computer software using a knowledge-base designed for use by a clinician involved in patient care as a direct aid to clinical decision-making. Characteristics of an individual patient were matched to information in the knowledge-base. Patient-specific information in the form of assessments (management options or probabilities) or recommendations were presented to the clinician and patient care with a CDSS was compared with patient care without one.
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	clinician performance, a measure of the process of care, or patient outcomes, including any aspect of patient well being
Range of Observations or Period of Follow Up	NS

Findings or results	<p>Three of four studies of computerised aids for determining the dose for toxic drugs reported statistically significant improvements in achieving therapeutic levels and three studies all with small sample sizes, evaluated the effects on patient outcomes and found no significant benefits or adverse effects compared with usual clinical practice. Findings were mainly negative for the effects of computerised decision aids for diagnosis with only one study of computer-assisted diagnosis examining a patient outcome a positive effect. In contrast to the findings for diagnosis, four of six studies of CDSSs that were designed to enhance the quality of preventive care showed statistically significant effects on clinician performance, again only one of the studies of computerised reminders for preventive care assessed the effects on patient outcomes but found no statistically significant effect.</p> <p>Findings were also generally positive for the effects of CDSSs in acute medical care. Seven of nine studies that assessed the effect of CDSSs on clinician performance in caring for active medical problems reported statistically significant effects on medical care processes. In summary: A few small studies showed that computer-assisted dose determination can help physicians achieve therapeutic drug levels, at least in the short-term, but larger, confirmatory studies with more important clinical outcomes are needed. A small number of studies on computer-aided diagnosis were found, but only one of these reported evidence on effectiveness. Several sound studies showed that recommendations built into computerised medical record systems can improve clinician compliance with practice guidelines for preventive and active care.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>The authors do not offer and recommendation for implementation. They conclude that as CDSSs mature, they offer increasingly exciting prospects for improving the effectiveness and efficiency of patient care. For all healthcare interventions, however, CDSSs have the potential for not only good but also for harm and waste. The literature on CDSSs is growing rapidly, but only a small proportion is devoted to evaluations of the effects of CDSSs used by clinicians in everyday practice. Assessment of most systems occurs primarily at earlier phases, such as measuring reliability, accuracy, and acceptability. It is appropriate for developers to evaluate their systems in a systematic way, progressing in steps from the laboratory to clinical application. It could be wasteful to skip from these early steps to full clinical trials, which should be reserved for mature systems.</p>

Further research	<p>With regards to future research, the authors argue that claims that CDSSs benefit patients should be judged by the same standards as is any such health claim; the accepted standard would be randomised controlled trials showing unequivocal benefits for important clinical outcomes. Unfortunately, rigorous evaluations of CDSSs are usually more difficult to conduct than evaluations of pharmaceuticals, for example, because blinding of providers is impossible, and clinical settings often preclude complete separation of the intervention and control groups. Studies of patient outcomes may have the added burden of requiring large numbers of participants and substantial budgets. Nevertheless, the studies the authors have reviewed show that current scientific methods are being applied to the testing of CDSSs and that some have enough effect on the process of care to warrant trials with important clinical outcomes. The authors look forward to such trials in due course. In the meantime, the lack of effect of some CDSSs on patient outcomes in the studies reviewed here may also reflect inappropriate study design or failure to measure outcomes that are responsive to the use of CDSSs. Alternatively, some CDSSs may aim to modify clinician behaviour without necessarily having an effect on patient outcome. Although it could be argued that effects on clinician performance alone may be worthwhile in situations leading to greater efficiency, the most convincing tests of most CDSSs will be their effect on patient well being.</p>
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REFERENCE	Jordan K, Porcheret M, Croft P. Quality of morbidity coding in general practice computerized medical records: a systematic review. <i>Fam Pract</i> 2004;21(4):396–412.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	16.5
Objective/Questions Addressed in the Review	To assess the quality, in terms of completeness and correctness, of morbidity coding in computerised general practice records through a systematic review.
No of Studies Included in the Review	24
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, Science Citation Index, Social Science Citation Index, CINAHL, English National Health Care database, the Cochrane Library and the National Research Register up to September 2002
Search Strategy	Keywords used were at three levels, with articles examined for at least one word in its title, abstract or keywords from each level. Level one keywords were: 'primary care', 'general pract*', 'family pract*', level two were 'morbidity*', 'computer*', 'record*', 'electronic', 'register', 'consult*', 'contact*'; and level three were 'agree*', 'valid*', 'accura*', 'complete*', 'correct*', 'reliab*'.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	computerised records or a computerised morbidity register
Setting	UK primary care
Patients Reviewed	NS
Pre-defined outcomes	(i) The completeness of consultation recording—for each contact a patient has with the GP, is there a morbidity code recorded on the computer? This is an important element of completeness because, if no code is allocated or if the contact goes unrecorded, then completeness of the database is compromised. Further, is each different clinical morbidity consulted about within one contact coded? (ii) The correctness of consultation recording—are the codes given during this contact appropriate? (iii) The completeness of a morbidity register—is everyone included on the register that should be? (iv) The correctness of a morbidity register—should everyone on a register be on that register?
Range of Observations or Period of Follow Up	NS

Findings or results	The quality of morbidity coding appears variable. Conditions with clear diagnostic features such as diabetes have higher quality recording than conditions with more subjective criteria such as asthma. It is difficult to ascertain an improvement in quality over time. The GPRD studies have shown reasonable correctness and completeness of morbidity registers (although poorer for some diseases such as anorexia nervosa and bulimia). The completeness of consultation recording was generally high. Many of the studies reported here looked at practices with explicit interests in recording information electronically or with a substantial amount of training in morbidity coding. Several multi-practice studies had to discard practices from their study which were unable to provide suitable data. This biases the sample in favour of the better recorders, leading to a higher quality of recording than that which would be achieved by examining all practices. The majority of studies were also based in one localised area (exceptions include the studies based on the GPRD), which makes generalisation difficult.
Conclusions, considerations for implementation, adoption or system design and development.	Training of practices, as shown in the GPRD studies can lead to a reasonable quality of coding. As practices increasingly use computers to record consultations and other medical information, there is a need to ensure that there is a high level of completeness and correctness of not just morbidity codes relevant to the consultation, but also information from external sources such as hospital letters.
Further research	The focus should be now be on methods to encourage and improve the quality of coding in general practice.

REFERENCE	Kaushal R, Shojania KG, Bates DW. Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review. <i>Arch Intern Med</i> 2003;163(12):1409–1416.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	19.5
Objective/Questions Addressed in the Review	To systematically review the cumulative evidence on the effects of CPOE and CDSSs on medication safety.
No of Studies Included in the Review	5
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, the Cochrane Library

Search Strategy	The MEDLINE search strategy was performed using the following MeSH terms: hospital information systems; decision support systems, clinical; and drug therapy, computer-assisted. In addition, the authors searched for key title words related to computerised order entry and combined the results of these searches with MeSH terms capturing adverse events and medical errors: medical error, iatrogenic disease, sentinel surveillance, and safety. The Cochrane Library was searched using similar key terms and title words. Reference lists from all relevant articles, including 2 systematic reviews were reviewed to identify additional primary studies.
Study Designs Eligible for Inclusion	RCTs, non-randomised controlled trials, observational studies with controls
Practitioner Targeted	NS
Intervention(s) and Comparisons	computerised systems for performing general order entry or CDSSs for guiding physicians in the order-writing process
Setting	inpatient
Patients Reviewed	NS
Pre-defined outcomes	surrogate outcomes, clinical outcomes, medication errors, ADEs, preventable ADEs and non-intercepted serious medication errors
Range of Observations or Period of Follow Up	NS
Findings or results	These studies provide evidence that the use of CPOE with CDSSs significantly decreases medication error and serious medication error rates at 2 institutions with home-grown systems. However, the effect on ADE rates has not been adequately tested because studies with sufficient power have not been performed. There is a strong correlation between medication errors and ADEs, so such applications will almost certainly reduce ADE rates. Nevertheless, medication errors have widely varying potential for harm, and it seems easiest to prevent those that rarely cause injury. The beneficial effects of CPOE systems extend beyond medication safety and include reduced costs and quality improvement. These benefits have been achieved by providing feedback about the appropriateness and costs of laboratory and radiologic tests, easy implementation of clinical pathways, improved quality measurement, and improved coding and billing.



<p>Conclusions, considerations for implementation, adoption or system design and development.</p>	<p>The authors believe that further studies targeted at a few critical questions are desirable but not a requirement before widespread adoption. Perhaps most important, a healthcare institution must garner financial and organisational support before introducing CPOE with CDSSs. Computerised physician order entry requires large up-front capital investment with more remote, albeit substantial, returns. Such investment is especially challenging when organisations are losing money. In addition to the financial obstacles, implementing sophisticated new clinical information systems presents substantial organisational challenges owing to the impact on institutional culture and clinical workflow and the need to accommodate existing institutional systems used for billing, laboratory, and pharmacy data. Purchasing commercial CPOE systems is generally more expensive than is internally developing systems. In general, as users become accustomed to CPOE and CDSSs, they are likely to accept computer suggestions with minimal reflection, emphasising the importance of testing decision support default settings and suggestions. When CPOE systems are not electronically linked to computerised pharmacy systems, pharmacists must manually re-enter orders into the pharmacy system, with a resultant increase in chance of error. The trigger level for computerised warnings must be set to the appropriate sensitivity. In situations with a potential for significant harm, it is important that providers receive warnings without being overwhelmed by alarms of marginal value. Hardware outages and software instability pose further risks. In particular, the reliability needed for CPOE is much higher than that required for systems that simply report laboratory test results. Finally, physicians can electronically write an order in the wrong patient's record, analogous to handwriting an order in the wrong patient's medical chart.</p>
<p>Further research</p>	<p>Research should focus on questions such as the following: What are the differences among various CPOE systems? What are barriers to adoption? What are the key decision support elements? How effective are specific pieces of decision support? How should these applications be implemented in community hospitals? Another area for further research consists of developing tools to assess the extent to which a specific commercial CPOE application will reduce the medication error rate or the preventable ADE rate. Comparisons among such commercial products will likewise be informative. In addition, the efficacy of individual decision support elements warrants further investigation. Larger studies need to be performed, as do studies identifying key, successful decision support elements.</p>

REFERENCE	Kawamoto K, Lobach DF. Clinical decision support provided within physician order entry systems: a systematic review of features effective for changing clinician behavior. <i>AMIA Annu Symp Proc</i> 2003;361–5.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	21.5
Objective/Questions Addressed in the Review	To help guide the efforts of CPOE designers by providing a rigorous, evidence-based assessment of the CDSS features that are most effective at influencing clinician behaviour in the context of computerised physician order entry.
No of Studies Included in the Review	12 papers describing 11 studies
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE (1966-December 2002), CINAHL (1982-October 2002), and the Cochrane Controlled Trials Register (Fourth Quarter, 2002)
Search Strategy	Combinations of multiple search terms, which included the following: decision support systems, clinical; decision making, computer-assisted; reminder systems; feedback; guideline adherence; medical informatics; communication; physician's practice patterns; reminder\$; feedback\$; decision support\$; and expert system. The authors also systematically searched the reference lists of included studies and of relevant reviews for potential studies.
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	physicians, physician assistants, and nurse practitioners
Intervention(s) and Comparisons	Computerised physician order entry (CPOE) systems were defined as computer-based system that allows clinicians to enter orders directly. Clinical decision support system (CDSS) were defined as any system designed to directly aid in clinical decision-making, in which characteristics of individual patients are matched to a knowledge-base for the purpose of generating patient-specific assessments or recommendations that are then presented to clinicians for consideration.
Setting	real clinical setting
Patients Reviewed	NS
Pre-defined outcomes	changes an important clinician behaviour
Range of Observations or Period of Follow Up	NS

Findings or results	Meta-regression analysis on the 10 control-CDSS comparisons revealed a significant association between the automatic provision of decision support and the finding of a statistically and clinically significant desired change in clinician behaviour (adjusted odds ratio, 23.72; 95% confidence interval, 1.75-¥). Indeed, of the 10 studies all 7 of the successful studies provided the decision support automatically, without the need for clinician initiative. On the other hand, this critical feature was absent from all 3 of the unsuccessful studies. For these studies, delivery of the decision support was dependent on the presence of user initiative. This finding is consistent with the results from our systematic review of electronic as well as non-electronic CDSSs.
Conclusions, considerations for implementation, adoption or system design and development.	The authors made no recommendations with regards to implementation but speculated that the findings will be of use to the designers and implementers of CPOE-based decision support systems as they leverage this technology to influence clinician behaviour and improve patient care.
Further research	No future research was indicated.

REFERENCE	Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. <i>BMJ</i> 2005;330(7494):765.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	20
Objective/Questions Addressed in the Review	To identify the specific features of clinical decision support systems most crucial for improving clinical practice.
No of Studies Included in the Review	70
No of Participants Studied in Total	130,000
Databases and Years Searched	MEDLINE (1966–2003), CINAHL (1982–2003) and the Cochrane Controlled Trials Register (2003)
Search Strategy	Combinations of the following search terms were used: decision support systems, clinical; decision making, computer-assisted; reminder systems; feedback; guideline adherence; medical informatics; communication; physician's practice patterns; reminder\$; feedback\$; decision support\$; and expert system. The authors also systematically searched the reference lists of included studies and relevant reviews.
Study Designs Eligible for Inclusion	RCTs

Practitioner Targeted	physicians, physician assistants, or nurse practitioners directly involved in patient care
Intervention(s) and Comparisons	Clinical decision support system were defined as any electronic or non-electronic system designed to aid directly in clinical decision-making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration.
Setting	real clinical setting
Patients Reviewed	NS
Pre-defined outcomes	assessment of improvements in clinical practice through patient outcomes or process measures
Range of Observations or Period of Follow Up	NS
Findings or results	<p>Most notably, 75% of interventions succeeded when the decision support was provided to clinicians automatically, whereas none succeeded when clinicians were required to seek out the advice of the decision support system (rate difference 75% (37% to 84%)). Similarly, systems that were provided as an integrated component of charting or order entry systems were significantly more likely to succeed than stand alone systems (rate difference 37% (6% to 61%)); systems that used a computer to generate the decision support were significantly more effective than systems that relied on manual processes (rate difference 26% (2% to 49%)); systems that prompted clinicians to record a reason when not following the advised course of action were significantly more likely to succeed than systems that allowed the system advice to be bypassed without recording a reason (rate difference 41% (19% to 54%)); and systems that provided a recommendation (such as "Patient is at high risk of coronary artery disease; recommend initiation of blocker therapy") were significantly more likely to succeed than systems that provided only an assessment of the patient (such as "Patient is at high risk of coronary artery disease") (rate difference 35% (8% to 58%)). Finally, systems that provided decision support at the time and location of decision making were substantially more likely to succeed than systems that did not provide advice at the point of care, but the difference in success rates fell just short of being significant at the 0.05 level (rate difference 48% ( - 0.46% to 70.01%)). Of the six features shown to be important by the univariate analyses, four were identified as independent predictors of system effectiveness by the primary meta-regression analysis. Most notably, this analysis confirmed the critical importance of automatically providing decision support as part of clinician workflow (<math>P \leftarrow 0.00001</math>).</p>

	<p>The other three features were providing decision support at the time and location of decision-making (<math>P = 0.0263</math>), providing a recommendation rather than just an assessment (<math>P = 0.0187</math>), and using a computer to generate the decision support (<math>P = 0.0294</math>). Among the 32 clinical decision support systems incorporating all four features, 30 (94% (80% to 99%)) significantly improved clinical practice. In contrast, clinical decision support systems lacking any of the four features improved clinical practice in only 18 out of 39 cases (46% (30% to 62%)). The subset analyses for computer-based clinical decision support systems and for non-electronic clinical decision support systems yielded results consistent with the findings of the primary regression analysis.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>On a practical level, our findings imply that clinicians and other healthcare stakeholders should implement clinical decision support systems that (a) provide decision support automatically as part of clinician workflow, (b) deliver decision support at the time and location of decision-making, (c) provide actionable recommendations, and (d) use a computer to generate the decision support. In particular, given the close correlation between automatic provision and successful outcomes (<math>P \leftarrow 0.00001</math>), the authors believe that this feature should be implemented if at all possible. If a clinical decision support system must depend on clinician initiative for use, the authors recommend that system use be carefully monitored and steps be taken to ensure that clinicians access the resource as intended. As a general principle, then, our findings suggest that an effective clinical decision support system must minimise the effort required by clinicians to receive and act on system recommendations. With regard to the three other system features shown to be important through direct experimentation, the authors think these features are important and desirable but not as crucial as the four features identified by our regression analysis. Thus, when feasible and appropriate, clinical decision support systems should also provide periodic performance feedback, request documentation of the reason for not following system recommendations, and share decision support results with patients. For the remaining clinical decision support system features the authors consider them optional but still potentially beneficial, especially if they will make it easier for clinicians to use the clinical decision support system or if the univariate analyses found that they were substantially more likely to be present in successful systems than in unsuccessful ones. Finally, with regard to the seven clinical decision support system features that could not be included in our regression analysis, the authors recommend that they be considered potentially important, especially if they reduce the time, effort, or initiative required for clinicians to receive and act on system recommendations.</p>

Further research	The promise of evidence-based medicine will be fulfilled only when strategies for implementing best practice are rigorously evidence-based themselves. In order to fulfil this goal in the context of clinical decision support systems, two important research needs must be addressed. Firstly, reports of clinical decision support system evaluations should provide as much detail as possible when describing the systems and the manner in which clinicians interacted with them, so that others can learn more effectively from previous successes and failures. Secondly, further direct experimentation is warranted to evaluate the importance of specific system features.
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REFERENCE	Lane SJ, Heddle NM, Arnold E, Walker I. A review of randomized controlled trials comparing the effectiveness of hand held computers with paper methods for data collection. <i>BMC Med Inform Decis Mak</i> 2006;6(23).
How does it meet inclusion criteria?	says it is a systematic review
CASP Total Score	15
Objective/Questions Addressed in the Review	To summarise the literature on randomised controlled trials focusing on the use of handheld computers compared to traditional paper
and pencil methods, where at least one of the following outcomes was assessed: data accuracy; timeliness; adherence to protocols; and/or patient preference.	
No of Studies Included in the Review	9
No of Participants Studied in Total	NS
Databases and Years Searched	NLM Gateway, a single interface that searches in "multiple retrieval systems", including MEDLINE
Search Strategy	The following text words were used, both separately and combined with "OR": "palm top computer," "PDA," "personal digital assistant," "pocket computer," "electronic diary," "diary keeping," "diary keeping methods," "electronic forms and data collection," "microcomputer," "palm pilot," "handheld computer," and the MeSH headings "data collection/*instrumentation" and "computers, handheld". The bibliographies and reference lists of these documents were reviewed by one researcher to identify other potentially relevant articles that fit the inclusion criteria.
Study Designs Eligible for Inclusion	RCTs

Practitioner Targeted	NS
Intervention(s) and Comparisons	PDA's where the use of handheld computers compared to traditional paper and pencil methods
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	data accuracy; timeliness; adherence to protocols; and/or patient preference
Range of Observations or Period of Follow Up	same day to 6 mos
Findings or results	In this review only two of the six studies found handheld computers to be more accurate, in three studies accuracy was similar and in one study the paper method was more accurate. Handheld computers are well accepted, and are more likely than paper methods to be the choice of the user. The ultimate results with handheld computers have in most trials been similar to those of the paper method, particularly when the performance of the paper method is already high, and therefore improved accuracy cannot be assumed. In addition, the preference by research subjects for handheld computers could result in improved adherence to data collection protocols for long-term studies, as evidenced by the markedly improved adherence and patient preference for the handheld computer group in the study having the longest observation period.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations with regards to implementation are made.
Further research	Future research should be directed towards the endeavour of making direct comparisons of adherence between methods as part of the larger project of validating handhelds for data capture among patient populations.

