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# eHealth and beyond


## Editorial



## Articles



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# Editorial: eHealth and beyond

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Today, citizens aged 65+ make up close to 18 % of the total population in all EU countries and the percentage of elderly will increase further in the following years. The most dramatic raise is expected in the 80+ age range. Ageing of the population together with unhealthy life styles are generating an increased prevalence of chronic conditions that place additional strains on both health and social support systems. In this scenario, existing health systems must make the transition to new models of care, with a shift towards integrated patient management [1, 2, 3].

The consolidated results of over 10 years of research on information and communication technologies (ICT) have generated evidence of the enabling role of ICT on the whole range of services, from life style and self health management, to improving health related quality of lives of patients and citizens, as well as managing chronic disease conditions such as asthma, chronic obstructive pulmonary disease (COPD), chronic heart disease (CHD) and mental health. Moreover, it is suggested that properly designed innovative health services supported by ICT may have a positive impact on chronic disease modulation and prognosis.

Despite the many advances in technology, deployment has lagged behind. The barriers originate at different levels and are associated to a multitude of technological, cultural, legal, political and market related factors.

How is Europe dealing with these challenges? In the first article, **Angelo Rossi Mori and co-authors** analyze the deployment of of Connected Health for chronic disorders as a perfect example for placing eHealth to the service of healthcare policies in order to effectively support the organizational models of shared care pathways. The authors argue that we need to consciously and systematically take the next step to move from “inter-operability” among systems to the “co-operability” among the actors in the care processes.

1 Epping-Jordan JE, Galea G, Tukuitonga C, Beaglehole R. Preventing chronic diseases: taking stepwise action. Lancet 2005 Nov 5;366(9497):1667-71.
2 Murray CJ, Lopez AD. Global mortality, disability, and the contribution of risk factors: Global Burden of Disease Study. Lancet 1997 May 17;349(9063):1436-42.
3 World Health Organization. (2000) Innovative Care for Chronic Conditions: Building Blocks for Action Global Report. ISBN-13 9789241590174.

The electronic health record (EHR), being probably the most characteristic shared information service, can exemplify this concept of a new level of needed governance to achieve co-operability. **Georg Heidenreich** and **Pantelis Aggelidis** introduce a six step approach to EHR interoperability that focuses on contractual responsibilities, rules and collaborative relationships for wide acceptance and common understanding of an EHR, far beyond technical Interoperability.

**EHTEL** argues that we are close to having the technology we need, including interoperability of information and the systems that share it, but we are not yet there in terms of cultural change of mentality, nor the flexibility to collaborate and share among actors. Over the next decade we should aspire to a much more common community care model, wherein information is part of the care process, eHealth becomes just an integral part of care, and where ICT and medical technology converge at the level of usefulness and value. Innovation has to be encouraged, rewarded and deployed, reducing not just 'time to market' for products and services but also 'time to generate value' in successful user deployments.

**Peter J. Groen** and **Douglas Goldstein** agree that achieving deployment of EHR, Personal Health Record and Health Information Exchange systems within the next decade is very likely and they will lay the foundation for dramatically improving healthcare. However, the need for radical reengineering and transformation of health care will start to come about when the next generation of current front end research results on Genomics, Nanotechnology and Implantable Systems, Robotics, and Wearable Systems are eventually implemented in the coming decades. The transformational management strategies in the 21st century – are to be based on Collaboration, Open Solutions, and Innovation.

Simulation and modeling has been extensively used in other sectors to support policy and management of change. As data collection is becoming comparable and more precise, care management and policy making with the help of ICT tools will become more feasible and will become part of the everyday decision support practice. **Efthymios Altsitsiadis and co-authors** identify significant adoption barriers due to lack of simulated-mass and simulation interconnectivity and recommend practitioners to turn to 'open' interoperable models as a mean to address the systemic complexity of high level decisions and to add sustainability to their work.