REFERENCE	Lee NJ, Starren J, Bakken S. A systematic review of user interface issues related to PDA-based decision support systems in health care. <i>AMIA Annu Symp Proc</i> 2005;1021.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	11
Objective/Questions Addressed in the Review	To explore user interface issues in the design and implementation of PDA-DSS in a healthcare setting.
No of Studies Included in the Review	15
No of Participants Studied in Total	NS



Databases and Years Searched	Ovid MEDLINE, CINAHL, PsycINFO, All EBM Reviews, and AMIA Annual Symposium Library
Search Strategy	The terms 'Computers, Hand-Held', and 'Decision support systems' and their subheadings were used in the database searches.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	PDA's with DSS
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS

Findings or results	Display issues were discussed in 6 papers. Font size/screen size, colour depth, and data entry issues were mentioned. Several strategies were suggested to improve these limitations, including reducing scrolling; using a one-tap entry method; using a dynamic user interface; and subdividing sections on multiple tabbed screens. Security issues, including confidentiality were mentioned in 5 papers. The papers offered solutions based on multiple-level security methods such as login and password, secure Web server, encrypted data transfer, Palm's unique device ID, RSA SecureID hardware token, and audit logs. Memory issues were discussed in 3 papers. The proposed solutions included the use of the additional memory, a memory-efficient data structure, and standard vocabularies. Web browser issues were mentioned in 2 papers, particularly, the imitations of the Palm's Clipper Web browser. Communication issues were discussed in 5 papers, including low bandwidth, the low reliability of both telephonic and wireless communication in some environments, and limitations of one way communication. Use of a new device and development of new technology were suggested as solutions for the last two issues.
Conclusions, considerations for implementation, adoption or system design and development.	With regards to adoption, the authors argue that user interface issues may be a major impediment to the acceptance of PDA-DSS in healthcare.
Further research	Whilst no explicit future research was suggested by the authors, they did note that user interface research for PDA-DSS is still in its infancy as compared to computer-based DSS. Although studies have identified issues and suggested strategies to address the limitations of PDAs, few have evaluated their effectiveness in terms of usability.

REFERENCE	Lisboa PJ. A review of evidence of health benefit from artificial neural networks in medical intervention. <i>Neural Netw</i> 2002;15(1):11-39.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	14
Objective/Questions Addressed in the Review	To assess the evidence for improvements in healthcare arising from the involvement of artificial neural networks in medical intervention.
No of Studies Included in the Review	NS
No of Participants Studied in Total	NS

Databases and Years Searched	PubMed
Search Strategy	Data collection consisted of a search of publications involving neural networks listed in the PubMed database under Randomized Controlled Trials (RCT) or Clinical Trials (CT). Additional publications of particular interest are also reviewed in the discussion of each medical domain.
Study Designs Eligible for Inclusion	randomised or non-randomised clinical trials
Practitioner Targeted	NS
Intervention(s) and Comparisons	neural networks
Setting	oncology, critical care and cardiovascular medicine
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Neural networks have had a clinical impact in specific areas, notably cervical cytology and early detection of AMI, where large-scale prospective multi-centre studies have been carried out.
Conclusions, considerations for implementation, adoption or system design and development.	There are other important factors that limit the take-up of intelligent decision systems generally, namely the need to design systems that address real clinical needs, and which are more readily integrated into the routine data-management environment of the user. Achieving this has been the hallmark of the few successful neural network applications that have made it into routine clinical use. Neural networks have a niche to carve in clinical decision support, but their success depends crucially on better integration with clinical protocols, together with an awareness of the need to combine different paradigms
	in order to produce the simplest and most transparent overall reasoning structure, and the will to evaluate this in a real clinical environment.
Further research	Implications for study design provided

REFERENCE	Lisboa PJ, Taktak AF. The use of artificial neural networks in decision support in cancer: a systematic review. <i>Neural Netw</i> 2006;19(4):408–415.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	13
Objective/Questions Addressed in the Review	To assess the benefit of artificial neural networks (ANNs) as decision-making tools in the field of cancer.

No of Studies Included in the Review	27
No of Participants Studied in Total	NS
Databases and Years Searched	PubMed 1994–2003
Search Strategy	Keywords ‘neural networks’. The search was limited to clinical trials and randomised controlled trials (RCTs). The search was repeated using the keywords (neural networks) and (cancer) from 1994 to the current date.
Study Designs Eligible for Inclusion	randomised or non-randomised clinical trials
Practitioner Targeted	NS
Intervention(s) and Comparisons	artificial neural networks in cancer
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Overall, the publications reviewed were favourable to the neural network approaches, although two of the most proficient studies, both about prostate cancer, drew conflicting conclusions results from very similar empirical results). Out of 27 trials, 21 showed an increase in benefit to healthcare provision and 6 did not. None of these studies however showed a decrease in benefit.
Conclusions, considerations for implementation, adoption or system design and development.	The authors argue that there is clearly some way to go before establishing the case for a performance advantage for neural networks over conventional statistical methods in the diagnosis of complex data, a finding that is supported by reviews of prostate cancer
Further research	Implications for study design provided

REFERENCE	Mair FS, May C, Finch T, Murray E, Anderson G, Sullivan F et al. Understanding the implementation and integration of e-health services. <i>J Telemed Telecare</i> 2007;13:36–37.
How does it meet inclusion criteria?	says it a systematic review
CASP Total Score	11
Objective/Questions Addressed in the Review	To examine the wider processes of engagement, enrolment and uptake of e-health services by health professionals and also to examine the roots of resistance, if any, to the use of new e-health systems.

No of Studies Included in the Review	66
No of Participants Studied in Total	NS
Databases and Years Searched	CSA, MEDLINE (PubMed) CINAHL, EMBASE and PsycINFO
Search Strategy	A search strategy was devised which combined the concepts of barriers and facilitators with multiple terms used to identify e-health initiatives across the four domains of engagement, enrolment, uptake and resistance of eHealth by professionals. In addition, a reference group of 22 experts in e-health were contacted with a request for details of 10 key papers on the barriers/facilitators to successful uptake of e-health systems.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	eHealth: management systems such as electronic medical records systems; (2) communication systems (both synchronous and asynchronous) which would include telemedicine and telecare; (3) decision support systems including computerised clinical decision support; (4) information systems including use of the Internet and other Web-based resources.
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	barriers and facilitators
Range of Observations or Period of Follow Up	NS
Findings or results	Examination of the main themes from these reviews identified three major types of barriers/facilitators: Technology design factors; Health professional interaction issues; Organisational factors. Key barriers included: Inadequate information management; Inadequate inter-agency cooperation; Intrusive technology/rigidity of system; Cost; Lack of testing of systems. Key facilitators included: Positive inter-agency co-operation; Flexibility; Ease of use; Organisational willingness; Ability to order information. Factors that could serve as both barriers or facilitators were: Health professional/patient relationships; Security.
Conclusions, considerations for implementation, adoption or system design and development.	Professional resistance is often cited as a factor that inhibits the implementation of e-health, when problems of implementation and integration are actually the key.
Further research	The authors state only their future work.

REFERENCE	Mitchell E, Sullivan F. A descriptive feast but an evaluative famine: systematic review of published articles on primary care computing during 1980–97. <i>BMJ</i> 2001;322(7281):279–82.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	19
Objective/Questions Addressed in the Review	To appraise findings from studies examining the impact of computers on primary care consultations.
No of Studies Included in the Review	89
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, Science Citation Index, Social Sciences Citation Index, Index of Scientific and Technical Proceedings, EMBASE and OCLC FirstSearch Proceedings
Search Strategy	Non-English language journals were included in the search. Books, bibliographies, and conference proceedings of related topics as well as citations in these books and articles and references provided by colleagues were also reviewed. The Cochrane Group for Effective Practice and Organisation of Care (EPOC) provided references of articles containing the term “computer,” and authors active in the field were asked about studies in progress and unpublished work.
Study Designs Eligible for Inclusion	prospective studies
Practitioner Targeted	physicians, nurses
Intervention(s) and Comparisons	any computing systems designed for use by a doctor
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	effects of computers on the consultation process, on general practitioners’ task performance, and on patient outcomes, potential barriers to effective implementation and use of computers, and doctors’ or patients’ attitudes towards computerisation
Range of Observations or Period of Follow Up	NS

Findings or results	<p>Six studies looked at consultation length, this increased by 48130 seconds in five of the studies, although this increase declined after variable time periods. Two studies found that doctors spent 11%100% more time on computerised records than they had on conventional records. This was mainly because of increased administrative tasks and preventive issues prompted by computer use. Computer use led to increases in doctor-centred speech and the number of medical topics raised, often at the expense of patient-centred activity. Practitioners were also less likely to continue interacting with patients when using computerised records than when using paper records and this did not diminish with increased familiarity. In an attempt to minimise this, patients in one study synchronised their speech with perceived pauses in practitioners' keyboard use. Immunisation rates improved by 834%in the nine studies of this issue. Performance of preventive tasks, such as blood pressure screening and cervical smears, improved by up to 47%. The greatest increases occurred when practitioners were prompted as part of the consultation. Disease management was also improved by use of computers. Four studies that evaluated standards of diabetes care found improvements of 569%. Studies evaluating hypertension management found improvements of 1853% in examinations. Prescribing improved with computer support: prescribing of generic drugs increased and prescribing costs declined. Computer use for ordering tests led to reductions of 675% in numbers of tests and cost-savings of 814%.</p> <p>Patient outcomes: Use of computers in management of hypertension significantly increased the number of patients with reduced diastolic pressure but results were inconsistent for anticoagulation. The introduction of computers to the consultation did not lead to any increase in service use either in visits to primary care or in referrals to secondary care. Four studies on patient satisfaction detected no significant changes when computers were introduced. Most practitioners willingly accepted computers as part of their working environment and were positive about their use. Many thought that computerised</p>
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	<p>records were more accurate than conventional records or that they improved patient care. Patients said that computers gave their doctors better access to records and that consultations were unaffected. However, five themes emerged that could prove major barriers to successful implementation of computers: privacy, the doctor-patient relationship, cost, time, and training. Loss of privacy and confidentiality was the commonest concern to patients. Many thought that computerised notes posed a greater threat to privacy and were more vulnerable to unauthorised access than conventional records and should therefore be restricted to non-sensitive information. One study found that some patients were unwilling to be completely frank about their problems in front of doctors using computerised records and would consider changing to another doctor. Both practitioners and patients were concerned about the possible negative impact of computers on the doctor-patient relationship. This concern was partly due to the logistics of incorporating a computer in the consultation and partly to the perception that computers would take over the doctor's role. Costs of computerisation were considered prohibitive, both by practitioners and patients. Many doctors said that the time commitment involved in learning and using computers was too great and was more than they had expected, resulting in additional stress. Finally, existing training in computer use was perceived as being poor, and it was thought that this should be made a component of doctors' continuing medical education. Most of the 89 studies in this review found positive effects of computerisation, showing, among other things, improvements in immunisations and preventive care and reductions in prescribing costs and unnecessary tests. Practitioners and patients were generally positive about computers, particularly in terms of access, accuracy, and the time saving properties of electronic patient records.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>No recommendations for implementation were made rather adoption issues were highlighted. However, the authors noted little has been done to alleviate fears of computers interfering in the consultation process and the doctor-patient relationship. The authors identified three new studies on consultation content for this latest review and again found that use of computers lengthened consultations. The proportion of time in a consultation that doctors spent not interacting with patients also increased, in one case by as much as 28% and this did not alter with improved proficiency in using computers. Another cause of anxiety for clinicians, and particularly for patients, was the issue of privacy and confidentiality of computerised records. Patients are not always made aware of the uses of information technology in</p>

	primary care, which may account for their ongoing concern over this issue.
Further research	Research must move forward to evaluate key outcomes for patients, practices, and the health service as a whole. Few studies have dealt with nursing research in general practice, and little has been published on the impact of computer systems on other members of the primary care team. Research might also be conducted on the best ways of integrating the computer into the consultation, starting with examples of current best practice and refining these in line with principles of effective communication.

REFERENCE	Montani S, Bellazzi R, Quaglini S, d'Annunzio G. Meta-analysis of the effect of the use of computer-based systems on the metabolic control of patients with diabetes mellitus. <i>Diabetes Technol Ther</i> 2001;3(3):347-56.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	18
Objective/Questions Addressed in the Review	To evaluate, through a meta-analysis study, whether the use of computer-based systems reported in the literature improves the metabolic control of diabetic patients.
No of Studies Included in the Review	16 papers on 17 clinical trials
No of Participants Studied in Total	318 children and 398 adults
Databases and Years Searched	MEDLINE (1967-2000)
Search Strategy	The following keywords were used: Clinical trial (publication type), randomized controlled trial (publication type); Diabetes mellitus (all fields, or MeSH, or textword); Computer (all fields or textword), therapy (textword), education (textword), instruct (textword); Outcome assessment (MeSH), patient satisfaction (MeSH), health status (MeSH), outcome (textword), benefit (textword), effect (textword). A further examination of the references of the articles found by the search procedure was performed. The HealthSTAR (National Library of Medicine) was searched as well.
Study Designs Eligible for Inclusion	randomised case-controlled trials
Practitioner Targeted	NS
Intervention(s) and Comparisons	computer-based aid, while controls were treated without
Setting	NS
Patients Reviewed	diabetic patients (both type I and type II)

Pre-defined outcomes	changes in HbA1c both in cases and controls, as a primary or as a secondary outcome
Range of Observations or Period of Follow Up	NS
Findings or results	A statistically significant reduction in HbA1c from baseline to follow-up in the computer treated group in comparison to the control group was obtained. Quantitatively, the average HbA1c reduction was equal to 20.25% (Appendix) when taking into account all the 14 admitted trials, and was even larger in the decision support systems subgroup (20.47%), in the day-by-day advisory systems one (20.49%), and in the telemedicine systems one (20.56%), thus confirming the general result.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation made rather a discussion of cost-benefit ensues. Applicability of patients management systems will heavily depend on the capability of the designers to take into account the potential differential benefit of such systems in comparison to the current situation; to this end, it will be probably crucial to provide also advantages to the users in the general process of acquiring, maintaining, and distributing knowledge, together with the advocated clinical impact. The organisation of clinical care is likely to change only if the benefit strongly overcomes the inertial force of the existent one.
Further research	The use of computerised systems may instead increase the frequency of patient/physician communications, thus promoting an IIT implementation more adherent to the DCCT recommendations. Additionally, other possible outcomes, such as the reduction in hypoglycemic episodes and in costs, the two main drawbacks of IIT(sic), should be investigated. The relative reduction of hypoglycemia frequency found in some trials pushes towards to necessity of collecting this indicator in all future studies, in order to assess a possible significance of the results. On the other hand, the introduction of IT solutions has to be examined within the overall process of diabetes care. From an organisational viewpoint, it will be important to evaluate the impact on the Health Care Service workflow. Since the patients management process is obviously human-centred, it is necessary to investigate how the traditional activities would be modified—and would benefit—from the introduction of IT: some tasks will require an additional workload from personnel (eg request for system suggestions, or data insertion if a proper integration with the Hospital Information System has not been designed), while some others will be sped up (eg therapy optimisation when data are frequently available through telecommunication, and when the physician is provided with data analysis tools). The approach of the involved agents (and in particular of patients, when dealing with day-by-day and telemedicine systems) towards

	technology is crucial. It will be compulsory to test, in the long run, the usage of computerised system, checking the problems related to disaffection or disillusion that may frequently arise.
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REFERENCE	Montgomery AA, Fahey T. A systematic review of the use of computers in the management of hypertension. <i>J Epidemiol Community Health</i> 1998;52(8):520-5.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	23.5
Objective/Questions Addressed in the Review	To assess the effect of computers and computer-based clinical decision support systems on the management of hypertension.
No of Studies Included in the Review	7
No of Participants Studied in Total	11962
Databases and Years Searched	Cochrane Library (1997 Issue 3), MEDLINE (1966-1997), BIDS science citation index (1981-1997), and EMBASE ( 1980-1997)
Search Strategy	Searches were made using the recommended Cochrane search strategy including the following Medical Subject Heading (MESH )terms: "computers", "microcomputers", "computer assisted therapy", "ambulatory care", "information system", "expert systems", "hypertension", "blood pressure", "blood pressure determination", and "mass screening". A citation search of previous reviews on the subject and of studies identified in the search, and the authors wrote to all authors requesting information about unpublished trials, additional data, and clarification of data when necessary was also made. The search included studies published in non-English language journals.
Study Designs Eligible for Inclusion	RCTs and quasi randomised controlled trials
Practitioner Targeted	NS
Intervention(s) and Comparisons	CDSSs defined as an active knowledge system that uses two or more items of patient data to generate case specific advice.
Setting	community or hospital-based ambulatory settings
Patients Reviewed	NS
Pre-defined outcomes	(a) patient uptake/administration (initial and follow up measurement of blood pressure in patients); (b) physician performance (knowledge and recording of information); and (c) blood pressure control achieved in hypertensive patients (control according to criteria used in primary studies)

Range of Observations or Period of Follow Up	NS
Findings or results	From these results, it is still not certain whether computers have a favourable effect on the management of hypertension. The three outcome dimensions measured were patient administration, physician performance, and blood pressure control, with six of the seven trials examining more than one outcome. Patient uptake/administration was evaluated in five trials, four of which reported significant improvement using a computer. Physician performance was evaluated in three trials, two of which reported improvement using a computer. Control of blood pressure was evaluated in six trials, two of which reported improvement using a computer. However, positive findings from two of the trials should be regarded cautiously because the possible effects of cluster randomisation may have been responsible for the significant results found. If this was the case, the number of trials reporting improvement in each of the outcome measures would be: patient uptake/administration, two of five; physician performance, one of three; control of blood pressure, one of six.
Conclusions, considerations for implementation, adoption or system design and development.	This review shows that computers may have a favourable influence on the uptake and administration of patients in hypertension management. Computer use in this area should be encouraged, particularly with regard to case finding and follow up. The results presented here do not seem to support any benefit in using computers in terms of physician performance and blood pressure control inpatients. Health authorities should take notice of developments in computer software that will allow effective targeting of resources to patients who are most at risk, and general practices should find ways of increasing their usage of computers in the management of hypertension in their practice population.
Further research	According to the authors, there has been enormous development both in software sophistication and doctors' use of computers, and further evaluation is warranted on physician performance and blood pressure control in patients.

REFERENCE	Nies J, Colombet I, Degoulet P, Durieux P. Determinants of Success for Computerized Clinical Decision Support Systems Integrated in CPOE Systems: a Systematic Review. <i>AMIA Annu Symp Proc</i> 2006;594–598.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	16

Objective/Questions Addressed in the Review	To identify, from published data, the features of such systems essential for their successful and durable use in practice and for care improvement. To identify the methodological characteristics of studies and the technical characteristics of CDSSs associated with efficacy.
No of Studies Included in the Review	59
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE up to July 2005
Search Strategy	Garg et al. was updated using the same search terms of hospital information systems, computer-assisted decision making, computer-assisted diagnosis, computer-assisted therapy, clinical decision support systems, randomised controlled trial and cohort studies.
Study Designs Eligible for Inclusion	randomised and non-randomised trials with a contemporaneous control group
Practitioner Targeted	NS
Intervention(s) and Comparisons	clinical decision support systems defined as t automatically provide the clinician with electronically formatted recommendations, care provide with the intervention compared to care provide without
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	clinical performance or patient outcomes
Range of Observations or Period of Follow Up	NS
Findings or results	CDSSs aiming to produce preventative reminders or to ensure the appropriate use of targeted healthcare resources gave positive results in a large proportion of studies. Conversely, CDSSs designed to provide support for diagnosis, drug prescription and disease or risk factor management tended to be less successful. This finding for the drug prescribing class of clinical objectives is not consistent with previous findings. A few characteristics of the content of the decision-making aid and the logistics of decision support seem to be associated with the success of the CDSS: system-initiated interventions, the provision of assistance without user control over output, systems in which data are automatically retrieved from the electronic medical record and systems providing corollary actions in the CPOE. Overall, these results are consistent with those of previous reviews despite several important differences in the methods of data selection and collection.

Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation or adoption were made.
Further research	Further studies should address two major research needs. Firstly, reports should provide as much detail as possible in descriptions of systems and their interactions with users, as recommended in a previous study. Secondly, reports would gain from the use of tools like the Cochrane EPOC "Data Collection Checklist" ensuring the standardisation of methodological reporting in studies of this type, which would facilitate more instructive systematic reviews, perhaps even focusing on certain clinical objective classes.

REFERENCE	Oren E, Shaffer ER, Guglielmo BJ. Impact of emerging technologies on medication errors and adverse drug events. <i>Am J Health Syst Pharm</i> 2003;60(14):1447–1458.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	18
Objective/Questions Addressed in the Review	To identify published studies that assessed the effects of the given technology, especially with respect to medication errors and ADEs, and to identify published studies that assessed the appropriateness of use of the technology.
No of Studies Included in the Review	11 CPOE, 7 ADM, 7 Bar-coding, 8 CMAR
No of Participants Studied in Total	NS
Databases and Years Searched	Previously published studies of CPOE, bar-coding, and CMARs were identified through a PubMed search for the period from 1982 (when CPOE was first integrated into hospital information systems) through March 2002. ADMs were searched from the inception of PubMed in 1966, since the first publications associated with ADMs appeared shortly thereafter (1969)
Search Strategy	The search strategy included the following MeSH terms: <ul style="list-style-type: none"> <li>• CPOE: Clinical pharmacy information systems, decision support systems, clinical drug therapy, computer-assisted/* methods, hospital information systems, information systems, medication errors/prevention and control, medical records systems/computerized, medication systems, hospital, user computer interface, and pharmaceutical preparations/*adverse effects.</li> </ul> Keywords: CPOE, computerized physician order entry.



	<ul style="list-style-type: none"> <li>• ADMs: Automation, clinical pharmacy information systems, medication errors/statistics and numerical data, medication systems—hospital, computer-assisted/*methods, medication errors/prevention and control. Keywords: ADM, automated dispensing machine*.</li> <li>• Bar coding: Clinical pharmacy information systems, clinical drug therapy, computer-assisted/*methods, hospital information systems, information systems, medication errors/prevention and control, medical records systems/computerized, hospital and user computer interface, automatic data processing/*methods. Keyword: Bar-cod*.</li> <li>• CMARs: Clinical pharmacy information systems, clinical drug therapy, computer-assisted/*methods, hospital information systems, information systems, medication errors/prevention and control, medical records systems/computerized, hospital and user computer interface. Keywords: medication administration record, MAR.</li> </ul> <p>The authors reviewed all references from the recovered articles, as well as from previously identified review articles. Studies were evaluated and included only if they were based in the United States and published in a peer-reviewed journal.</p>
Study Designs Eligible for Inclusion	controlled studies
Practitioner Targeted	NS
Intervention(s) and Comparisons	CPOE, automated dispensing machines (ADMs), bar coding, and computerised medication administration records (CMARs).
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	medication errors, ADEs or appropriateness of use
Range of Observations or Period of Follow Up	NS
Findings or results	While a number of new technologies have been recommended in an effort to reduce medical errors and ADEs, the authors found few studies that confirmed such an association. In our review, five studies observed a decrease in medication errors associated with ADMs. No studies confirm that CMARs improve patient outcomes through the reduction of errors or improvements in work processes.

Conclusions, considerations for implementation, adoption or system design and development.	<p>No recommendations for implementation made, the authors note that costs, institutional cultural barriers and logistical challenges, such as training users, installing and upgrading equipment, and implementation, all likely contribute to slow transition to CPOE. For ADMs the authors note that considerable inter-user variability in the reduction of medication errors has been documented. Whether nursing overrides should be permitted remains controversial. Cost is an additional consideration in the implementation of ADMs. With regards to bar-coding, pharmaceutical manufacturers have not agreed on a standard approach to the implementation of bar-coding, delaying widespread implementation. Additionally, bar-coding may require changes in packaging, as well as additional computer programming for unusual doses. Consequently, potential increases in costs associated with re-packaging and re-labelling in the pharmacy must be considered. Reasons for the lack of widespread use may include the difficulty of transferability of the technology, human and organisational factors, and logistical challenges. Costs associated with the development and maintenance of new technologies potentially range into the millions of dollars per year. Before a new technology can be recommended for broad use, the technology should be demonstrated to result in a reduction in medication errors and ADEs and have been evaluated for appropriateness of use. Furthermore, these findings should be demonstrated in a variety of settings in order to confirm the extent to which they are transferable to multiple institutions. Organisational and human factors cannot be entirely eliminated from patient care. Technologies are only as successful as they are usable, and no battery of technologies is likely to compensate entirely for cumbersome workflow and human stress and fatigue. Understanding the bridge between effectiveness in controlled circumstances and efficacy in the real world in which technologies are applied will be critical to optimising benefits to patients, providers, and the healthcare system.</p>
Further research	<p>Few studies evaluating the impact of CPOE on patient outcomes have been conducted, studies to-date lack generalisability. Few studies have examined the application and outcomes associated with bar-coding in the hospital therefore further evaluation is warranted. Very few investigations have evaluated the appropriateness of use of these technologies.</p>

## REFERENCE

Poissant L, Pereira J, Tamblyn R, Kawasumi Y. The impact of electronic health records on time efficiency of physicians and nurses: a systematic review. *J Am Med Inform Assoc* 2005;12(5):505–16.

How does it meet inclusion criteria?	systematic review in title
CASP Total Score	25
Objective/Questions Addressed in the Review	To estimate the extent to which an EHR affects clinicians' documentation time and to identify factors that may explain efficiency differences observed across studies.
No of Studies Included in the Review	23
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, CINAHL, HEALTHSTAR, and Current Health databases from 1996 to January 2004
Search Strategy	Search strategies were specific to the database and included the Medical Subject Headings (MeSH) associated with key words that reflected EHRs and workflow. The MEDLINE search strategy included the following terms: health informatics, electronic records, medical records systems, medical informatics, information systems, computerized patient records, workflow, time and motion, task performance and analysis, work re-design. When searching the CINAHL and HealthSTAR databases, the key words efficiency, organizational, hospital information systems, and workload were added to the search strategy used for the MEDLINE database. Only French or English full-text papers published in peer-reviewed journals and proceedings were selected for further review. Reference lists of selected papers were examined to identify other relevant articles. Finally, publications of key authors, selected based on their expertise and quality of publications in the area of workflow and EHRs, were looked at using the Web of Science Citation Index.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	Physicians and nurses
Intervention(s) and Comparisons	EHR but not defined
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	documentation for patient care and time
Range of Observations or Period of Follow Up	NS

Findings or results	<p>Results of this review suggest that nurses are more likely than physicians to gain time efficiencies by using a computer system to document patient information. Among all 11 studies on nurses, six reported a reduction in documentation time when using a computer. Among those, the relative time differences ranged from 22.1% to 245.1% and each of these studies assessed the time efficiency of bedside terminals or computerised systems that were accessible through either bedside terminals or central station desktops. Conversely, studies that reported the impact of EHR use on the total working shift are on average favourable. When the weighting algorithm was applied to the individual studies, the authors determined that, on average, using bedside terminals saved nurses 24.5% of their overall time spent documenting during a shift, which compared advantageously with the use of central station desktops (23.5%). Despite similar weighted averages between bedside terminals and central station desktops, the five studies that assessed bedside terminals were consistent and showed a time reduction, while the two studies looking at central station desktops had opposite results. Regardless of the system (bedside or central station desktops) being evaluated, most differences between paper and computer documentation systems were statistically significant.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>The need for a good fit between the EHR and routine clinical practice is recognised as essential and time efficiency is one of several factors that is used to assess the quality of this integration. Time efficiency is recognised as an important facilitator or barrier of EHR implementation. Results of this review suggest that nurses are more likely than physicians to gain time efficiencies by using a computer system to document patient information. Several reasons may explain the difference between nurses and physicians. First, nurses and physicians document different types of information. Nurses often document using standardised forms or care plans while physicians rarely use standardised templates to write their clinical notes. Retrieval or viewing of information is part of the work processes of both nurses and physicians. However, it is much more intricately related to the documentation process of physicians. This may have played an important role in time efficiencies of CPOE systems that combine retrieval, viewing of information, data entry, and, in many cases, responses to alerts and reminders. These additional factors are difficult to capture by time and motion or work-sampling methods as both have limited capacity in capturing simultaneous activities and these may have accounted for the extra time that physicians take to document or enter orders on a computer. Several studies have shown that computers increase the completeness of information being documented. This additional information available</p>

	<p>available to physicians will influence the time required to retrieve information and their motivation to use EHRs if part of that information is perceived as unnecessary to their clinical activities. While both nurses and physicians see the added value of integrating EHR into their daily practice physicians and nurses differ in their incentives to use the EHR and in their speed of adoption. These can be influenced by the fact that nurses tend to work in a single location and will therefore be more frequently exposed to the EHR in contrast to physicians who tend to work in several locations, both inside and outside the hospital. The degree of exposure to a newly implemented EHR may influence the learning curve and ability to become an efficient user more rapidly. As employees of a healthcare organisation, nurses may be more likely to receive support from clinical leaders and paid training sessions, both of which have been identified as essential requirements for EHR adoption. The autonomy and accountability of nurses and physicians are different and may influence their performance. Those may explain why nurses tend to be more time efficient than physicians. Both groups also differ in their work processes. For example, nurses are part of a care team and need to verbally transmit information to their colleagues at the end of their working shifts. The use of computers has been shown to reduce the time devoted to the end-of-shift report and this change in workflow may have been a strong incentive for nurses to become efficient users of the system. Our results support this assumption, with all studies examining the impact of EHR over working shift periods, reporting favourable time efficiencies compared to those with patients or patient encounters as the sampling units. In summary, the authors learned that expectations of EHR implementation projects that documentation time will be decreased are unlikely to be fulfilled, especially with physicians. The authors suggest that a shift from the user's efficiency to the organisation's or even the system's efficiency is needed. Such a shift will require that the EHR be seen as a tool that can transform work processes and support innovation in care delivery.</p>
Further research	<p>The optimal time period for assessment of time efficiencies post-implementation of EHRs remains a challenge and will require further research. To understand the role that system use may play in time efficiencies, standardised audit trail information needs to be collected that would allow assessment of the extent to which individual components of a system are used. This review clearly highlighted the absence of any consistency or agreement on a standard time period after which a system should be tested. In fact, 25% of the studies in our review neglected to mention the time period in which the evaluation was performed despite the importance of this time period on adoption, use, and efficiency rates. For</p>

	<p>informed and valid comparisons of time efficiency within and across studies, timed standardised tasks would be helpful in establishing baseline expected efficiencies as some EHRs may not have the capacity to be time efficient in comparison to paper charting, regardless of the user or the environment. Knowing this information prior to EHR implementation will influence the deployment and training strategies. The focus on time efficiency should then be oriented toward the overall processes of care delivery rather than toward the potential time gains in performing specific activities, like documenting or ordering tests. Further studies are required to examine the role of clinicians, professional practice, and organisational environment in facilitating or not the efficient use of EHRs. Future research is required to examine whether the capacity of the EHR to improve the overall care delivery process of patients will likely outweigh the barrier associated with the additional time required to use the system. New methods to measure the impact of the EHR on time efficiency from an organisation's or a system's perspective will have to be developed. Further research is needed to examine the impact of EHR on system efficiency and how this will influence adoption rates by all users, particularly physicians.</p>
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REFERENCE	Randell R, Mitchell N, Dowding D, Cullum N, Thompson C. Effects of computerized decision support systems on nursing performance and patient outcomes: a systematic review. <i>J Health Serv Res Policy</i> 2007;12(4):242–249.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	19
Objective/Questions Addressed in the Review	To examine the effect of computerised decision support systems (CDSSs) on nursing performance and patient outcomes.
No of Studies Included in the Review	8 studies described in 9 papers
No of Participants Studied in Total	more than 24000
Databases and Years Searched	MEDLINE, CINAHL, EMBASE, British Nursing Index (BNI), HMC Health Management Information Consortium, the Cochrane Controlled Trials Register, ASSIA, Sociological Abstracts, PsycINFO, INSPEC, SIGLE, National Research Register and Social Science Citations Index up to April 2005
Search Strategy	Searches were not limited by language. Search terms referring to the technology, such as 'decision support systems', 'expert system' and 'reminder systems', were used. The search was re-run in May 2006 to identify more recently

	published studies. Reference lists of included studies and relevant reviews were also searched. Experts in the field were contacted to identify recently published work, conference publications and unpublished studies.
Study Designs Eligible for Inclusion	randomised controlled trials (RCTs), controlled clinical trials (CCTs), controlled before and after (CBA) studies and interrupted time series (ITS) studies
Practitioner Targeted	Nurses
Intervention(s) and Comparisons	CDSSs were described as designed to aid clinical decision-making, matching patient characteristics to a computerised knowledge-base to generate patient-specific assessments or recommendations.
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	professional performance and/or patient outcomes
Range of Observations or Period of Follow Up	NS
Findings or results	Nurses with CDSS compared to nurses without CDSS. In summary, in one study CDSS use improved performance while in another it was associated with poorer performance and no study found an impact of CDSS on patient outcomes. However, two studies were too small to identify clinically important effects as statistically significant, if they existed. Equally, the finding of no significant difference may be the result of contamination in two of the studies. In summary for nurses with CDSS compared to other health professionals without CDSS three RCTs comparing nurses using CDSS with doctors for anticoagulation management found no significant difference in terms of patient outcomes, suggesting that CDSS may help nurses to manage anticoagulation as effectively as doctors. However, these studies were underpowered to detect important adverse consequences of poor anticoagulation management such as death. The two studies of triage for first contact care suggest CDSS to be beneficial in terms of performance, with significantly decreased GP workload when nurses used CDSS. While one study suggests that CDSS is detrimental to patient outcomes another study suggests that it is CDSS to be beneficial in terms of some patient outcomes.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation made. The authors argue that the present enthusiasm for supporting healthcare practice through introduction of new technologies means that CDSSs have been introduced without adequate evaluation. This is followed by extensive discussion on how best to evaluate guidelines with CDSSs.



Further research	Differences in results across the studies suggest that future studies should seek to explore the significance of each component for nursing performance and patient outcomes. It is first necessary to evaluate adequately the protocol before development of a CDSS begins. Then the CDSS should be evaluated against its paper-based counterpart following the phases outlined in the MRC framework for evaluation of complex interventions. As well as enabling evaluators to distinguish between the impact of the protocol and the impact of the technology, evaluating the CDSS against its paper-based counterpart would help identify contexts in which a paper-based solution is as effective, preventing unnecessary expenditure on computer-based interventions. In order to distinguish between the impact of the CDSS and the impact of the practitioner, data should be collected on levels of use and on adherence to recommendations. If adherence is greater in one arm of the trial, reasons for this can then be explored; collection of qualitative data could be useful for this, as demonstrated by qualitative studies of CDSS use in first contact care. As discussed above, contamination is a significant issue facing RCTs in this area as inadvertent application of the intervention, or aspects of the intervention, to the control group can dilute the effects of the intervention. Therefore, randomisation should be at the practitioner or unit level. There is enormous unexplained variation between health professionals using CDSS and this must be considered in study designs; it is important that more than one nurse be included in the trial and that the actual number of nurses included in the trial should be reported.
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REFERENCE	Rosado B, Menzies S, Harbauer A, Pehamberger H, Wolff K, Binder M et al. Accuracy of computer diagnosis of melanoma: a quantitative meta-analysis. <i>Arch Dermatol</i> 2003;139(3):361–367.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria, quality assessment and meta-analysis
CASP Total Score	18
Objective/Questions Addressed in the Review	To critically review the contemporary literature on computer diagnosis of melanoma, evaluate the accuracy of such computer diagnosis, analyse the influence of study characteristics, and compare the accuracy of computer diagnosis of melanoma with human diagnosis.
No of Studies Included in the Review	30, 10 included in meta-analysis
No of Participants Studied in Total	11849 skin lesions

Databases and Years Searched	MEDLINE from January 1991 to March 2002
Search Strategy	The MEDLINE search was performed using the keywords automated diagnosis or computer diagnosis restricted by the term melanoma, published in English or German.
Study Designs Eligible for Inclusion	Original data
Practitioner Targeted	NS
Intervention(s) and Comparisons	automated computerised diagnosis
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	The results of our meta-analysis show that the computer diagnosis of melanoma is reliable and comparable with the diagnostic accuracy achieved by human specialists. The authors note that the diagnostic accuracy of such systems will vary greatly depending on how the lesions were selected. The diagnostic difficulty of the sample will depend on whether the lesions were selected by specialists or non-specialists. It will also depend on whether the clinical diagnosis was made by the unaided eye or with the superior method of dermoscopy and whether the lesions were gathered in a primary care setting or in a specialised pigmented skin lesions unit.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation are made. A number of methodological deficiencies are noted by the authors who argue that because of these limitations, it is too early to say that the computer is going to replace dermatologists in the diagnosis of melanoma. However, it can be expected that automated diagnostic systems will become commercially available very soon.
Further research	Ideally, a prospective, randomised, controlled multi-center trial comparing computer diagnosis with human diagnosis should be carried out to evaluate the validity of such systems.

REFERENCE	Rothschild J. Computerized physician order entry in the critical care and general inpatient setting: a narrative review. <i>J Crit Care</i> 2006;(4):271–278.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	17

Objective/Questions Addressed in the Review	To evaluate the effects of CPOE on clinical and surrogate outcomes in hospitalised patients in both general and critical care settings.
No of Studies Included in the Review	18
No of Participants Studied in Total	NS
Databases and Years Searched	Ovid MEDLINE from dates January 1, 1966 to September 1, 2003, PreMEDLINE, EMBASE, and All EBM Reviews (which includes the Cochrane Database of Systematic Reviews, the American College of Physicians [ACP] Journal Club, the Database of Abstracts of Reviews, and Effects and the Cochrane Central Registry of Controlled Trials).
Search Strategy	Electronic database searches were conducted in October 2003. The following medical subject headings (MeSH) terms were used: computerized physician order entry, CPOE outcomes, physician order entry, clinical decision support systems, computer assisted drug therapy, computerized medical record systems, and hospital information systems. Key text words were also used with MeSH terms to further refine the searches, including: patient safety, medical errors, adverse drug events, critical care, intensive care unit, and clinical guidelines. In addition, reference articles were manually searched using bibliographies from reviewed articles.
Study Designs Eligible for Inclusion	RCTs including quasi-randomised processes such as alternate allocation, prospective observational studies with controls such as interrupted time series. Systematic reviews and meta-analyses were also eligible for inclusion if restricted to inpatient studies evaluating CPOE.
Practitioner Targeted	NS
Intervention(s) and Comparisons	CPOE—clinicians to enter orders directly into a computer workstation that is linked to a hospital clinical information system. Real time linkage of orders to a computerised knowledge-base provides immediate order evaluation and feedback and facilitates the use of assistive technologies such as decision support. A computerised clinical decision support system (CDSS) is software designed to aid clinical decision-making by using patient specific information that is compared to a knowledge-base such as clinical practice guidelines and results in evaluations or recommendations. CDSSs that are not associated with concurrent CPOE were excluded.
Setting	general and critical care inpatient
Patients Reviewed	NS

Pre-defined outcomes	Clinical and surrogate outcomes: clinical outcomes are mortality, morbidities, adverse events, and length of stay; surrogate outcomes include medical errors, costs or charges, and intermediate outcomes (eg laboratory results) with well established connections to the clinical outcomes of interest such as clinical guideline compliance or the use of institutional best practices
Range of Observations or Period of Follow Up	NS
Findings or results	The studies of CPOE and medication prescribing provide the strongest evidence for the benefits of CPOE on clinical outcomes. Three studies demonstrated that CPOE significantly reduced the incidence of serious medication errors, including adverse drug events (ADEs) while the paediatric ICU study failed to show that CPOE reduced ADEs. Two medication-related studies also demonstrated that CPOE reduced patient length of stay. Surrogate outcome improvements associated with CPOE included reduced medication and/or overall hospital costs and increased selection of appropriate drugs and correct drug dosing. The third category of CPOE interventions in general and critical care inpatient settings concerned injury prevention or prophylactic measures and non-medication-related resource utilisation. Of the 8 studies in this category, only a single study failed to demonstrate a beneficial effect as a result of CPOE. Interestingly, the same research group was able to improve guideline compliance with a modification in the delivery of their CDSS.
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation were made. The authors did note though that there are several important concerns for hospitals when deciding to incorporate CPOE into inpatient care processes. These concerns include costs, implementation challenges, physician acceptance, unintended consequences, and the currently limited choice of vendor offerings. Unintended consequences may include increased or different types of medical errors such as entering orders in the wrong patient's record, incorrect default dosing or decision support, disruption of usual routines, cognitive fragmentation from screen switching during order entry, and errors in the communication and coordination process. These potential obstacles need solutions in order for CPOE to become "business as usual" while providing care for general and critical care inpatients.
Further research	More critical care research on CPOE is indicated. The long-range effectiveness of CPOE interventions are in need of additional research. The lack of evaluation of commercial systems was noted as was the lack of studies sufficiently powered to detect clinical outcomes.