New challenges also emerge as eHealth becomes an integral part of care. They are associated to privacy and -linked to it – acceptance of these new working models. How ready are we to accept cameras in our living room? **Griet Verhenneman** observes that despite the existing legal protection mechanisms of protection of personal data, the right to privacy and the right to personal portrayal, the use of cameras as a next step in eHomecare will have to be based on the consent of the patient. Once more the profile of a well informed health care consumer is emerging opening up yet more ethical issues and societal challenges. Interestingly enough this issue affects also individuals that that are filmed when interacting with the patients during occasional visits in monitored home environments.

Another example of legal and ethical issues associated to RFID/Wi-Fi tracking and collection of sensitive data and affecting user acceptance are amongst the aspects evaluated by **D. S. Stodolsky** and **C. N. Zaharia** in the last paper of this special volume.

# Deploying Connected Health among the Actors on Chronic Conditions

## An example of a Copernican Attitude towards Co-operability

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connected health, eHealth roadmaps, care pathways, co-operability, Copernican requirements, Structural Telemedicine, MICK landscape

Most eHealth deployments are centred on technological solutions, and organizational changes of increasing complexity are arranged around them (a "Ptolemaic" attitude).

We argue that in parallel a "Copernican" attitude should gain relevance: the roadmaps towards a "Connected Health" should be centred on the healthcare action plans, supported by suitable eHealth solutions (as EHR and Telemedicine), structurally embedded in the organisational models of shared care pathways. Our focus moves from the "inter-operability" among systems to the "co-operability" (i.e. ability to cooperate) among the actors in the care processes.

We apply the above principles to the management of chronic diseases, through an analysis made out of three steps. In step 1, we stratify the patients with respect to their need for care in different phases of the evolution of most chronic conditions. We obtain three stereotypical "meta-situations" that show similar organisational models across the diseases and the specialties:

1. healthy people and early phases of a disease, which require just a regular attention by the health system and by the citizens themselves;
2. stable, predictable phases that require the proactive management of a (single) condition by multiple actors, which perform stable care tasks according to an agreed care plan;
3. highly complex situations, with the interaction of multiple chronic conditions that require the continuous adaptation of variable care tasks.

We also consider a fourth meta-situation, on the support for the daily activities of the patient and the assistance to the informal caregivers to alleviate their burden.

In step 2, we characterize all of them in a systematic way, from the point of view related to organization, information and communication, and we depict the typical patterns of care management involved, depicting the formal and informal actors that take part in the care processes, describing their roles, their tasks and their mutual responsibilities. In step 3, we investigate the "Copernican requirements" about the Management of Information, Communication and Knowledge

- MICK (the "MICK landscape") related to each pattern of care management, which is a prerequisite to figure out any appropriate ICT solution.

> "Most eHealth deployments are centered on technological solutions, and organizational changes of increasing complexity are arranged around them (a "Ptolemaic" attitude); the roadmaps towards a "Connected Health" should be centered on the healthcare action plans, with a "Copernican" attitude, structurally embedded in the organisational models of shared care pathways, to move from the "inter-operability" among systems"

# 1 Introduction

Healthcare is a crucial sector for the economy of European Member States; in particular, the increase of elderly people and chronic diseases asks for new models of care, able to assure an economically sustainable evolution of the healthcare systems [Council of the European Union (2007)].

Within each country, there is a need to assure the continuity of care across healthcare facilities and to facilitate the access to healthcare and social services. A key challenge is the close coordination of the activities of the healthcare (and social) professionals for shared care, as well as the proactive involvement of the patients themselves and of their families (patient empowerment) in the daily management of the diseases.

At the same time, the governance over the healthcare system should become more effective, i.e. the quality and the appropriateness within the processes of healthcare provision should improve and a number of medical errors should be systematically prevented, thanks to a more explicit definition and optimization of the processes themselves [ANCIEN Consortium (2009), Ministry of Health and Long-Term Care (2007)].

The ICT solutions are ready to face the needs of information and communication among clinicians and the needs of the citizens / patients / consumers; their deployment however has not yet been successful, as expected. Chronic disease management is a sector where the role of technologies – in support to the "systemic" deployment of proper care models and effective governance – could be decisive. Therefore we consider at this point the evolution of the eHealth strategies, with a particular emphasis on the application to chronic diseases, in order to answer the following questions:

- What was good and what was wrong with the policies and strategies so far?
- How to improve the effectiveness of deployment?
- How to obtain a realistic approach and the wide applicability in clinical setting?