REFERENCE	Saba L, Caddeo G, Mallarini G. Computer-aided detection of pulmonary nodules in computed tomography: analysis and review of the literature. <i>J Comput Assist Tomogr</i> 2007;31(4):611–619.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria, quality assessment and meta-analysis
CASP Total Score	21.5
Objective/Questions Addressed in the Review	To evaluate the role and the sensitivity of the pulmonary nodules CAD in CT, also to evaluate CAD plus radiologist sensitivity in detection of pulmonary nodules, and compare different acquisition techniques (thin slice vs thick slice and low dose vs normal dose). The authors tried to underline pitfalls inherent with the use of the CAD systems.
No of Studies Included in the Review	20
No of Participants Studied in Total	827 patients and 2717 pulmonary nodules detected by CAD
Databases and Years Searched	MEDLINE and PubMed from January 2001–August 2006
Search Strategy	Database searches used the search terms “computer aided detection pulmonary,” “computer aided detection lung,” “CAD pulmonary,” “CAD lung,” and “pulmonary nodules automated detection.” In addition to the abstract search in the MEDLINE database, references were obtained from the references of retrieved articles. Also, an internet search was performed by using Google search. The authors also used the search engine of the Radiological Society of North America (available at <a href="http://www.radiology.rsnajnl.org">www.radiology.rsnajnl.org</a> ), which serves Radiology and Radiographics, the search engine of the American Journal of Roentgenology (available at <a href="http://www.ajronline.org">www.ajronline.org</a> ), and the search engine of the Journal of Computer Assisted Tomography and European Radiology (available at <a href="http://www.jcat.org">www.jcat.org</a> and <a href="http://www.springerlink.com">www.springerlink.com</a> , respectively). Unpublished research was not included and language was restricted to English.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	radiologists
Intervention(s) and Comparisons	CAD for pulmonary nodules using CT
Setting	patients not phantoms
Patients Reviewed	NS
Pre-defined outcomes	CAD sensitivity
Range of Observations or Period of Follow Up	NS

Findings or results	The authors observed an overall sensitivity of 79% for the CAD and of 92% for CAD plus radiologist; CAD sensitivity was 80% and 74% for thin slice and thick slice protocols, respectively.
Conclusions, considerations for implementation, adoption or system design and development.	Results of our review indicate that CAD may be an effective tool in the diagnosis of pulmonary nodules, and the use of CAD plus radiologist give better results than the use of only radiologist's analysis. In particular, CAD shows its best potentialities in detecting nodules located in the central areas of the lungs where, moreover, the radiologist shows a lack of efficacy. The use of thin slice and the normal-dose protocols gave better results. Although false-positive rate is still a drawback, CAD showed an increased sensitivity that expenses the low specificity; reduction of the number of false-positive findings will be an important focus of ongoing developments. The high false-positive rate of CAD requires radiologist to look each suspected nodule to confirm it as true nodule, but the trend is in reducing the FP rates, providing better information; however, radiologists would be able to delete correctly false-positive detections. Computer-aided detection tools are useful to support radiologist's detection performance, but all suspected lesions detected by CAD must always be interpreted by radiologist to rule out false positives.
Further research	It is important, in our opinion, that other studies evaluate what number of FP detection would be acceptable with CAD in the routine clinical practice.

REFERENCE	Sanders DL, Aronsky D. Biomedical informatics applications for asthma care: a systematic review. <i>J Am Med Inform Assoc</i> 2006;13(4):418–427.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	17.5
Objective/Questions Addressed in the Review	To characterise medical computing applications for asthma by examining the clinical domains and various aspects of patient care for which computer applications have been developed.
No of Studies Included in the Review	64 publications of 51 unique projects, 21 prospective studies on impact
No of Participants Studied in Total	numbers listed but not tallied
Databases and Years Searched	PubMed (MEDLINE), OVID CINAHL, OVID All Evidence Based Medicine Reviews: Cochrane Database of Systematic Reviews (DSR), ACP Journal Club, and Database of Abstracts of Reviews of Effectiveness (DARE), ISI Web of Knowledge SM—Web of Science from their start date through February 1, 2005

Search Strategy	<p>Searches in PubMed were performed using MeSH term and keywords, while the other databases were only searched using keywords. Each search required the presence of the concept “asthma” in combination with any of the following terms: “medical informatics,” “decision support,” “informatics,” or “computer-assisted instruction.” Included MeSH terms were asthma, combined with medical informatics, decision support techniques, informatics, or computer-assisted instruction. The authors considered articles published in peer-reviewed journals, including review articles and surveys, and conference proceedings that described or evaluated such applications. Only articles in English with available online abstracts at the time of searching were included. Abstracts, poster presentations, and editorial publications were excluded, as were studies that did not involve patient care.</p>
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	<p>Computer-augmented asthma care was defined broadly and included diagnosis or detection systems, applications for the prevention or monitoring of symptoms and outcomes, decision support tools for asthma treatment including electronic implementation of practice guidelines, and patient-centred education tools.</p>
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	<p>Among the 21 prospective trials, 13 measured a clinical and 8 a non-clinical outcome. Seven (54%) of the 13 studies with a clinical outcome reported a positive effect, while the remaining 6 found no statistically significant change. Improved clinical outcomes included decreased hospitalisation rates increased vaccination rates for asthmatic patients and decreased need for rescue medication by patients. Among the eight studies assessing a non-clinical outcome, seven (88%) showed a statistically significant positive effect of the computerised intervention. The improvements included increased dust mite prevention measures increased patient knowledge about asthma self-management and improved adherence to guideline recommendations by clinicians.</p>



Conclusions, considerations for implementation, adoption or system design and development.	Only a minority of studies occurred in a functioning clinical environment, while two-thirds reported on research in a pilot or other early stage. This may demonstrate that research appearing promising in early stages may not necessarily be beneficial or practical in widespread use. Taken together, these two evaluations reveal that few studies reported a sufficient level of maturity to determine large benefits to clinical practice, and highlight areas that are amenable to further feasibility testing and clinical application. No studies examined asthma care in the hospital and only two considered emergency room care. Because of the profound differences in workflow and time constraints between different patient care settings, applications developed for one setting, even if successful, may not be practical or beneficial in other areas. Comprehensive care for asthmatic patients is multi-disciplinary and requires coordination and communication between patients and providers in the home, outpatient, and acute care settings. This will require a high degree of integration between computer systems such as electronic patient records across many locations. Additionally, there is a need to individualise asthma treatment plans and to revise therapy based on patient response. Simply replicating static care guidelines into a computer system will be an inadequate solution to provide the individualised and dynamic care needed by patients. Effective systems will need to track patient outcomes over time and be able to generate personalised care plans for both acute and chronic asthma care.
Further research	The authors highlight the current need for studies to assess the evaluation of applications in the various clinical environments; they also note the lack of prospective trials for the detection or diagnosis and monitoring/prevention domains and evaluation of the impact of using computerised systems to implement asthma care guidelines.

REFERENCE	Shea S, DuMouchel W, Bahamonde L. A meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting. <i>J Am Med Inform Assoc</i> 1996; 3(6):399–409.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria and meta-analysis
CASP Total Score	19.5
Objective/Questions Addressed in the Review	To assess the current state of the evidence concerning the effectiveness of these systems and to provide a summary estimate of the magnitude of the effect of computer-generated reminders across studies.

No of Studies Included in the Review	16
No of Participants Studied in Total	NS
Databases and Years Searched	The MEDLINE (1966-December 1995), Nursing and Allied Health (1982-October 1995), and Health Planning and Administration (1975-November 1995)
Search Strategy	Databases were searched using the key phrase "reminder systems." Examination of retrieved articles for references missed by the database search produced 28 more articles. Additional database searches were performed using the following key words: software, computers, ambulatory care, preventive health services, primary prevention, HMO, family practice, professional practice, attitude to computers, automatic data processing, primary health care, and decision support systems/management.
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	NS
Intervention(s) and Comparisons	computer-generated reminders for preventative care compared to a control group that received no intervention
Setting	outpatient
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Computer reminders increased preventive practices compared with a control group for four of the six groups of preventive practices, including vaccinations, breast cancer screening, colorectal cancer screening, and cardiovascular risk reduction, and for all six practices combined (OR 1.77; 95% CI 1.38-2.27) (Table 5). Manual reminders increased preventive practices compared with a control group for the same four groups of preventive practices and for all six practices combined (OR 1.57; 95% CI 1.20-2.06). Computer plus manual reminders increased preventive practices compared with a control group for all six groups of preventive practices and for all six combined (OR 2.23; 95% CI 1.67-2.98). Thus, both methods of generating reminders were effective overall. Both methods had the greatest effect on vaccinations, somewhat smaller effects on colorectal cancer screening and cardiovascular risk reduction, and lesser effects on breast and cervical cancer screening. Overall, and over the time periods studied, computer reminders increased preventive practices by 77% compared with a control group. The interpretation of this

	effect in terms of an absolute increase in delivery of preventive services to patients will depend on the baseline prevalence of compliance with the recommended preventive service.
Conclusions, considerations for implementation, adoption or system design and development.	The impact of manual reminder systems on physician completion of recommended preventive manoeuvres was approximately equivalent to the impact of computer-generated reminders in the studies included in our analysis. This finding suggests that computer-generated reminders are as acceptable to physicians and other primary care providers as reminders generated by other sources; it also suggests that, in choosing a method for generating reminders, issues of cost, sustainability, and auditability will dominate. Formidable technical issues also must be addressed before computer-based reminder systems can have widespread use in healthcare systems. These include difficulties in capturing the necessary clinical data; the need for standards for coded medical vocabulary, medical logic frames, and clinical and medical knowledge databases; confidentiality and data security; legal issues; and the capital and operating costs of such systems. Nonetheless, such systems have now progressed to the proof-of-concept stage, at least in the ambulatory setting with regard to preventive care. Finally the authors note that consensus on guidelines is more important than merely adopting new technology.
Further research	No future research was indicated.

REFERENCE	Shebl NA, Franklin BD, Barber N. Clinical decision support systems and antibiotic use. <i>Pharm World Sci</i> 2007;29(4):342–349.
How does it meet inclusion criteria?	Systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	19.5
Objective/Questions Addressed in the Review	To summarise the relevant literature available regarding the use of CDSS and antibiotics. The objectives were to review, summarise and appraise randomised controlled trials (RCT) and 'before and after' trials published on CDSS used to support the use of antibiotics, and to identify gaps in the existing literature.
No of Studies Included in the Review	28
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE (1966–2006), EMBASE (Excerpta Medica, 1980–2006) and International Pharmaceutical Abstracts (IPA, 1970–2006)

Search Strategy	A literature search was carried out in October 2006 using MeSH terms for MEDLINE and using combinations of the following terms '(Decision support systems) or (clinical decision support systems) AND (antibiotics) or (anti-infectives) or (antibacterials) or (antimicrobials). The reference sections of all retrieved articles were also manually searched for further publications. The authors included any research paper relating to the use of CDSS and antibiotic use.
Study Designs Eligible for Inclusion	All studies used but focussed on RCTs, CBAs
Practitioner Targeted	NS
Intervention(s) and Comparisons	CDSSs but no a priori definition was used for CDSS as stated by the authors, electronic and non-electronic interventions included
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Descriptive studies and review articles comprised the majority of articles included (25%) respectively, followed by before and after studies (15%). Only five RCTs and five 'before and after' studies were reviewed. Eight of the ten studies identified a statistically significant advantage for CDSS. Four RCT studies focused on the process of care and only one study examined the cost-effectiveness of the CDSS as well as patient outcomes. All five 'before and after' studies focused on both process of care and patient outcomes.
Conclusions, considerations for implementation, adoption or system design and development.	Generalising the success and benefit of CDSS is not possible as seven of ten studies reviewed were conducted in the USA. On a practical level, the limited range of clinical settings in which the CDSS were created and tested also limits the generalisability to succeed outside these settings. CDSS should be developed according to the need and requirements of the specific setting. Different settings and practice policies will dictate the type of CDSS required. Physicians' and patients' attitudes toward CDSS may also dictate its potential failure or success within a system. The idea of increasing the clinicians' willingness to use CDSS indicates that even in the presence of CDSS many clinicians may choose not to use it. The reasons for this are unknown. Before introducing CDSS it is important to consider the users' needs, attitude and gaps in their knowledge. Perhaps the gradual introduction of paper-based decision support systems before investing large sums of money in a computerised system would be beneficial. These paper-based systems should be designed by the clinicians

	(users) to enhance their knowledge. Once the first step has been established, implementing an electronic CDSS maybe encouraged and its benefit or lack of benefit evaluated.
Further research	Future RCTs and before after trials should include information regarding the baseline characteristics for the control and intervention group along with the sample size and unit of allocation. Efforts to prevent contamination and to ensure that both the control and intervention groups are treated equally should also be addressed. The authors note a lack of standardised definition for CDSSs, a need to conduct studies in a variety of settings using a variety of methodologies.

REFERENCE	Shekelle PG, Morton SC, Keeler EB. Costs and benefits of health information technology. <i>Evid Rep Technol Assess</i> 2006;(132):1-71.
How does it meet inclusion criteria?	says its a systematic review
CASP Total Score	23.5
Objective/Questions Addressed in the Review	To assess the evidence-base regarding benefits and costs of health information technology (HIT) systems, that is, the value of discrete HIT functions and systems in various healthcare settings, particularly those providing paediatric care.
No of Studies Included in the Review	256
No of Participants Studied in Total	NS
Databases and Years Searched	PubMed, Cochrane Controlled Clinical Trials Register, and Cochrane Database of Reviews of Effectiveness (DARE) published since 1995
Search Strategy	Personal files were contributed by project staff, consultants, and technical expert panel members in response to a request for any applicable unpublished literature on the costs and benefits of HIT. Initially the authors were given the list of titles from another project's November 2003 search of PubMed, which sought systematic reviews published in English from 1995 to 2003. The author's own search for studies of HIT began with an electronic search of PubMed on January 6, 2004 for reports of original research as well as any additional articles about HIT published since 1995. No initial limitations on design or language were imposed. Several other sources of evidence were considered, based on the recommendations of an external group.
Study Designs Eligible for Inclusion	systematic reviews, meta-analyses, studies that tested a hypothesis, and predictive analyses
Practitioner Targeted	all clinical settings but with a focus on paediatrics

Intervention(s) and Comparisons	health information technology (HIT) systems not defined
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	benefits and costs
Range of Observations or Period of Follow Up	NS
Findings or results	<p>A small body of literature supports a role for HIT in improving the quality of podiatric care. Insufficient data were available on the costs or cost-effectiveness of implementing such systems. The ability of Electronic Health Records (EHRs) to improve the quality of care in ambulatory care settings was demonstrated in a small series of studies conducted at four sites (three U.S. medical centres and one in the Netherlands). The studies demonstrated improvements in provider performance when clinical information management and decision support tools were made available within an EHR system, particularly when the EHRs had the capacity to store data with high fidelity, to make those data readily accessible, and to help translate them into context specific information that can empower providers in their work. Despite the heterogeneity in the analytic methods used, all cost-benefit analyses predicted substantial savings from EHR (and healthcare information exchange and interoperability) implementation: The quantifiable benefits are projected to outweigh the investment costs. However, the predicted time needed to break even varied from three to as many as 13 years.</p> <p>Specifically, Pediatrics</p> <ol style="list-style-type: none"> <li>1. Limited empiric evidence exists to support a benefit for HIT use in paediatrics in the areas of medication safety, clinical decision-support, process improvement, and cost reduction.</li> <li>2. Only one scientific study weighed these benefits against the costs or cost-effectiveness of implementing HIT systems in paediatric healthcare settings.</li> <li>3. A majority of HIT systems for use in paediatric practices were tested and/or developed in academic settings, and the ability to generalise these findings to commercially available systems used in non-academic settings is limited.</li> </ol> <p>EHRs and the Quality of Ambulatory Care</p> <ol style="list-style-type: none"> <li>1. A small set of high quality studies shows that implementation of a comprehensive ambulatory EHR improves quality of care. Available evidence focuses primarily on the impact of ambulatory EHRs on decreasing overused health services by enhancing access to data, providing capabilities for real-time analysis of clinical data, and acting as platforms for decision support.</li> </ol>

2. Ambulatory EHRs improve the structure of care delivery, improve clinical processes, and enhance outcomes. Most available evidence shows the effects of ambulatory EHRs on processes of care.
3. Interpreting the precise causal effects of ambulatory EHRs on quality is difficult due to lack of systematic and detailed descriptions of system capabilities, limited data (either qualitative or quantitative) on the workflow re-design and organisational changes that accompanied implementation of an ambulatory EHR (or implementation of a new function in an existing EHR package), use of ad hoc measures to assess quality, and use of study designs that do not explicitly take into account sources of bias and confounding. Thus, while existing evidence may have high internal validity, the generalisability of findings is limited.
4. Although substantial potential exists, evidence for the ability of ambulatory care EHRs to improve quality by making healthcare more consumer- and patient-centred is scant.

#### Economic Value of an HIT and EHR System

1. The main quantifiable benefits of an EHR system were savings from data capture and access; decision support to improve efficiency, quality, and safety of care; business management related to staffing, billing, and overheads; and streamlining patient flow.
2. Few studies quantitatively assessed the costs to implement an EHR system and the financial benefits reaped from it.
3. All the cost-benefit analyses of an EHR system predicted that the financial benefits would significantly outweigh the costs, in a timeframe that varied from three to thirteen years, but this evidence is limited to large organisations and multi-functional EHR systems.
4. The positive economic estimates for EHR system implementation are encouraging but are based on limited evidence at this time. Only limited empirical evidence supports the assumptions made in the predictive analyses. Most studies omitted the costs of implementing an EHR system that were associated with the temporary loss of productivity and the cost of process re-designs. Moreover, realisation of the financial return is highly sensitive to the organisation's financial incentives.
5. There is some evidence regarding the positive economic value of implementing component parts of an EHR system, with models suggesting that many of the benefits do not accrue unless a broadly functional system is implemented.



<p>Conclusions, considerations for implementation, adoption or system design and development.</p>	<p>In general, some organisations have already realised major gains through the implementation of multi-functional, interoperable HIT systems built around an EHR. However, widespread implementation of HIT has been limited by a lack of generalisable knowledge about what types of HIT and implementation methods will improve care and manage costs for specific health organisations. The impact of HIT implementation on cost and quality will not be consistent across institutions, independent of context. The specific context within which HIT is implemented, including the setting, the clinical issues, and the patient populations, greatly influences its use and effects. More widespread implementation of HIT is limited by the lack of generalisable knowledge about what types of HIT and methods for its implementation will result in changes in benefits and costs that are specific for specific health organisations, especially for small practices and small hospitals. With regards to barriers to implementation the authors in summary, reported that studies have identified a large number of barriers to the implementation of HIT. These barriers can be classified as situational barriers (including time and financial concerns), cognitive and or physical barriers (include physical disabilities and insufficient computer skills), liability barriers (including confidentiality concerns), and knowledge and attitudinal barriers. Cutting across all these categories, however, may be the need for clinical medicine as it is now practiced in the majority of settings to undergo a major structural and ideological reorganisation, so it can be integrated with and enjoy the benefits of HIT.</p>
<p>Further research</p>	<p>The reporting of HIT development and implementation requires fuller descriptions of both the intervention and the organisational/economic environment in which it is implemented. High on the list of future research is the need for agreed-upon standards for reporting HIT implementation studies, similar in purpose to the CONSORT standards for the reporting of clinical therapeutics trials.</p> <p>2. The organisational change and workflow re-design required by and accompanying HIT implementation (or implementation of a new HIT function) need to be described and measured with greater validity, reliability, and precision in order to understand the impact of HIT on care delivery. Without such information, the true “intervention” remains unclear, and the generalisability of results will remain limited. This kind of reporting will require the development and dissemination of publishing standards.</p>

3. While HIT implementation does not easily lend itself to randomised trials, better use of quasi-experimental study designs and other study designs of high internal validity could greatly enhance the clinical relevance of results, reduce bias and confounding, and increase the generalisability of findings. Currently, the published literature is dominated by simple pre-post implementation designs.
4. Creative, alternative research methodology should be considered to estimate costs and benefits of HIT as a supplement to traditional hypothesis-testing studies. Traditional experimental or quasi-experimental approaches may be impractical because they are expensive, time-consuming, and interfere with HIT implementation. Qualitative studies are often subjective, descriptive, and lack generalisability. Simulation modelling is a promising alternative to generate knowledge and evidence; it is different from analytical modelling where the result functionally depends on the input (a number of parameters). Simulation, or dynamic, modelling uses a set of rules that define how the system being modelled will change in the future, given its present state, existing knowledge, and foreseeable uncertainties. For complex problems like HIT implementation, where time dynamics is important and experimenting with the real system is expensive or impossible, simulation modelling can support estimates of cost, benefit, and net value of HIT systems. The costs and benefits of HIT depend not only on the internal system (the practice environment) but also on the interactions with the external system, including consumers (patients and potential users of the healthcare system), medical service suppliers (laboratories, radiology centres, other healthcare organisations), technology suppliers, and the regulatory and financing systems an organisation operates. Multi-perspective studies are needed to investigate the flow of costs and benefits in order to maximise the benefits of HIT in the larger healthcare delivery system. Again, simulation modelling may be the best methodology for this type of research.
6. The conceptual foundation for the impact of EHRs on improving care is strong. More research concerning the efficacy and effectiveness of EHRs across healthcare settings, providers, and patient populations needs to be carried out. Such research will require focusing on how EHR tools are implemented and utilised in day-to-day practice, a broadening of environments to include non-academic/non-integrated network practices, the development of methods and instruments directed at evaluation of externally developed systems, and a broader understanding of the human factors issues relevant to healthcare.

7. More research is needed on which specific components of an EHR are beneficial and also on evaluating new specific components—for example, clinical decision-support. Much of the existing decision support relies on simple rules, and it should be possible to provide substantially better assistance with the use of more-complex rules and models.
  8. More research is needed to evaluate the effects of EHRs on improving quality by making care more consumer-centred.
  9. Process and outcome benefits of HIT that are important and unique to paediatrics must be better quantified, given the unique workflow and information needs of paediatric organisations and practice settings. A growing body of epidemiologic studies has demonstrated the frequency of medication errors in the paediatric healthcare setting. Well designed studies are needed to demonstrate empirically the benefit of HIT in improving patient safety, not only in the hospital environment, but also in ambulatory and other settings.
  10. Well designed studies measuring the costs of HIT implementation and resultant benefits in paediatrics and other vulnerable populations (eg chronically ill, disabled, etc.) are needed, especially in non-academic settings and with commercially available HIT systems.
- Recommendations Regarding Public and Private Types of Organisations to Perform the Proposed Research and/or Analysis

The assessment of HIT implementations of greatest relevance to most U.S. healthcare institutions will occur in non-academic settings. Most non-academic settings have limited research expertise or infrastructure to design and support a research project on HIT. If extramural funds are desired for an evaluation of HIT implementation, the ability to secure funding coincident with the project plan is difficult, if not impossible, especially given the funding cycle of grants.

Also, to use a pre-and post-implementation design, the researcher needs funding for an extended period of time to collect enough data to adequately power the study before the HIT system is in place. For financial and pragmatic reasons, this pre-implementation data collection cannot delay the HIT implementation process.

Therefore, the authors would suggest that for HIT research to be feasible in non-academic settings with commercial systems, some important steps should be taken:

	<ol style="list-style-type: none"> <li>1. Create incentives (eg matching funds) for non-academic medical centres and provider organisations to perform high-quality evaluations of vendor-based HIT implementation. These projects should be funded by organisational dollars and support should be provided for academic investigators to partner with such organisations. These measures would help organisations that lack a built-in research infrastructure to conduct rigorous research.</li> <li>2. Provide a number of extramural funding mechanisms (government, state, foundation, or even vendor) to evaluate HIT with limited-funding cycles, allowing for adequate pre-implementation measurements and/or rigorous study design. The investigators typically do not determine the timing of implementation, which is often delayed, and funders must be cognisant of this and not penalise the investigators, by disallowing no-cost extensions.</li> <li>3. Devise a standard means to adequately assess and describe the “socio-technical” milieu of an organisation relevant to HIT implementation.</li> </ol>
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REFERENCE	Shiffman RN, Liaw Y, Brandt CA, Corb GJ. Computer-based guideline implementation systems: a systematic review of functionality and effectiveness. <i>J Am Med Inform Assoc</i> 1999; 6(2):104–114.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	16.5
Objective/Questions Addressed in the Review	To perform a detailed analysis of the functionality delivered by current computer-based implementation systems. In this paper, the authors analyse which information management services have been delivered by recently described guideline implementations. The authors also review the effectiveness of the computer-based interventions in influencing clinicians' behaviour and changing patient outcomes.
No of Studies Included in the Review	25 papers describing 20 discrete systems
No of Participants Studied in Total	NS
Databases and Years Searched	OVID MEDLINE and CINAHL from 1992 through January 1998

Search Strategy	Search terms included the following MeSH headings—algorithm, computer-assisted decision making, computer-assisted therapy, consensus statement, guideline adherence, health planning guidelines, health services research, medical audit, practice guideline, process and outcome evaluation, quality assurance, quality of health care, and reference standard—and the following text words—remind\$, alert\$, guideline\$, implement\$, and computer\$. Books and bibliographies of primary and review articles were also reviewed.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	computers used as part of an implementation strategy for clinical practice guidelines
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	In 14 of the 18 studies that assessed adherence, some level of improved adherence was described. In several reports, adherence improvements occurred for some of the measured outcomes but not for all. Failure to improve adherence using computer-based strategies was reported in four studies. In both studies with negative evaluations of user satisfaction arduous data entry was suggested as a reason for poor system acceptance. Few studies examined patient outcomes to validate the effectiveness of the systems.
Conclusions, considerations for implementation, adoption or system design and development.	Since most general practitioners already use computers for prescribing (Social Surveys 1993) the opportunity exists to make comprehensive support for drug dosage widely available.
Further research	No explicit future research was noted. However, the authors did call for more controlling of confounding factors in evaluations, weak methodology, lack of sufficient detail provided and also noted a lack of studies assessing patient outcomes.

REFERENCE	Sintchenko V, Magrabi F, Tipper S. Are we measuring the right end-points? Variables that affect the impact of computerised decision support on patient outcomes: a systematic review. <i>Med Inform Internet Med</i> 2007; 32(3):225–40.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	18.5
Objective/Questions Addressed in the Review	To study the impact of the type of clinical decisions and decision-support systems as well as the severity of patient presentation on the effectiveness of EDSS use.
No of Studies Included in the Review	24
No of Participants Studied in Total	175 to 18000
Databases and Years Searched	MEDLINE (PubMed) and the Database of Abstracts and Reviews (DARE) from 1 January 1994 to 31 January 2006
Search Strategy	Search terms included were searched with the following combination of medical subject headings (MeSH), text words, and publication types: ('outcome' or 'outcomes') and ('decision support system' or 'situation assessment tool' or 'computerised decision support' or 'expert system') or ('health technology' or 'computer-assisted diagnosis' or 'computer-assisted patient management' or 'electronic prescribing' or 'electronic test ordering' or 'artificial intelligence' or 'mobile computing'). The search was carried out in February 2006 and was limited to English-language publications. The reference lists of the articles selected for inclusion were also reviewed.
Study Designs Eligible for Inclusion	RCTs
Practitioner Targeted	health professionals in clinical practice
Intervention(s) and Comparisons	EDSS, not defined thought comparing patient care using an EDSS to care without one
Setting	clinical setting
Patients Reviewed	NS
Pre-defined outcomes	Level 1 and 2
Range of Observations or Period of Follow Up	3–12 mos

Findings or results	<p>Overall, 13 (54%) of the studies showed a positive result, and 11 (46%) were negative. Of the positive studies, only one showed an improvement in Level 1 clinical outcomes with a majority of studies (50% or 12/24) demonstrating an improvement only in surrogate outcomes and other variables (Level 2 outcomes) as indirect measures of clinical outcomes (<math>P=0.04</math>). Critiquing and consultative systems demonstrated positive impact in 83% and 50% of controlled studies, respectively. Furthermore, only one consultative system which supported drug dosing as a part of provider order entry showed an improvement in patient length of stay (Level 1 outcome) along with a decrease of inappropriate dosing and frequency (Level 2 outcomes). All systems targeting clinical decisions related to acute disease or acute exacerbation of chronic disease improved patient outcomes compared with 38% of systems focused on the management and treatment of chronic conditions (<math>P=0.005</math>). For example, no benefit with respect to the management of asthma, angina, or major depression was observed. Two of five RCT targeting decisions related to diabetes reported significant changes in compliance with practice guidelines. In both studies, the EDSS was a part of integrated care interventions to improve evidence-based management of chronic conditions. In summary more than half of the trials identified in our search showed a clinical benefit, and no study found the use of a decision-support system to be detrimental. Reviewed evidence suggested that the effectiveness of EDSS is dependent on or can be predicted by the severity of patient presentation, type of clinical decisions, and type of decision support. It appears that EDSS were more effective in acute care than when less well structured chronic care decisions were targeted by decision support. Considering the setting of care, all eight (100%) in-patient studies were positive, compared with only five out of 16 (31%) primary care studies. The most common improvement in practice observed was the increase in adherence to clinical guidelines and protocols. The magnitude of the improvement in compliance ranged from 13% to 17% in a majority of successful interventions to a 227% increase in overall compliance with recommended diabetes care procedures in the prompted group of physicians in one study.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>The authors argue that critiquing EDSS have worked better, providing reminders for preventive care or assisting with drug prescribing and that implementation of EDSS in these areas should be a high priority. It is clear that the major factor limiting sustainable impact of EDSS on clinical practice is lack of knowledge of clinicians' information processing, information needs and evidence uptake. The absence of a significant effect on clinical outcomes may reflect problems with the integration of systems within the clinical decision process or the level of</p>



	EDSS adoption rather than unsatisfactory performance of a particular system itself. It would be consistent with current evidence that EDSS use, and acceptance by health-care practitioners remains low.
Further research	The choice of outcome measures depends on the stated goals of a particular study. The choice of not only quantitative measures of outcomes, but also some qualitative measures Computerised decision support on patient outcomes which may result in clinically as well as statistically significant improvements, is warranted. It would be appropriate to investigate the effects EDSS may have on patient outcomes, should these systems be widely introduced in clinical practice. The outcome indicator of choice for EDSS assessment should have the statistical power to detect differences in quality of decision-making. The most important conclusion that can be drawn is that such a complex intervention as clinical EDSS may require new or different metrics of assessment to be able to fully describe the impact of the system under study on clinical decisions and patient outcomes. By measuring the right thing, the authors mean measuring a variable that constitutes a well chosen compromise between finality and responsiveness or sensitivity to changing professional conditions. The main arguments for this are (a) the EDSS interventions are aimed at the health-care practitioner but outcome measures are patient-based; (b) the intervention is indirect, in the sense that in itself it does not influence disease activity; and (c) the effects on outcomes are expected to be relatively small, and so the outcome measures used to date may not be sensitive enough to detect small but clinically relevant changes. Because of the resource-intensive nature and logistical complexity of RCT, there is a call for a broader investigative approach to address the lack of evidence on clinical effectiveness of EDDS and a suggestion to employ interrupted time series when intervention is tested repeatedly both before and after EDSS use as a more practical alternative study design allowing detection of many confounding variables. Further research is needed to quantify the range of benefits of EDSS and explore new measurement metrics to enable detection of clinically significant changes in patient outcomes and to enhance the appropriate clinical use of electronic decision support. Evaluation studies should be explicit about determinants of external validity.

REFERENCE	Smith MY, Depue JD, Rini C. Computerized decision-support systems for chronic pain management in primary care. <i>Pain Med</i> 2007;8(SUPPL 3):S155-S166.
How does it meet inclusion criteria?	says it's a systematic review

CASP Total Score	20
Objective/Questions Addressed in the Review	To address the following questions: (i) To what extent have CDSSs been utilised in the context of chronic pain management? (ii) What are the characteristics of these systems? and (iii) To what degree have they been evaluated and in what types of clinical settings?
No of Studies Included in the Review	9 studies describing 8 CDSSs
No of Participants Studied in Total	
Databases and Years Searched	OVID MEDLINE (1966 to April 2006), CINAHL (1982 to April 2006), PsychINFO (1967 to April 2006), HealthSTAR (1981 to April 2006), EMBASE, Cochrane Library, Computer and Information Systems Abstracts, Electronics and Communications Abstracts, Proust Digital Dissertations, Computer Retrieval of Information on Scientific Projects (CRISP), LISA, ERIC, Computer and Information Systems Abstracts, and Dissertation Abstracts.
Search Strategy	Key search words employed included the following: computer-generated decision support systems and expert systems. Additional terms included: chronic pain, primary care, tailored reports, personalised computer-based information, disease management for chronic pain, patient goals, pain diagnosis and management, decision support systems, neural networks, and fuzzy logic. The authors also conducted a manual search to supplement the automated search. The manual search was not limited in time period and included articles that had been referenced in other articles. English language publications only.
Study Designs Eligible for Inclusion	descriptive and evaluative studies
Practitioner Targeted	clinician and patients
Intervention(s) and Comparisons	CDSS as any electronic system designed to assist in clinical decision-making regarding chronic pain management, and in which patient-specific assessments and recommendations were generated for use by a clinician and/or patient.
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	NS
Range of Observations or Period of Follow Up	NS
Findings or results	Patient and clinician acceptability ratings of CDSSs ranged from moderate to high. Due to insufficient data, definitive conclusions concerning the impact of CDSSs on provider performance and patient outcomes were not possible.

Conclusions, considerations for implementation, adoption or system design and development.	<p>No recommendations were made with regards to implementation rather further research is need. Poor usability and practitioner non-acceptance of computer recommendations can serve as significant barriers to system adoption in routine clinical practice. User preferences regarding the presentation of computer output, including content, formatting (eg colour, graphics), and length, have not been solicited in most instances either. Similarly, there are few published data concerning technical difficulties (eg type and number of system crashes or touch-screen calibration problems) encountered by CDSS users. Both issues have important ramifications for future system refinements. Additionally, there is a paucity of information on contextual circumstances (eg presence of a local “champion” of the system) or the processes used to integrate the CDSS into the existing clinical workflow, key considerations for successful system implementation. Significantly, none of the systems reviewed were integrated with existing electronic records systems, nor did they include reminder or documentation functionalities, features which have all been shown to increase the likelihood of physician adoption. This lack of integration may reflect the fact that widespread adoption of electronic records systems by healthcare institutions has been a relatively recent occurrence. Potentially this trend, coupled with pressures from major accrediting agencies to document the provision of pain screening and treatment, along with the recent publication of primary care pain management guidelines, may serve to spur additional, more rigorous research on the use of CDSSs for chronic pain management in primary care. Demonstrating the clinical value of these systems is a critical step in convincing healthcare organisations and clinicians that the benefits of investing in a CDSS for pain management outweigh potential risks. In particular, physicians need to be assured that this type of system can enhance rather than erode their decision-making abilities, and that time spent learning how to use a CDSS yields measurable improvement in patient health and well being.</p>
Further research	<p>The effects of CDSSs on provider and patient outcomes remain understudied, and their potential to improve doctor–patient collaboration and self-care largely untested. Other major patient outcomes, such as healthcare utilisation, healthcare costs, pain relief, pain medication usage, communication with healthcare provider about pain, functional status, and QOL, have not been examined. The authors note that most studies have been conducted within the inpatient/tertiary care setting. The authors argue for large-scale, randomised controlled trials of sufficiently mature systems and that such trials are imperative for understanding system effect on provider performance and patient outcomes.</p>

REFERENCE	Sullivan F, Mitchell E. Has general practitioner computing made a difference to patient care? A systematic review of published reports. <i>BMJ</i> 1995; 311(7009):848–852.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	18.5
Objective/Questions Addressed in the Review	To review findings from studies of the influence of desktop computers on primary care consultations.
No of Studies Included in the Review	30
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, BIDS (which accesses the science, social science, and arts and humanities citation indexes), and GPlit (the primary care subset of the biomedical database)
Search Strategy	Searches used “computers in medicine,” “primary care,” “family practice,” and “medical informatics” as the search terms. Also reviewed were books’ bibliographies, and conference proceedings of related topics as well as citations in these books and articles and references provided by colleagues.
Study Designs Eligible for Inclusion	prospective studies
Practitioner Targeted	physicians and nurses
Intervention(s) and Comparisons	any computing system designed for use by a doctor, either in routine clinical practice or for a specific research project
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	effects on the consultation process, on doctors’ task performance, and on patient outcomes
Range of Observations or Period of Follow Up	NS
Findings or results	Three studies showed that consultations were 48–54 seconds longer when a computer was used. This difference was mainly due to tasks involving the computer. Doctor initiated and “medical” content of the consultations increased at the expense of a reduction in patient initiated and “social” content. Only one study tried to observe the longer-term impact of introducing a computer to consultations. After 30 months it found that consultations were on average 90 seconds longer—10 minutes as compared with 8 1/2 minutes for controls. Only one study found no change in the content of the consultations and used a subjective measure to detect differences in the “standard of care attained.”

	<p>Studies of the effects of computers on clinician performance were the most numerous and were concerned with preventive care, clinical tasks, screening, and repeat prescribing. Many used a more robust methodology, including patient follow up. The emphasis was on immunisation and other preventive tasks (14 studies) and on prescribing (four), fewer studies being concerned with the management of disease (diabetes, one study; hypertension, one study). Only one study examined the performance of doctors in recording presenting symptoms and in generating problem lists. Most of the improvements were in the positive direction (table III). Immunisation rates improved by 8–18% and other preventive tasks performed improved by up to 50%. The biggest improvements were noted when single rather than repeated measurements were performed.</p> <p>Results were better when studies concerned more deprived patient populations emphasising the potential for opportunistic case finding to reverse the “inverse care law” when supported by an adequate information infrastructure. Consultation-based prompting could work only for attenders. Letters or telephone contacts, usually by a nurse, were more effective strategies for those who rarely visited.</p> <p>Early studies of prescribing confirmed the anticipated time savings for doctors and receptionists, which probably persuaded most practices to buy computers in the first place. Further studies showed that more generic prescribing is encouraged as electronic formularies are adopted, which partly explains the 13–30% reduction in prescribing costs reported.</p> <p>Both studies examining process measures of chronic disease management suggested that improvements are encouraged.</p> <p>Only three studies could be classified as examining patient outcome. One study found an effect while the remaining two studies, which used patient satisfaction as an outcome measure, failed to detect any appreciable change.</p>
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation made. The authors argue that only by clearly documenting the successes, failures, and lessons learnt will computers enable general practitioners “cum technologica caritas.”
Further research	Future research should centre on outcomes of care for patients. The authors highlight a need to look at new methods of evaluating these major changes in “the essential unit of medical practice” such as quasi-experimental and pragmatic trials. The introduction of new aspects of information technology (such as Medline access, Cochrane databases and decision support systems) should also be examined.