## 1.1 "Ptolemaic" attitude vs. "Copernican" attitude

In this paper, we argue that so far the eHealth deployment was mostly driven by a "Ptolemaic" attitude, with the technological solutions in the centre and the organizational changes arranged around them; instead we adopt at this point a "Copernican" attitude, i.e. centred on healthcare strategies and care processes, with the design of the suitable technological solutions as a consequence [Rossi Mori A (2007)].

We apply this attitude to one of the most relevant priorities in the healthcare sector: chronic disease management [Department of Health, UK (2004)]. Therefore we divide the healthcare context into three stereotypical levels for risk stratification and population management (inspired by the so called Kaiser Pyramid), which involve similar organisational models for different conditions. Each level corresponds to a distinctive phase in the evolution of most chronic conditions:

1. Healthy people and early phases of a disease, which require just a regular attention by the health system. With the right support, the citizen (with the informal carers) can learn to be an active participant in his own care, preventing the disease or learning how to live together with his/her conditions. This support can help him/her to prevent complications and slow down deterioration.
2. Stable phases, with a predictable behaviour, that require a proactive management of a (single)

condition. The care ideally follows an authoritative clinical pathway and a multidisciplinary team performs a set of stable care tasks, according to an agreed care plan. Patient and informal carers (family, friends & volunteers) are possibly assisted by a Care Manager, acting both as an interface towards the care facilities and as a coach to promote the patient empowerment, in order to improve compliance towards the care plan.

3. Highly complex situations, where the interaction of multiple chronic conditions requires the continuous adaptation of variable care tasks. The situation is usually so peculiar, that no statistics are possible and thus evidence-based studies are not feasible. Therapy is adjusted according to a continuous assessment of its effects on the evolution of the clinical status of each particular patient. It calls for a Case Manager that "supports the health system" to achieve the coherent management of the disease, i.e. that properly involves and synchronizes health professionals, providers, patient and informal carers.

In addition to the three "clinical" meta-situations above, we also consider a fourth one, when the consequences of chronic diseases (especially in elderly people) require a support on the daily activities of the patient, with the assistance to the informal caregivers to alleviate their burden.

All together, the four "meta-situations" above make up the raw basis for further analysis towards our final objective, i.e. the optimal strategic usage of the spectrum of the potential eHealth solutions, with a special focus on chronic conditions.

### 1.2 The development of the MICK Landscape

The historical approach to chronic conditions is driven by the medical specialties and thus the analysis of the care processes is usually disease-oriented, i.e. it isolates its own complex of professionals, patients and facilities for each chronic disease. Instead, we suggest to look at the medical knowledge and at the national, regional and local healthcare action plans to identify the different patterns of care management across the diseases and the specialties implied in those plans, and then to characterize the resulting patterns in a systematic way from the point of view related to organization, information and communication, as far as possible independent from the particular chronic disease involved [Gordon C (2004), Rossi Mori A (2008), Rossi Mori A (2009)].

We work out a set of "typical" patterns of care management involved by each meta-situation, describing the formal and informal actors that take part in the care processes, their roles, their tasks and their mutual responsibilities.

In chapter 2, we present a discussion on the aspects of the eHealth phenomenon more interrelated to chronic conditions, and in chapter 3, we focus on two promising eHealth services: EHR and Telemedicine. Then in chapter 4 we finally describe, for each pattern of care management, the requirements for the Management of Information, Communication and Knowledge - MICK (the "MICK landscape"), which constitute a crucial milestone in order to figure out any ICT solution.

## 2 The eHealth phenomenon

In order to cope with the governance of the eHealth phenomenon applied to chronic conditions, we first identify the factors that influence the evolution of this sector, either as a set of bottom-up, autonomous decisions, either as coordinated actions suggested or supported by the authorities of a large jurisdiction (e.g. by legislation, economic incentives, common infrastructures).