REFERENCE	Tan K, Dear PR, Newell SJ. Clinical decision support systems for neonatal care. <i>Cochrane Database Syst Rev</i> 2005;(2):CD004211.
How does it meet inclusion criteria?	Cochrane review
CASP Total Score	23
Objective/Questions Addressed in the Review	To examine whether the use of clinical decision support systems has an effect on <ol style="list-style-type: none"> <li>1. the mortality and morbidity of newborn infants and</li> <li>2. the performance of physicians treating them</li> </ol>
No of Studies Included in the Review	2
No of Participants Studied in Total	NS
Databases and Years Searched	Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 1, 2004), MEDLINE (from 1966 to August 2004), EMBASE (1980–2004), CINAHL (1982 to August 2004) and AMED (1985 to August 2004)
Search Strategy	<p>The authors used a search strategy utilising the following Medical Subject Heading (MESH) terms: \computer assisted decision making", \artificial intelligence", \hospital information systems", \computer-aided diagnosis", \computer-aided therapy" and \algorithms". A search filter for randomised controlled trials was used. Age restriction used was \infants (0–23 months)" . The details of the search strategy used for searching the databases are given below:</p> <p>Search Strategy</p> <ol style="list-style-type: none"> <li>1. randomised controlled trial.pt.</li> <li>2. controlled clinical trial.pt.</li> <li>3. randomised controlled trials.sh.</li> <li>4. random allocation.sh.</li> <li>5. double blind method.sh.</li> <li>6. single blind method.sh.</li> <li>7. or/1–6</li> <li>8. animal.mp. not human.sh. [mp=title, abstract, registry number word, mesh subject heading]</li> <li>9. 7 not 8</li> <li>10. clinical trial.pt.</li> <li>11. exp clinical trials/</li> <li>12. (clin\$ adj25 trial\$).ti,ab.</li> <li>13. [(singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 blind\$].mp. or mask\$.ti,ab. [mp=title, abstract, registry number word, mesh subject heading]</li> <li>14. placebos.sh.</li> <li>15. placebo\$.ti,ab.</li> <li>16. random\$.ti,ab.</li> </ol>

17. research design.sh.
18. or/10-17
19. 18 not 8
20. 19 not 9
21. comparative study.sh.
22. exp evaluation studies/
23. follow up studies.sh.
24. prospective studies.sh.
25. (control\$ or prospectiv\$).mp. or volunteer.ti,ab.  
[mp=title, abstract, registry number word, mesh subject heading]
26. or/21-25
27. 26 not 8
28. 27 not (9 or 20)
29. 9 or 20 or 28
30. exp Decision Making, Computer-Assisted/
31. computer assisted decision making.mp. [mp=title, abstract, registry number word, mesh subject heading]
32. (computer\$ adj3 decision\$).mp. [mp=title, abstract, registry number word, mesh subject heading]
33. (clinic\$ adj3 decision\$ adj3 computer\$).mp. [mp=title, abstract, registry number word, mesh subject heading]
34. 30 or 31 or 32 or 33
35. exp Arti cial Intelligence/
36. arti cial intelligence.mp. [mp=title, abstract, registry number word, mesh subject heading]
37. (arti cial adj2 intelligence).mp. [mp=title, abstract, registry number word, mesh subject heading]
38. 35 or 36 or 37
39. exp Diagnosis, Computer-Assisted/
40. computer assisted diagnosis.mp. [mp=title, abstract, registry number word, mesh subject heading]
41. (computer\$ adj3 diagnos\$).mp. [mp=title, abstract, registry number word, mesh subject heading]
42. exp Therapy, Computer-Assisted/
43. computer assisted therapy.mp. [mp=title, abstract, registry number word, mesh subject heading]
44. (computer\$ adj3 therap\$).mp. [mp=title, abstract, registry number word, mesh subject heading]
45. computer assisted treatment.mp. [mp=title, abstract, registry number word, mesh subject heading]
46. (computer\$ adj3 treat\$).mp. [mp=title, abstract, registry number word, mesh subject heading]
47. 39 or 40 or 41
48. 42 or 43 or 44 or 45 or 46
49. exp Hospital Information Systems/
50. hospital information system\$.mp. [mp=title, abstract, registry number word, mesh subject heading]
51. (hospital\$ adj3 informat\$ adj3 system\$).mp. [mp=title, abstract, registry number word, mesh subject heading]



	<p>52. 49 or 50 or 51</p> <p>53. exp ALGORITHMS/</p> <p>54. algorithm\$.mp. [mp=title, abstract, registry number word, mesh subject heading]</p> <p>55. 53 or 54</p> <p>56. 34 or 38 or 47 or 48 or 52 or 55</p> <p>57. 29 and 56</p> <p>58. limit 57 to (human and all infant )</p> <p>The reference list of selected articles was reviewed. The authors were approached and asked about ongoing trials and unpublished studies. Hand searching of the relevant journals was also undertaken.</p> <p>2. Published abstracts.</p> <p>The authors comprehensively searched the proceedings of international meetings to identify relevant published abstracts from Proceedings of the Annual American Medical Informatics Symposium, MEDINFO and IEEE in Biomedical Engineering.</p> <p>3. Database of the Cochrane Central Register of Controlled Trials (CENTRAL) The authors searched the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library) Disk Issue 1, 2004 with the above strategy.</p> <p>4. Databases of the Neonatal Cochrane Review Group (CRG) of the Cochrane Collaboration. The authors searched the Neonatal CRG database with the strategy as described above.</p> <p>5. Databases of the Effective Practice and Organisation of Care (EPOC) Review Group of the Cochrane Collaboration. The authors searched the EPOC database with the strategy as described above.</p> <p>6. Internet-based resources Internet-based resources were looked at by consulting the web site (<a href="http://www.neonatology.org">www.neonatology.org</a>) and a search for the relevant web pages was done using search engines.</p>
Study Designs Eligible for Inclusion	The authors included studies that have the randomised controlled trial design. The authors also included trials with a quasi-randomised design. The authors included studies that have used either patient, staff (medical and nursing) or hospital/unit as the unit of randomisation.
Practitioner Targeted	NS
Intervention(s) and Comparisons	<p>CDSS for clinical decision support in neonatal care. Also included studies comparing different types of CDSS.</p> <p>Specifically included studies describing CDSS for:</p> <ol style="list-style-type: none"> <li>1. computerised physician order entry (CPOE)</li> <li>2. computerised physiological monitoring</li> <li>3. diagnostic systems</li> <li>4. prognostic systems.</li> </ol>

Setting	NS
Patients Reviewed	neonates
Pre-defined outcomes	<p>Primary outcome measures:</p> <ul style="list-style-type: none"> <li>i. mortality within the first 28 days of life</li> <li>ii. mortality within the first year of life</li> <li>iii. effects (eg improvement, or otherwise, in diagnostic accuracy, time-saving, more efficient use of resources) on physician or nursing staff performance</li> </ul> <p>Secondary outcome measures:</p> <ul style="list-style-type: none"> <li>i. staff 's non-satisfaction or non-compliance</li> <li>ii. costs (cost of introducing the system, cost reduction in patient care)</li> </ul> <p>Outcome measures specific to the type of CDSS:</p> <ul style="list-style-type: none"> <li>1. CPOE systems—incidence of adverse drug events</li> <li>2. computerised physiological monitoring—short-term physiological parameters (eg arterial blood gases, blood pressure) within the follow up period</li> <li>3. diagnostic systems—accuracy (level of agreement with physicians) and reliability</li> <li>4. prognostic systems—accuracy (level of agreement with physicians) and reliability</li> </ul>
Range of Observations or Period of Follow Up	NS
Findings or results	There are insufficient data from randomised trials to determine the benefits or harms of CDSS in neonatal care.
Conclusions, considerations for implementation, adoption or system design and development.	NS
Further research	Before CDSS are introduced the effects of the technology should be systematically studied using the randomised controlled study design (with either cluster randomisation or randomisation at the individual patient level).

<b>REFERENCE</b>	Thiru K, Hassey A, Sullivan F. Systematic review of scope and quality of electronic patient record data in primary care. <i>BMJ</i> 2003;326(7398):1070
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	19.5
Objective/Questions Addressed in the Review	To describe system and organisational factors that affect quality of the data in EPR in primary care.
No of Studies Included in the Review	52

No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, EMBASE, CINAHL, PsycINFO, Science Citation Index Expanded, Social Sciences Citation Index, Cochrane database, DARE, NHS National research register, Nursing Collection, Web of Science, Conferences Proceedings 2000–1 (American Medical Informatics Association, Primary Health Care Specialist Group of the British Computer Society)
Search Strategy	Bibliographic search 1990–2001 and citations searches 1980–2001. Electronic patient records* MEDICAL RECORD, INFORMATION SYSTEMS Computerised data, database, electronic patient record “Quality” Quality, validity, accuracy, reliability, sensitivity, specificity, positive predictive value, consistency, completeness Primary care GENERAL PRACTICE, FAMILY PRACTICE, PRIMARY CARE, Publications restricted to English. Contacts as follows: DIEP Database (database of informatics in primary care (Tayside centre for general practice)), SCHIN (Sowerby Centre for Health Informatics at Newcastle), CHIMR (Centre for Health Information Management Research), PRIMIS (Primary Care Information Services), Three dissertations on quality of primary care data (details available from authors)
Study Designs Eligible for Inclusion	No editorials, letters, poster presentations or coding studies
Practitioner Targeted	NS
Intervention(s) and Comparisons	EPR not health maintenance organisational (HMO) systems, administration systems, stand alone registers and pharmacy databases
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	data quality measured or scoped
Range of Observations or Period of Follow Up	NS
Findings or results	The authors identified 15 studies that used EPR data for research or practice management. Although the intention of these studies was not to measure data quality, they gave insight into issues of data validation. These studies relied more on measures of positive predictive value than on measures of sensitivity (table 1) to meet their needs. Fourteen studies considered the diagnostic status of the patient, with 10 publications dealing primarily with information on patient identification and case validation. Three used survey techniques to establish diagnostic status. Of the 12 retrospective investigations, seven used centralised datasets.

These “scoping” studies were more than twice as likely to present confidence intervals than studies that measured data quality (10/15 (67%) 11/37 (30%)). Prescribing data are generally the most sensitive. The ability to link prescriptions with diagnosis was the favoured means of identifying patients and establishing the predictive validity of diagnostic codes. The sensitivity of other EPR elements was wide ranging, while positive predictive value was consistently high. Those diseases with clear diagnostic criteria were generally better recorded, as were data on specific procedures. Lifestyle and socioeconomic data were rarely studied and then only in terms of sensitivity. Results indicated lower recording levels than for diagnosis and medication. Eight studies were prospective, in which a network of practices was established from which to extract data. Although these studies were prospective, the data extraction was primarily cross sectional. The remaining articles were cross sectional or retrospective surveys. Two studies were interventional: one a case-control study involving onsite training and the other a before and after software update study. Both showed substantial improvements in recording levels after the intervention. A retrospective cohort study of data conscious practices that took advantage of generic national services also showed an increase in completeness and accuracy of EPRs over five years. Structured data (codes, classifications, and nomenclatures) were most commonly investigated. Although textual data were mentioned, they rarely received detailed attention. Only one study considered textual data in any detail. Twelve documents did not present their data structure (that is, coding system name) while most did not present the precise codes being investigated. UK publications generally used Read and OXMIS (Oxford medical information systems) codes. In other countries the ICPC (international classification of primary care) codes were more widely used. ICD (international classification of diseases) codes act as a referencing standard for these primary care coding systems. When there were deficits in descriptive ability of a coding strategy, subsidiary codes (for example, chapter headings from British National Formulary; Prescription Pricing Authority) were used to enhance the data.

Quality of data (reliability) was usually measured with rate comparisons. Data validity was expressed under a range of terms (completeness, correctness, accuracy, consistency, and appropriateness), which were rarely defined. Sensitivity (completeness) was the commonest such index. One study used video recording of the consultation to evaluate the EPR content compared with the use of notes and UK national statistics (fourth national study of morbidity in general practice, MSGP4) for comparative measures. Seven studies

	<p>carried out questionnaire and telephone surveying for a reference standard with data gathered from the patient, carer, or both. These studies involved the sampling of a study population from the database for subsequent validation through questionnaires. The reference standard varied from “life time experience of morbidity” to more structured investigation of diagnostic status through validated questionnaires. Triangulation with multiple sources (prescription data, clinician diagnosis in EPR, or notes) was used for further validation.</p> <p>Twenty four studies used clinical information gathered during the consultation as a reference standard. Seventeen publications used triangulation within the EPR to test internal consistency of data. Fifteen studies were conducted after 1994. Twelve relied on medication data as the internal reference standard. Sixteen used paper-based information as the reference standards. Often EPR diagnostic status was appraised through electronic prescribing information and subsequently validated against the paper notes. Hospital discharge details have also been used to evaluate EPR diagnostic status through practitioner responses, discharge summaries, and consultants’ letters. Time of diagnosis and referral data were also evaluated under this reference standard. Dissonance between data from secondary and primary care has been documented, though the presence of hospital diagnosis and procedural data have been found to improve the quality of data in primary care. Eighteen studies used national statistics or survey data as a reference standard for data reliability. A third of UK studies used MSGP4 as a reference standard for rate comparisons.</p>
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementing data accuracy improvement strategies made. Although the authors note that the accuracy reported in studies is biased towards better performing sites, they point to the importance of UK databases such as GPRD as suggestive of the importance of data quality in the UK.
Further research	<p>The element of the EPR being investigated (numerator) and the components of the reference standard used to appraise its quality (denominator) were often not clearly defined within the literature (for instance, diagnostic code/diagnostic criteria). When they were defined there was inconsistency between studies. This makes comparisons risky and meta-analytical interpretation of results impossible. It may be a reflection of the immaturity of the discipline that more standardised approaches have not yet evolved.</p> <p>Measurement theory requires that both the concepts of validity and reliability be addressed. Reliability (a precursor to validity) is a measure of stability and is appraised through the</p>

	<p>subjective comparison of rates and prevalence. Many studies used old statistics (for example, MSGP4) or variations between practices to make judgments on the reliability of “live” data. Such methods cannot measure validity of the EPR in reflecting the “truth.” Sensitivity and positive predictive value, the most widespread measures of data validity, presuppose that the selected denominator is an adequate representation of this truth. Surveys and questionnaires can be of dubious accuracy. Reference standards that emanate from the patient and carers present different but important perspectives on morbidity or concordance with treatment. What is the real health status of the patient? The answer exists in subjective (perceived), objective, and diagnostic dimensions. Each needs to be measured by different techniques and its appropriateness for EPR validation considered. To aid interpretation of the resulting proportions and to facilitate comparisons between populations confidence intervals should be provided. In the longer-term the authors recommend the establishment of internal reference standards based on those objective and diagnostic EPR elements recognised as having high positive predictive value (that is, diagnostic codes, prescriptions, test results, referral outcomes, procedural codes). Such reference standards can then be used to explore measures of sensitivity.</p>
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REFERENCE	Tomasi E, Facchini LA, Maia MF. Health information technology in primary health care in developing countries: a literature review. <i>Bull World Health Organ</i> 2004; 82(11):867–74.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	17.5
Objective/Questions Addressed in the Review	To explore the debate and initiatives concerning the use of IT in primary healthcare in developing countries.
No of Studies Included in the Review	52
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE, Latin American and Caribbean Health Science Literature Database (LILACS), Cochrane Library and Web of Science, EMBASE (demonstration version) and the web site www.hi-europe.info from 1992–2002
Search Strategy	Publications were identified by an initial generic search using words from any database field (ie words from titles, keywords and abstracts) after which all keywords yielding relevant publications were listed. Some of the search terms used were: <ul style="list-style-type: none"> <li>• database management systems AND primary health care;</li> </ul>

	<ul style="list-style-type: none"> <li>• health information AND primary health care;</li> <li>• IT AND primary health care;</li> <li>• information systems AND primary health care;</li> <li>• software AND primary health care; and</li> <li>• software AND ambulatory care information systems.</li> </ul>
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	NS
Intervention(s) and Comparisons	computerised systems
Setting	primary care
Patients Reviewed	NS
Pre-defined outcomes	benefits, barriers to implementation and improvement requisites
Range of Observations or Period of Follow Up	NS
Findings or results	<p>When compared to manual registration, the main advantages of electronic patient registries (EPR) are greater accuracy and a higher proportion of correct information; time saved in locating information; more economical use of financial resources; and greater ease and speed of recovery of patient data. Several articles reported on the limitations of such technologies, highlighting the resistance and difficulties of using EPR among health-care professionals, especially physicians. Emphasis was also placed on aspects related to confidentiality of information and respect for privacy, the need for continuing training and support for human resources, and the lack of automatic standardisation and codification of the data entered. Most authors agreed on the need for a gradual replacement of paper-based registries with electronic ones, as well as on the need for user-friendly interfaces, and for at least minimal training programmes. The first group of process and programmatic action evaluation and management (PPAEM) systems identified were those concerning patient referral and “counter-referral activities” (ie the return of the patient to his or her physician after specialist consultation) both between different levels of care (eg to specialists or hospitals) and, for example, for the electronic return of the results of laboratory examinations. Their main advantages are reliability, speed and the optimisation of available resources. The second group of applications were those designed for the monitoring of patients linked to specific health programmes, such as immunisation at mother and child clinics, antenatal care and diabetes programmes. This monitoring was mainly carried out by means of “notices” generated when patients missed scheduled appointments, and the issuing of pre-</p>



appointment reminders. The advantages reported included reductions in registration errors, identification of absentees, integration of prevention and control activities, and detection of risk factors and complications. A third set of publications was concerned with the analysis and extraction of selected information from electronic patient registries, allowing the identification of risk factors and groups of at-risk patients and the obtainment of care-quality indicators and their comparison between different health units. The authors agreed that such systems could assist with evaluations of morbidity and patterns of drug prescription, allow managers to monitor compliance with conduct and norms regulated between different levels of care, and optimise the prevention and early detection of risk factors. One limitation is the lack of studies evaluating the impact of the use of these systems on quality of care. Another drawback is the lack of standardisation among the different systems which reduces the usefulness of automatically generated indicators. When data entry is retrospective, there is a tendency to transfer the deficiencies of a manual registry to the computerised registry. It is often necessary to develop additional system tools, such as, for example, codification of the reasons for appointments. This category of products includes mainly those that function as computerised protocols for patient management, both for diagnosis and treatment, including electronic prescription and requests for laboratory tests. These may be rule-based systems, cognitive and simulation (Bayesian) systems, or tree-decision systems that could include active patient participation. Problems such as hypertension and cardiopathies in general, asthma, and depression are among the most cited examples of clinical decision-support (CDS) systems. Such health problems, together with prevention programmes, constitute the main reasons for utilisation of primary healthcare, making the adoption of standardised protocols that can be optimised with the support of IT easier. Positive experiences have been reported to result from implementation of these systems, including increases in physician adherence to standardised therapeutic plans, cost reduction, and easier standardisation and regulation of requests for secondary and tertiary healthcare and for examinations, thus reducing variability between services. From an administrative point of view, it is possible to obtain greater adhesion to public policies. Standardised programmes for the early detection of diseases would tend to have greater diagnostic value thus contributing towards the promotion of equity, and the reduction of complications and costs related to more complex treatments. As with the other technologies reviewed, the limitations were related to the low adhesion rates among health-care professionals, the great variety of

	systems available which hindered evaluation of their validity and reproducibility, and difficulties in standardisation and integration with other applications.
Conclusions, considerations for implementation, adoption or system design and development.	<p>With regard to EPR the main lessons are related to system security, especially the maintenance of privacy and confidentiality. The interconnection between different systems and software is another relevant issue. It would be imperative to adopt standards for vocabulary, contents, images, objects and communication tasks. The finding of a low level of adhesion among physicians to protocols for computerisation in primary healthcare is almost ubiquitous. Although the reasons have yet to be explained, it is possible that the autonomy regarding clinical decisions—a paradigm of traditional medical practice —must be made to coexist with regulated and more cooperative activities, although this will be no easy task. Furthermore, a substantial number of the articles reviewed stressed the need for continued motivation and training for all team members as an important requisite for the success of any initiative in this area. This lesson would be very relevant to the establishment of IT in primary healthcare systems. It may be pertinent here to quote the reflections by Branco on the significance of training, that is, the amplification of knowledge: "... knowledge of the logic behind health information production and flux must be provided to all persons involved, and should include the understanding of the goals of the systems to which they have access, and of the utilisation possibilities of the information produced ...". In the consideration of CDS systems in particular, emphasis has been placed on quality and safety concerns. The main drawbacks of such systems include the lack of consensual standardisation for a number of conditions, the probably negative effect on the physician–patient relationship (for example, the perception that computers take over the physician's role), the difficulty in addressing complex conditions, the profusion of different systems with different formats, and the need for training and support.</p>
Further research	<p>Another consensual aspect was the difficulty of finding adequate methods for evaluation, given the enormous variety of applications and contexts in which IT is used. The results of specific evaluations lack external validation, because health services are extremely variable in terms of population seen, team composition, qualifications, motivation and extent of computerisation. This hampers comparability and generalisability. In addition, the complexity of clinical and organisational management processes is often underestimated.</p>

REFERENCE	van der Meijden MJ, Tange HJ, Troost J, Hasman A. Determinants of success of inpatient clinical information systems: a literature review. <i>J Am Med Inform Assoc</i> 2003;10(3):235–243.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	19
Objective/Questions Addressed in the Review	To analyse evaluation studies of inpatient patient care information systems requiring data entry and data retrieval by healthcare professionals, published between 1991 and May 2001, to determine the attributes that were used to assess the success of these systems and to categorise these attributes according to the Delone and McLean framework. The authors also examined how the attributes were measured and what methodologies were used in the evaluation studies.
No of Studies Included in the Review	33 articles describing 29 different information systems
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE and EMBASE (1991 to May 2001) and Current Contents (1998 to May 2001) 1999 and 2000 Annual AMIA Symposium proceedings and the 1995 and 1998 Medinfo conference proceedings
Search Strategy	Medline was searched using the following Medical Subject Headings: evaluation studies, medical record systems—computerised, and nursing records. Additionally, MEDLINE, EMBASE and Current Contents were searched with the following text words and phrases: medical record*, nursing record*, evaluat*, technology assessment, electronic, and computer* in all possible combinations. Exclusion criteria were guidlin* and decision support. MEDLINE, EMBASE were searched for references in English or Dutch. The bibliographies of selected articles were not searched for additional relevant literature.
Study Designs Eligible for Inclusion	objectivist and subjectivist
Practitioner Targeted	NS
Intervention(s) and Comparisons	patient care information system defined as a clinical information system in use in inpatient settings, requiring data entry and data retrieval by healthcare professionals themselves
Setting	inpatient
Patients Reviewed	NS
Pre-defined outcomes	NS

Range of Observations or Period of Follow Up	NS
Findings or results	<p><b>System Quality</b></p> <p>Several authors reported a decrease in time spent on documentation in comparison with paper. In three studies users complained about the (complicated) methods to enter patient data electronically. Two authors who conducted open-ended interviews, found that rigidity and factors intrinsic to the system created extra work and accounted for the inconvenience.</p> <p><b>Information Quality</b></p> <p>All relevant studies found an increased completeness of record content. In the perception of users, availability and timeliness of information were positive aspects. For bedside nursing documentation systems, an improvement in timeliness of certain types of information was observed. Order entry systems increased the availability of information about orders and improved timeliness by reducing the time between sending the order and having the results available or the orders executed.</p> <p><b>Usage</b></p> <p>Ambiguous results were reported for frequency of use. In three studies of bedside nursing documentation systems chart reviews showed a significant increase in number of entries and frequency of use. In contrast, two other nursing documentation system studies and one order entry system study identified no significant change in frequency of use.</p> <p><b>User Satisfaction</b></p> <p>Overall user satisfaction was rather high in all but one study. Overall satisfaction was correlated most strongly with ease of use, productivity or impact on patient care in the case of one order entry system. Systems that were withdrawn were done so predominantly because of user resistance.</p> <p><b>Individual Impact</b></p> <p>In contrast to this voluntary change in documentation habits, in four studies the system was reported to force users to change their work practices. This led to problems with the acceptance of the systems. Only one of these systems survived, after adaptations. Two studies showed that those who perceived a higher workload judged a shift in responsibilities negatively.</p>

	<p><b>Organisational Impact</b></p> <p>An improvement in the communication between professionals or departments was reported in two studies. Users perceived that information systems reduced the number of phone calls to request tests/examinations and their results. In two studies, time saved from documenting increased time spent on patient care. Furthermore, rapid availability of test results was perceived to have a positive impact as well. Other POEs were shown to improve correct documentation of orders. A third aspect of organisational impact related to costs. One study observed considerable time-savings due to more efficient work routines; others reported a reduction in the number of redundant tests.</p> <p>Two systems were withdrawn, and the failure was partly explained by the choices made during development regarding technology, extent of user involvement, intended re-design of work practices, and re-design of the record format. In these studies data were collected with interviews and questionnaires</p> <p>Also in other studies, required alterations in established work practices provoked resistance or led to an increase in time spent on documentation.</p> <p><b>Implementation Process</b></p> <p>Insufficient two-way communication— for example, about the progress of the implementation or the expected benefits of the system—had a negative influence on the adoption of information systems.</p> <p><b>Organisational Culture and Characteristics</b></p> <p>Visible management support is essential, as are the lines of authority. In two studies, the persons responsible for implementing the information system did not have decision-making authority. This disconnection between the organisational structure and information system implementation strategy complicated the implementation significantly.</p>
Conclusions, considerations for implementation, adoption or system design and development.	No recommendations for implementation or adoption made on methodological considerations for future research.
Further research	Our review showed that evaluations assessing several attributes of different factors were more informative. Formative evaluations—aiming at improving the information systems during development or implementation—were hard to find in the reviewed literature. Most evaluations concerned systems in use and were summative evaluations. A thorough evaluation should include all appropriate success factors, but

	the moment to measure each varies from factor to factor. An evaluation should start before the development and should have no fixed end. One could think of a kind of post-marketing surveillance as is usual in medication registration procedures. The integration of qualitative (observations, interviews) and quantitative (questionnaires, work sampling) data collection methods provides an opportunity to improve the quality of the results through triangulation. In evaluations of information systems that employ multiple methods the data from different sources complement each other to provide a more complete picture.
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REFERENCE	van der Sijs H, Aarts J, Vulto A, Berg M. Overriding of drug safety alerts in computerized physician order entry. <i>J Am Med Inform Assoc</i> 2006;13(2):138–147.
How does it meet inclusion criteria?	systematic search strategy, application of inclusion/exclusion criteria
CASP Total Score	17.5
Objective/Questions Addressed in the Review	To provide insight into physicians' handling of safety alerts by asking the following questions: How often and in what situations are safety alerts overridden? Why do physicians override them? What effects ensue? What understanding of alert overrides can lead to improved alerting systems?
No of Studies Included in the Review	17 for the first part and 193 in the second
No of Participants Studied in Total	NS
Databases and Years Searched	MEDLINE and EMBASE databases from January 1980 to December 2004
Search Strategy	English-language publications were found with the following MeSH headings and text words: computerized physician (medication) order entry, CPOE, electronic prescribing, computerized prescribing, medical record systems computerized and alert *, remind *, prompt *, order check, critic*, critiq*, decision support systems clinical, reminder systems, drug therapy computer assisted and overrid*, medical error, adverse drug events, and attitude. The authors also checked literature references of three recent systematic reviews and one synthesis of review paper. Full articles were included, but also proceedings when pertinent. The references of these publications were checked also. The refined selection was used for the first part of this review. To learn how alerting could be improved, the authors examined all publications from the search for characteristics of unsolicited safety alerts as well as measures to minimise error-producing conditions.

Study Designs Eligible for Inclusion	NS
Practitioner Targeted	physicians and other clinicians
Intervention(s) and Comparisons	CPOE not defined but the authors note that systems frequently include integrated decision support components
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	overriding of unsolicited drug safety alerts that appear during the prescription process
Range of Observations or Period of Follow Up	NS
Findings or results	Eight studies showed 49% to 96% alert overrides, except for high-level overdose alerts, which are overridden in 27%. Standardisation of alert levels is largely absent, making comparison of override rates difficult.
Conclusions, considerations for implementation, adoption or system design and development.	It should be emphasised that only unjustified overriding is problematic from a safety perspective. The authors advise entry of overriding decisions to gain deeper insight into (justified) overriding. Alerting systems may contain error-producing conditions and customising is necessary, regardless of the use of a commercially available or a manually constructed database. Specificity or sensitivity should be increased as the result of consensus meetings between physicians and pharmacists. This customisation process may be time-consuming and difficult because increasing sensitivity increases the total number of alerts and probably the percentage of inappropriate alerts, which decreases specificity. Required entry of reasons for overriding to prevent unintended overriding may result in an unacceptable time burden for physicians but gives useful information for system improvement. Disallowance of order entry (hard stops) is unacceptable in the opinion of the authors because decision support cannot replace the physicians' responsibility for the treatment of the patient. It is questionable whether entering a simple password will prevent unintended overriding. Many physicians complain about the poor signal-to-noise ratio and admit alert overriding because the alerts are not serious or are irrelevant. In studies on overriding, chart review did not reveal any adverse drug event in more than 97% of cases. Furthermore, in daily practice, adverse drug events often occur when the patient has moved to another point in the care chain, no longer within control of the physician(s) responsible for the event. Physicians believe that too many irrelevant alerts are presented and ask that alerts "they already know" be turned off. However, if specificity is high and alerts are only presented in potentially unsafe situations, specialists who already know them are



	<p>not bothered by them. Furthermore, forgetfulness and oversight instead of a knowledge deficit are often the cause of generation of alerts and these problems can emerge in specialists as well as in residents. A testable hypothesis is whether specialists receive fewer alerts on their specialty than residents. Presenting correct alternative actions is very difficult because they should include the right alternative drug, dose, and frequency for the patient's particular situation. The authors therefore propose to present concise information that can help physicians make a correct decision but to prevent selection of an alternative action with one click because indications may deviate from the indications on which the advice is based. Decision support may result in physicians fully relying on the system and feeling safe if alerts are absent. Sensitivity problems can be divided between the absence of alerts within a particular alert feature and lacking alert features. Today, decision support on genetic profiles influencing drug-drug interaction effects is often lacking and physicians will not expect alerts of this type. If some type of alerting is present, physicians will have trust in complete decision support of that type, and increasing sensitivity as well as manually checking defensive gaps in the alerting system should achieve this. These gaps may change over time because of local customisation and should result in a change in the pharmacy check to ensure patient safety. Which factors influence this pharmacy check are not clear.</p>
Further research	<p>It is still not clear whether interactions on administration time, the level of seriousness, and the alternative action should be shown to the prescribing physician. The following hypotheses could be tested. Directing alerts on administration time to nurses or pharmacy technicians reduces the number of administration errors. Presentation of different levels of seriousness increases the override rate compared to one level of seriousness. Presentation of an alternative increases the number of unjustified cancellations or changes of order. Before testing these hypotheses, it would be useful to gain insight in the cognitive processes playing a role when physicians are confronted with different types of alerts. None of the studies addressed this aspect of alert overriding. Rasmussen describes three levels of human performance (skill-, rule-, and knowledge-based behaviour) and three corresponding ways in which information is perceived, depending on intentions and expectations of the receiver. It is not clear which level of human performance is used in interpretation and handling of drug safety alerts and which factors determine this performance level. Understanding reasons for and causes of overriding in particular cases is necessary for development of effective alerting systems that are acceptable to users.</p>

REFERENCE	Walton RT, Harvey E, Dovey S, Freemantle N. Computerized advice on drug dosage to improve prescribing practice. <i>Cochrane Database Syst Rev</i> 2001;(1):CD002894.
How does it meet inclusion criteria?	Cochrane review
CASP Total Score	23
Objective/Questions Addressed in the Review	To determine: 1. Whether there is clear evidence that computerised advice on drug dosage is beneficial and hence whether such advice should be more widely available. 2. What further research is required to assess the value of such advice in settings where it might be of use.
No of Studies Included in the Review	15
No of Participants Studied in Total	NS
Databases and Years Searched	Cochrane Effective Practice and Organisation of Care Group (EPOC) specialised register, MEDLINE (1966 to June 1996), EMBASE (1980 to June 1996)
Search Strategy	Search terms were (\Computer Systems"[MESH] OR \Artificial Intelligence"[MESH]) AND (prescr* OR \drug therapy"[MESH] AND (\Comparative Study"[MESH] OR \Clinical Trials"[MESH]). The authors also hand searched the journal Therapeutic Drug Monitoring (1979 to June 1996), reference lists from primary articles, and made contact with experts. The authors searched without language restrictions.
Study Designs Eligible for Inclusion	RCTs; Interrupted time series analyses; Non-equivalent group studies with pre and post measures (controlled before and after studies).
Practitioner Targeted	Any health professional (for example doctors, nurses or pharmacists) with responsibility for patient care.
Intervention(s) and Comparisons	Computer advice on drug dosage; The computer systems that gave the advice usually required a health professional to type in data for example about the patient's age, weight and previous drug levels. The program then calculated the most appropriate drug dose often using individualised mathematical models of the distribution of the drug in the patient's body. The drug was usually administered by a nurse in tablet form, however the authors included studies where the computer directly administered the drug to the patient for example as an infusion. Studies where the computer-controlled infusion was not under the control of a clinician were excluded.
Setting	NS
Patients Reviewed	NS

Pre-defined outcomes	<ol style="list-style-type: none"> <li>1. Proportion of patients where the therapeutic regimen is changed due to computer advice.</li> <li>2. Proportion of patients with unwanted effects of drug therapy.</li> <li>3. Proportion of patients with plasma drug concentrations or physiological parameter within therapeutic range at standard time intervals after starting treatment.</li> <li>4. Differences in drug levels or values for physiological parameters across study groups</li> <li>5. Time to achieve therapeutic control.</li> <li>6. Proportion of patients with improved outcome from computer advice, such as reduced incidence of bleeding on warfarin.</li> </ol>
Range of Observations or Period of Follow Up	NS
Findings or results	<p>Comparison 1. Giving the health professional computer advice, or allowing the computer to administer the drug directly, leads to a change in drug dosage. Studies reporting changes in dose were separated into three groups: initial dose, maintenance dose, and total amount of drug used. Four studies provided outcomes for the analysis on initial dose. Initial doses tended to be higher with computer support. Eight studies provided data on maintenance dose. Overall, the pooled effect showed a tendency for doses to be higher in the computer groups, but this did not reach statistical significance. Two trials reported a change in total dose used; combined they showed a significant increase with computer support although this result is based on data from only 44 patients.</p> <p>Comparison 2. Decisions on drug dosage based on computer advice lead more often to drug levels within the therapeutic range. Six studies measured changes in therapeutic drug levels with computer support. Generally, the proportion of patients with drug levels in the therapeutic range were higher in the computer groups, but this failed to reach significance.</p> <p>Comparison 3. Decisions on drug dosage based on computer advice lead more often to a physiological parameter being maintained within the desired range (for example, blood pressure or prothrombin time). Five trials yielded outcomes for this comparison. The trials and their outcomes were clinically heterogeneous so pooling of effect sizes was not attempted.</p> <p>Comparison 4. Decisions on drug dosage based on computer advice lead to more rapid control of a physiological parameter. Two trials were included in this comparison. The statistical heterogeneity between the trials was low, and when combined they showed a significant benefit, indicating more rapid control with computer support.</p>

	<p>Comparison 5. Decisions on drug dosage based on computer advice lead to fewer unwanted effects than conventional dose adjustment. Four studies that evaluated the impact of computer advice on toxic drug levels were included in this comparison. Combined they showed a significant effect in favour of the computer group. Six studies assessed the effect of computer support on adverse reactions. Once again, the results favoured the computer group.</p> <p>Comparison 6. Computer advice given in real time is more effective than that given by delayed feedback. No outcomes were available for this comparison.</p> <p>Comparison 7. Patient-based outcomes of drug therapy were improved by dose adjustment using computer advice. Patient-based outcomes, excluding unwanted effects, were relatively few. Five studies reported the length of time spent in hospital and overall they showed a significant reduction in hospital stay.</p> <p>Additional comparison</p> <p>The authors also examined the hypothesis that computer advice on drug dosage reduced the cost of healthcare. Both studies on computer support for aminoglycoside dosage reported economic data although neither conducted a full cost minimisation analysis.</p> <p>Although doses with computer support tended to be higher than those used by unaided doctors, toxic drug levels and adverse effects were significantly reduced. Taking all the studies together, the reduction in the risk of experiencing a toxic drug level when patients were treated with computer support was 0.12 which means that eight patients would have to be treated with computer support to prevent one having a toxic level. Adverse reactions to drugs are seen less commonly than toxic serum levels but the risk of unwanted clinical effects was reduced by 0.06 meaning that one unwanted effect would be prevented for every 18 patients treated with computer support.</p>
Conclusions, considerations for implementation, adoption or system design and development.	<p>Since most general practitioners already use computers for prescribing (Social Surveys 1993) the opportunity exists to make comprehensive support for drug dosage widely available. Most studies did not identify potential barriers to change. Of those that did, the commonest suggested barrier was clinical uncertainty about the best course of action (Ruiz 1993; Burton 1991; Mungall 1994; White 1987).</p>

Further research	<p>Future evaluations will need to be more rigorously conducted, building on the experience gained from earlier work. Further studies are necessary to examine the effects of computer support in more general use and to develop appropriate systems. Future trials should be pragmatic in design, analysed by intention to treat, include economic evaluation and include adverse reactions as an outcome. More studies should assess costs.</p> <p>Implications for research</p> <ol style="list-style-type: none"> <li>1. any studies so far have been too small to demonstrate clinically significant effects and most do not record sample size calculations.</li> </ol> <p>Adequate power is essential.</p> <ol style="list-style-type: none"> <li>2. The studies that the authors identified usually randomised patients to treatment or control groups. This means that the same physician may be treating the intervention and the control groups and hence there is a high likelihood of contamination. Study designs should be carefully chosen to avoid this effect.</li> <li>3. To realise the full benefits of computer support for drug dosage, more studies should be conducted in primary care, where most prescribing takes place. Systems developed for secondary care will need modification and testing in the new setting.</li> <li>4. Future studies should evaluate <ol style="list-style-type: none"> <li>a. patient-based outcomes (unless there is definite evidence that control of dosage improves outcome)</li> <li>b. adverse effects of computer support (such as numbers of patients with toxic drug levels)</li> <li>c. economic effects of computer interventions</li> <li>d. potential barriers to implementation of systems.</li> </ol> </li> </ol>
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REFERENCE	Wu RC, Straus SE. Evidence for handheld electronic medical records in improving care: a systematic review. <i>BMC Med Inform Decis Mak</i> 2006;6:26.
How does it meet inclusion criteria?	systematic review in title
CASP Total Score	19
Objective/Questions Addressed in the Review	To assess the evidence for mobile or handheld electronic medical records (EMRs) in improving patient care.
No of Studies Included in the Review	2
No of Participants Studied in Total	9 practitioners and 152 patients
Databases and Years Searched	MEDLINE, CINAHL, EMBASE, and the Cochrane Library from 1966 to September 2005

Search Strategy	The searches used the following strategy: handheld technology AND electronic medical record AND randomized controlled trial. For handheld technology, the following terms were used: computer peripherals; computers, handheld; handheld; mobile; pda; personal digital assistant; palm pilot; palmtop; point of care; tablet; and wireless. The electronic medical record search used the following terms: computer communication network; electronic chart; e-chart; epr; ehr; electronic health record; electronic patient record; hospital information systems; and medical records. To identify randomised controlled trials (RCTs), the authors used the search strategy that has been developed and refined by the Cochrane Effective Practice and Organization of Care Group. The authors retrieved potentially relevant articles and reviewed their reference lists for additional articles. The full search strategy is available from the authors upon request. There were no language restrictions.
Study Designs Eligible for Inclusion	RCTs and SRs of RCTs
Practitioner Targeted	clinicians
Intervention(s) and Comparisons	handheld electronic medical record for patient care with a control group that was either a desktop EMR or the paper chart
Setting	NS
Patients Reviewed	orthopaedic patients
Pre-defined outcomes	relevant to clinical care such as a decrease in errors, improved review of information, improved ordering of medications or tests, improved documentation or improved satisfaction
Range of Observations or Period of Follow Up	NS
Findings or results	In the study that measured documentation time, the group using PDAs took longer to document. In the study looking at number of diagnoses, the group using PDAs documented more correct diagnoses, but also recorded more redundant or false diagnoses.
Conclusions, considerations for implementation, adoption or system design and development.	While handheld EMRs may improve patient care by improving documentation, reducing medical errors, and improving decision support, currently there is limited evidence of effectiveness. This highlights another area where informatics interventions are being implemented widely without rigorous evaluation.
Further research	More rigorous evaluations are required in multiple populations. Preferably, clinical outcomes should be measured.

REFERENCE	Yarbrough AK, Smith TB. Technology acceptance among physicians: A new take on TAM. <i>Med Care Res Rev</i> 2007; 64(6)650–672.
How does it meet inclusion criteria?	says it's a systematic review
CASP average score	20
Objective/Questions Addressed in the Review	To critique empirical research on physician technology acceptance and relate this to the TAM conceptual framework.
No of Studies Included in the Review	18
No of Participants Studied in Total	NS
Databases and Years Searched	PubMed, ABI Inform/Complete January 1996–November 2006
Search Strategy	Queries used the following keywords: "physician technology acceptance," "barriers to technology acceptance," and "TAM." Searches were restricted to peer-reviewed articles in the English language only.
Study Designs Eligible for Inclusion	NS
Practitioner Targeted	physicians
Intervention(s) and Comparisons	technology—unspecified
Setting	NS
Patients Reviewed	NS
Pre-defined outcomes	barriers to physician acceptance of IT
Range of Observations or Period of Follow Up	NS
Findings or results	Interruption of traditional practice patterns; lack of evidence regarding benefits of IT; organisational issues, and system specific issues were identified as barriers to physician technology acceptance. The authors also note that recent research suggests that the TAM is a good predictor of physicians' behavioural intent to accept technology.
Conclusions, considerations for implementation, adoption or system design and development.	The single most important attribute a clinical information system should have is speed for physicians. Successful implementation requires a physician's environment to have a collaborative organisational culture that emphasises teamwork and without such a culture, process re-design to make clinical information systems workable and efficient is impossible. The ability to customise and organise the knowledge captured on a local level is critical for physician technology acceptance. Additionally, the level of comfort a physician has with the computer also factors into their



	acceptance of technology. Furthermore, the lack of evidence that available technologies increase productivity or quality of care provides no incentive for physician technology acceptance.
Further research	The authors suggest that the TAM can be expanded to include know barriers and more contextual factors to tailor its use and prospective testing of the model is warranted.