## 2.1 The driving factors for the eHealth roadmaps

Three driving forces are interacting in the eHealth Roadmap arena:

1. The first driving force is the market. It is most intrinsically linked to the history of healthcare informatics. Several products and services were gradually expanding across facilities, and the scale of deployment and contracts was slowly increasing.
2. The second driving force is derived from the Ptolemaic attitude. In several countries, the inter-sectoral national / regional policies and the eGovernment actions on ICT promote the diffusion of common methods, architectures and infrastructures.
3. The third driving force is derived from the Copernican attitude. It should originate from the healthcare milieu, i.e. from the national and regional policies and thus from the related priorities on the Healthcare System (e.g. the National Plans for prevention, for oncology, for mother and child, …).

During the last 10 years there has been an increasing awareness that the scale of eHealth phenomenon has been moving from the level of the individual healthcare facility (and the spontaneous evolution of the market) to the level of large jurisdictions, asking for an intervention of the authorities to take care of the process and to set up an appropriate governance. In various countries, the eGovernment plans started to cope with this new challenge, mainly through the development of common basic infrastructures across multiple sectors (e.g. broadband, electronic signature).

The third driving force, specific for the healthcare sector, has not yet been exploited as needed [10]. In principle, it should take into account the trend to cope with the extreme fragmentation of care activities and to point towards a change of focus from hospitals for acute conditions to the management of chronic conditions in the territory. It is expected to provoke a deep rethinking of the care models and a reconstruction of the unity of actions about the patient (e.g. by shared clinical pathways for continuity of care), with a stress on prevention, on primary care and, in particular, on chronic disease management. This transformation could be facilitated by an intense usage of eHealth solutions.

In several countries, innovative healthcare programs are directed to put into practice the clinical evidence already cumulated on chronic conditions [Maggini M, Raschetti R, Rossi Mori A et al (2008), Wagner EH et al. (2002)], which require approximately three quarters of the healthcare resources and a continuous commitment by the patients and their families. Nevertheless, rarely those programs (which involve education, self-audit, governance & enhanced communication) are the kernel of the technological innovation in the sector.

The action plans to reorganise the healthcare system may involve a massive reallocation of resources; the deployment of ICT solutions is a secondary issue within this change process, even if they can be a key factor to enable the change itself.

In fact, the reorganisation of the healthcare processes may be facilitated by a pervasive adoption of ICT; it can positively impact on decision processes of professionals and lifestyle of citizens, and thus may modify their behaviour, to improve quality, optimise expenditure, increase appropriateness, as well as reduce medical errors and duplication of procedures.

## 2.2 The focus of the technological attitude

The Ptolemaic attitude is able to cope correctly with the governance on the two technological layers of eHealth, mainly driven by the market and by a myriad of decisions in local facilities:

- The first layer deals with enabling preconditions, i.e. infrastructures and basic services to support the upper layers. It includes the physical infrastructure (hardware, basic software & networks); identifiers and master indexes about citizens, professionals and facilities; authentication and access authorization; regulations and standards.
- The second layer provides useful services for citizens and professionals to improve the efficiency of operational processes (transfer of electronic documents, portals & public health information flows).

This attitude inspired several national / regional programs on eHealth (e.g. included in the eGovernment action plans), which however have not always been complemented by companion programs on regulations, education of managers and professionals, and by a revision of the number and job profiles of eHealth professionals.

Nevertheless, the current technology-driven eHealth solutions are not related to a change in the intrinsic nature of the care processes, even if they are able to improve speed, quality and quantity of many operational procedures, with a significant economic return.

## 2.3 The focus of the attitude by the World of Health

In addition to the above technological attitude, a Copernican attitude should aim at providing the technological toolkit to support the healthcare action plans that improve quality and appropriateness for the daily routine of care provision, as well as for the healthcare system as a whole. Therefore, we identify two healthcare-driven layers:

- The third layer includes all the solutions that facilitate the routine of care provision and promote an adequate behaviour for citizens and healthcare professionals. On one side, it regards the initiatives to improve the capture, recording and transmission of specific clinical data, and to ensure continuity and coherence of decisions / procedures among different care professionals. On the other side, it regards the services to actively involve patients, families & volunteers in the care management and in order to facilitate the adoption of appropriate lifestyles.
- The fourth level regards the clinical governance, which concerns the structural interventions on the clinical pathways to promote greater quality and appropriateness during routine, to catch up an accurate resources control, to realize an effective management of services, to allow the self-assessment of professionals, to drive the rewriting of the clinical processes, to introduce new care models, and to inspire the medium and long term healthcare policies.