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## APPENDIX 5:

### Bibliography of systematic reviews, health technology assessments, supplementary references and trials

SRs on impact on quality and or safety—appraised<sup>1–57</sup>

SRs on barriers, success, adoption and implementation—appraised<sup>58–68\*</sup>

\* No data extraction or critical appraisal due to inability to obtain full text

HTAs—not appraised<sup>69–102</sup>

Supplementary reports of included studies<sup>103–109</sup>

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## APPENDIX 6:

### Table of trials (n=284)

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## GLOSSARY

**Access**—to be able to place orders with N3 and get access to the full functionality of the customer website you need to be registered as a customer. There is a contractual requirement to be completed before any customer can have access to an N3 service. This is called an ‘access agreement’ and will need to be signed by an authorised person within the organisation and N3SP

**Active errors**—errors attributable to frontline professionals who prescribe, dispense or monitor medication

**Adverse drug events (ADE)**—adverse events arising from medication use. An unwanted occurrence after exposure to a drug that is not necessarily caused by the drug

**Adverse drug reaction (ADR)**—any undesirable effect of a drug beyond its anticipated therapeutic effects occurring during clinical use

**Advisory boards**—established to ensure the National Programme for IT engages with stakeholders, such as patients, the public, and health and care professionals.

**Adoption**—construed as the acceptance and incorporation of eHealth applications into everyday practice regardless of the degree of assimilation

**Architecture**—the selection, design, and interconnection of the hardware of a computer system

**Archiving**—a method of transferring information created during operations into a more permanent form.

**Artificial intelligence (AI)**—a branch of computer science and engineering that deals with intelligent behaviour, learning, and adaptation in machines. Research in AI is concerned with producing machines to automate tasks requiring intelligent behaviour. Examples include control, planning and scheduling, the ability to answer diagnostic and consumer questions, handwriting, speech, and facial recognition.

**Audit trail**—a record showing the occurrence of specified events relevant to the security of a computer system.

**Authenticated**—the confirmation following user authentication that the end user is actually the person he/she purports to be.

**Automated data collection**—the direct transmission of physiological

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information from monitoring devices to either a bedside display system or a computer-based patient record

**Bandwidth**—an industry standard term to measure the amount of data you can send through a network or modem connection. The more bandwidth, the more information that can be transferred at one time.

**Broadband**—a telecommunications medium composed of a bandwidth high enough to transmit high quality voice transmissions and a wide band of frequency. Television, microwave, and satellite transmission are all example of this medium. This is used mainly in relation to Internet access.

**Browser**—also known as a Web browser. Any program that permits access and searches on the World Wide Web.

**BS7799**—the British standard for information security management. This standard provides a comprehensive set of controls comprising best practices in information security.

**Care Record Development Board (CRDB)**—brings together patients and service users, the public, and social and healthcare professionals. It will identify the values, principles and processes of care and ensure that these are taken into account in the implementation of systems in NPfIT

**CFH**—see NHS Connecting for Health

**Choose and Book (C&B)**—one of NPfIT's headline deliverables. An e-booking system operating across the NHS to give patients more choice and control over hospital appointments

**Clinical information system (CIS)**—refers exclusively to the information regarding the care of a patient, rather than administrative data, this hospital-based information system is designed to collect and organize data.

**Computer-aided detection/diagnosis (CAD)**—refers to a type of CDSS used for image interpretation and sample analysis

**Computerised (electronic) decision support systems (CDSS)**—software applications that integrate patient data (input) with a knowledge-base and an inference mechanism to produce patient specific output in the form of care recommendations, assessments, alerts and reminders to actively support practitioners in clinical decision-making

**Community health information network (CHIN)**—a popular system of communication created for common use by health professionals, patients and the community. This system fuses hospital information systems

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(HIS) with medical databases, community health information, and on-line computer services

**Community Health Index (CHI) number**—a computer based population index used in Scotland that has as its main function the support of delivery of primary care services. CHI contains details of all Scottish residents registered with a general practitioner; it was originally envisaged as a population-based index to help assess the success of immunisation and screening programmes

**Compatibility**—refers to the ability of two pieces of hardware (a personal computer and a printer, for example) to work together. Standards, published specifications of procedures, equipment interfaces, and data formats are essential to decreasing and possibly eventually extinguishing incompatibility.

**Computer history taking system (CHTS)**—a history taking system (eg computer programme) tool that aids the clinician in gathering data from the patient to inform a diagnosis or treatment plan

**Computer network**—an interconnection of a group of computers. Networks may be classified by what is called the network layer at which they operate according to basic reference models considered as standards in the industry.

**Computerised medical record (CMR)**—this involves transferring paper documents into a computer system. This is done either through handwriting or transcription and is transferred into digital form with image scanning, optical character recognition scanning, or hybrid systems of these

**Computerised patient record (CPR)**—a record, in electronic form, that is comprised of individual patient information that resides in a system capable of providing access to complete and accurate patient data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids.

**Computerised provider order entry (CPOE)**—denotes the use of computers to enter, modify, review and output or communicate orders such as prescriptions, laboratory tests or radiological images, or referrals

**Computer Sciences Corporation (CSC)**—the LSP for the North West and West Midlands Cluster and North East and Eastern Clusters, delivering software developed by its main subcontractor iSoft.

**Connectivity**—the ability to send and receive information between two locations, devices, or business services

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**Data**—in computer science, data is any information in a form suitable for use with a computer. Data is often distinguished from programs.

**Detailed care record (DCR)**—all notes taken from a patient by healthcare professionals can be considered as the patient's detailed care record. The degree to which this record is accessible by a healthcare professional depends on whether they are providing the patient with care, their role in the treatment given and the patient's own wishes

**Dictionary of Medicines and Devices (dm+d)**—the source of terminology and a common health language for medicines and devices used in healthcare

**Digital medical record (DMR)**—a less-known term that stands for a vision of web-based medical records

**Diffusion of innovations**—the study of how, why, and at what rate new ideas and technology spread through cultures

**Download**—the process of transferring files or software from another computer to your computer

**eHealth**—a relatively recent term for healthcare practice which is supported by electronic processes and communication. The term is inconsistently used: some would argue it is interchangeable with healthcare informatics, while others use it in the narrower sense of healthcare practice using the Internet. The term can encompass a range of services that are at the edge of medicine/healthcare and information technology

**Electronic health record (EHR)**—refers to an individual patient's health record in digital format

**Electronic patient record (EPR)**—the EPR concept grew out of the CPR concept and, for a while, was the main term used. Now, some consider this term synonymous to the CPR term; however, an increasing number of individuals state that the EPR vision differs from the CPR

**Electronic medical record (EMR)**—an electronic healthcare information system regarding one patient. The EMR can be used as a natural stepping-stone toward an Electronic Patient Record and Digital Medical Record

**Electronic medication administration record (eMAR)**—an electronic record in which the clinicians who actually administer drugs record what has been given

**Emergent behaviours**—patterns generated from complex systems which

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cannot be predicted from study of the simpler elements from which they emerge

**Electronic prescribing (ePrescribing)**—the use of computing devices to enter, modify, review and output or communicate prescriptions

**Ergonomics**—see human factors

**Error**—an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome

**Electronic Transmission of Prescriptions (ETP) Programme**—is part of the NPfIT of the NHS, develops and implements the EPS

**Electronic Prescribing Service (EPS)**—enables prescribers, such as GPs and practice nurses, to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice.

**Front Line Support Academy**—provides learning opportunities for staff involved in the implementation of IT in the NHS and social care. The Academy works with staff to change and improve patients' experience of their care

**General Medical Services (GMS)**—the rules used to manage payments to family doctors as part of the GPs' contract

**GP2GP**—part of NPfIT. Enables patients' EHRs to be transferred directly from one practice to another

**Health Level 7 (HL7)**—a volunteer organization that provides a framework (and standards) for the exchange, integration, sharing and retrieval of electronic health information. A HL7 message consists of the following data elements: Message type; Message event; Message structure; Segment

**Health informatics**—or medical informatics—is the intersection of information science, computer science and healthcare

**Health information exchange (HIE)**—the mobilisation of healthcare information electronically across organisations within a region or community

**Healthcare Information and Management Systems Society (HIMSS)**—the healthcare industry's membership organisation exclusively focused on providing leadership for the optimal use of healthcare information technology (IT) and management systems for the betterment of healthcare

**Heuristic**—loosely defined or informal rule often arrived at through

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experience or trial and error (eg gastrointestinal complaints that wake patients up at night are unlikely to be functional). Heuristics provide cognitive shortcuts in the face of complex situations, and thus serve an important purpose. Unfortunately, they can also turn out to be wrong

**High Reliability Organizations (HRO)**—high reliability organizations refer to organizations or systems that operate in hazardous conditions but have fewer than their fair share of adverse events. It is worth noting that, in the patient safety literature, HROs are considered to operate with nearly failure-free performance records, not simply better than average ones

**Hospital information system (HIS)**—integrated, computer-assisted systems designed to store, manipulate, and retrieve information concerned with the administrative and clinical aspects of providing medical services within the hospital. Used to store and retrieve patient information, this integrated computer-based system may include or be linked to laboratory and radiology information systems (LIS and RIS)

**Human factors (or Human factors engineering)**—refers to the study of human abilities and characteristics as they affect the design and smooth operation of equipment, systems, and jobs.

**Human-readable**—refers to a representation of information that can be naturally read by humans.

**Iatrogenesis**—an adverse effect of medical care, rather than of the underlying disease (literally ‘brought forth by healer,’ from Greek *iatros*, for healer and *gennan*, to bring forth); equivalent to adverse event

**Implementation** - implementation encompasses the consideration, procurement or development, and the planned introduction of eHealth applications

**Industry Liaison**—provides information and guidance to IT suppliers who would like to be involved in providing products and services to NPfIT. It also supplies information to the National Programme on product innovations and developments in IT.

**Inference mechanism**—the underlying logic, or algorithm of a CDSS

**Information Technology (IT)**—defined by the Information Technology Association of America (ITAA) as “Öthe study, design, development, implementation, support or management of computer-based information systems, particularly software applications and computer hardware.” IT deals with the use of electronic computers and computer software



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to convert, store, protect, process, transmit and retrieve information, securely

**Information Standards Board (ISB)**—established in 2001 to provide an independent mechanism for the approval of information standards in the NHS

**Interface**—the connection between two devices; applies to both hardware and software.

**Internet**—a worldwide, publicly accessible series of interconnected computer networks that transmit data by packet switching using the standard Internet Protocol (IP)

**Internet Protocol (IP)**—a data-oriented protocol used for communicating data across a packet-switched internetworking

**Internetworking**—involves connecting two or more distinct computer networks or network segments together to form an inter-network

**Interoperability**—see compatibility

**Knowledge-base**—the collection of clinical knowledge underpinning CDSSs

**Laboratory information system (LIS)**—also sometimes known as clinical laboratory information systems: Information systems, usually computer-assisted, designed to store, manipulate, and retrieve information for planning, organising, directing, and controlling administrative and clinical activities associated with the provision and utilisation of clinical laboratory services.

**Lapse**—a glitch in cognition, eg failing to recall a drug name or a dose

**Latent errors**—errors which lie dormant in the system until conditions are right for their expression

**Legacy systems suppliers**—the commercial companies that supply the current/existing IT systems and software in use in the NHS. Also known as existing systems suppliers

**Local Area Network (LAN)**—a computer network covering a small geographic area, like a home, office, or group of buildings, eg a hospital

**Local implementation**—an NPfIT management group and individual project teams have responsibilities for implementation in each SHA. They coordinate and manage the progress of the programme by dealing with a variety of issues, including progress monitoring, problem solving, risk management, planning, good practice and allocating resources.

**Local Service Providers (LSPs)**—responsible for making sure the new



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systems and services delivered through the NPfIT meet local requirements and are implemented efficiently.

**Logical observation identifiers names and codes (LOINC)**—standards for test or procedure names

**Medication process**—five steps in medication management: prescribing, dispensing, administering, monitoring and systems control

**Medication use review**—interventions aimed at both the administering and monitoring stages of the medication process checking patients' need for and understanding of their medicines

**National Application Service Provider (NASP)**—a supplier selected to provide one of the NPfIT national solution services.

**National Infrastructure Service Provider (NISP)**—responsible for providing networking and support services.

**National knowledge service (NKS)**—established as part of the Government's response to the Bristol enquiry (Learning from Bristol January 2002), the NKS is developing a strategic approach to the management of the £150M annual NHS expenditure on knowledge and information services; and to obtaining the best value from such investment

**National Programme Board**—has overall responsibility for all areas of work within the NPfIT

**National Programme for IT (NPfIT)**—is responsible for procurement and delivery of the multi-billion pound investment in new information and technology systems to improve the NHS

**National Service Frameworks (NSFs)**—set national standards and service models for a specific service or care group. They set up programmes of implementation and performance management against which progress in an agreed timescale can be measured.

**National Supplier Board**—focuses on development and technology, implementation, service and contract management

**New National Network for the NHS (N3)**—the broadband network currently in place by NPfIT. N3 provides reliable supporting IT infrastructure, world class networking services and sufficient, secure connectivity and broadband capacity to meet current and future NHS IT needs. N3 is replacing NHSnet, the current private NHS communications network, in England and Scotland, providing a reliable service at every site where NHS services are delivered or managed.

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**N3 Service Provider (N3SP)**—the N3 National Service Provider

**Near miss**—any situation that could have resulted in an accident, injury or illness for a patient, but did not, due to chance or timely intervention by another

**Network**—a set of nodes, points or locations which are connected via data, voice, and video communications for the purpose of exchanging information. Interconnected telecommunications equipment used for data and information exchange. Consists of different types, LAN, MAN, and, WAN being examples

**Neural networks**—a computer architecture, implementable in either hardware or software, modelled after biological neural networks.

**NHS Care Record System (NHCCRS)**—or patient care record. Currently under development, this will be an electronic store of over 50 million health and care records which can be accessed by health professionals where and when they are needed. It will also give patients secure Internet access to their own health record

**NHS Connecting for Health (NHS CFH)**—supports the NHS to deliver better, safer care to patients, via new computer systems and services, that link GPs and community services to hospitals

**NHS Purchasing and Supplies Agency (PASA)**—the NHS purchasing agency responsible for over £2bn of goods and services in terms of commissioning, performance management and strategic planning.

**NHSnet**—the NHS private IP network provided by BT and Cable and Wireless which will be replaced by N3.

**NHSmail**—a secure national email and directory service. It was developed specifically to meet NHS and BMA requirements for clinical email between NHS organisations.

**Node**—a critical element of any computer network. It can be defined as a point in a network at which lines intersect or branch, a device attached to a network, or a terminal or other point in a computer network where messages can be created, received, or transmitted

**Organisational issues**—a comprehensive term applied to the socio-technical considerations relevant to the implementation and adoption of eHealth applications

**Output-based specification (OBS)**—each prospective supplier to the National Programme must meet rigorous technical requirements. These are set out in an output-based specification

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**Packet switching**—a communications paradigm in which packets (discrete blocks of data) are routed between nodes over data links shared with other traffic.

**Patient administration systems (PAS)**—the foundations of any clinical IT system are formed by PAS, managing and recording patient identification, admissions, bookings and discharge and shape the platform upon which to build EHRs

**Patient Care Record (PCR)**—see NHS Care Record System

**Payment by Results (PBR)**—the money that hospitals receive is linked to the amount of work they do, fixed by a national tariff

**Picture Archiving and Communications System (PACS)**—one of NPfIT's headline deliverables. A system capable of acquiring, transmitting, storing, retrieving, and displaying digital images and relevant patient data from various imaging sources and communicates the information over a network.

**Patient Medical Record Information (PMRI)**—synonym for the EHR, addresses parts of a patient's health information from various records

**Patient safety**—freedom from accidental or preventable injuries produced by medical care

**Patient safety incident**—any unintended or unexpected event that lead to death, disability, injury, disease or suffering for one or more patients

**Personal digital assistants (PDA)**—handheld computers also known as pocket computers or palmtop computers

**Personal health record (PHR)**—recording of pertinent information concerning patient's illness or illnesses.

**Personal medical services (PMS)**—a locally-agreed alternative to General Medical Service (GMS) for providers of general practice

**Primary Care Trust (PCT)**—responsible for commissioning all healthcare in their community

**Program**—set of instructions that detail a task for the computer to perform. In this sense, data is thus everything that is not program code

**Programming language**—an artificial language that can be used to control the behaviour of a machine, particularly a computer

**Quality Management and Analysis Subsystem (QMAS)**—provides reporting, forecasting and payment information for improving services within the Quality and Outcomes Framework implemented by British Telecom

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**Quality and Outcomes Framework (QoF)**—as part of a new NHS contract, introduced in 2004, GP practices are rewarded for achieving clinical and management quality targets and for improving services for patients within a Quality and Outcomes Framework. Sets out a voluntary system of financial incentives for improving quality within the General Medical Services contract for GP payments.

**Quality of Service (QoS)**—defined as ‘the capability to control traffic-handling mechanisms in the network such that the network meets the service needs of certain applications and users subject to network policies’ N3 Catalogue Service definition.

**Regional Health Information Organizations (RHIOs)**—are key to the US National Health Information Network. RHIOs are multi-stakeholder organisations expected to be responsible for motivating and causing integration and information exchange in the nation’s revamped healthcare system

**Remote Access**—enables NHS staff to access the N3 network whilst they are undertaking their duties away from their base

**Roll Out**—the period and activities of progressively going live in each cluster starting with the Early Adopters. This is backed by the user training by the NHS LSPs.

**Root cause analysis**—a technique involving a retrospective review of a patient safety incident to identify what, how and why it happened

**Slip**—an unintended act such as writing the wrong dosage schedule perhaps as a result of diversion of attention of the prescriber

**Source code**—a computer science (commonly just source or code) is any sequence of statements and/or declarations written in some human-readable computer programming language.

**Spine**—the name given to the national database of key information about a patient’s health and care and forms the core of the NHS Care Records Service. It will include patient information like NHS number, date of birth, name and address, and clinical information such as allergies, adverse drug reactions and major treatments.

**Standards-based clinical messaging systems**—these communicate the “orders” with other clinical systems, using, for example HL7 or LOINC

**Supplier Liaison**—the function of Supplier Liaison is to assist IT suppliers to locate information on the National Programme and to provide contact

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details for those organisations that have been awarded contracts

**Summary Care Record (SCR)**—a key element of the NHS Care Record System. The General Practice summary will be the main or only active part of the SCR; in time it will be supplemented by other contributions. Over time, a SCR will be built up from selected information in a patient's Detailed Care Record. The SCR can be seen by authorised healthcare professionals treating patients anywhere in England, if patients wish them to.

**Systematized Nomenclature of Medicine Terminology Solutions (SNOMED-CT)**—a systematically organised computer processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, micro-organisms, pharmaceuticals etc. It allows a consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps organising the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research

**Telemetry**—the science and technology of automatic measurement and transmission of data via wires, radios, or another medium from stations based in remote locations to receiving stations for recording and analysis

**Tunnelling protocol**—a network protocol which encapsulates a payload protocol, acting as a payload protocol. Reasons to tunnel include carrying a payload over an incompatible delivery network, or to provide a secure path through an non-trusted network

**Type A ADR**—drug reactions related to dose and pharmacological effect and are potentially preventable

**Type B ADR**—drug reactions, which are idiosyncratic and were occurring after initial use of a drug, are not predictable and thus not preventable

**User authentication**—the process of ensuring an end user is actually the person he/she purports to be.

**User interface**—the graphic and design components of a Web page that directs users on how to access the information contained in that Web site.

**Virtual private network (VPN)**—a communications network using a tunnelling protocol through another network, dedicated for a specific network

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**Wide Area Network (WAN)**—a geographically dispersed telecommunications network. The term distinguishes a broader telecommunication structure from a local area network (LAN).

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