Chronic disease management requires not only the practical support by the two Ptolemaic layers, but mainly the diffusion of the proper components of the two Copernican layers.

## 2.4 Interoperability and Cooperability

A lot of effort is being directed towards a pervasive deployment of the first layer, including infrastructures, regulations and economic incentives to the healthcare providers.

On the top of it, it is nowadays possible to set up the second layer (operational workflows,

technology-driven) over large jurisdictions: it provides recognised benefits to the citizens and a significant economic return (by increasing the efficiency); however, it is not stimulating a cultural and behavioural change in the professional attitudes and it is perceived as an additional burden in the professional activities, without a correspondent (clinical) return.

The management of chronic diseases requires to move towards to the third layer (clinically oriented processes, healthcare-driven); however, this route is not straightforward and requires a diverse approach with respect to the technology-driven solutions of the second layer: they belong to two different ecosystems.

To clarify this difference, in table 1 below we characterize two different patterns of interaction among the healthcare professionals (and with the patients), which distinguish the two layers:

- The second layer mainly deals with "activities with subordinate responsibilities". The ordering physician maintains the main responsibility of the healthcare action (primary care mandate); the other involved professionals have partial and subordinated responsibilities, with a bounded autonomy in their decisions, and should report to the ordering physician. The communication is usually documented according to established modalities, e.g. through the messaging, standard in routine usage, for diagnostic services.
- The third layer mainly deals with "activities with parallel responsibilities". Several healthcare professionals (and the patient himself, his family and volunteers) may have a mandate at the same time on different care aspects of the same patient. Their cooperation may be formalized by more or less explicit agreements or individual plans. The communication is usually not formalised enough and heavily depends on the current clinical context.

For subordinate responsibilities it is important and useful to achieve the interoperability (as a contraction for "ability [of systems] to interoperate"). For the parallel responsibilities (and in particular in the context of chronic disease management) it is also crucial to look for an additional objective, which could be called "co-operability" (as a contraction for "ability [of people] to cooperate"). To allow for an effective processing of clinical information, free text must be avoided and the clinical data must be captured and transmitted according to common coding schemes [Rossi Mori A (2007), Rossi Mori A et al (2007a), Rossi Mori A et al (2007b)].

**Table 1 – Comparison between activities with subordinate and parallel responsibilities**

| activities with subordinate responsibilities | activities with parallel responsibilities |
|---|---|
| activated by an order, a prescription, … | May be autonomously activated |
| prescription<br>medical report, discharge letter<br>organizational activities, e.g. eBooking<br>consultation (ending in a clinical report) | • multidisciplinary evaluation team<br>• stable roles on defined care plans (according to multidisciplinary reference pathways)<br>• stable cooperation between hospital and GPs e.g. for pre-admission and post-discharge follow-up<br>• stable cooperation between specialized services and GPs, e.g. on diabetology, oncology, mental health, …<br>• autonomous professionals (patient-driven coordination) |

| | |
|---|---|
| the modalities of interaction were tested and fixed for many years, yielding consolidated usages of communication | the modalities of communication (as care pathways, clinical dataset, clinical indicators) are spontaneous and flexible; often are informal or partially formalized; usually heavily depend on the clinical context (patient status) |
| **connecting systems, system interoperability** | **connecting people, cooperability among professionals** (and with citizens) |
| partial and subordinate mandates, referring back to the issuing professional administrative activities | • distributed responsibility<br>• between physicians<br>• between physicians and other healthcare professionals<br>• between social professionals and healthcare professionals<br>• proactive role of the patient |
| predefined forms on paper or as electronic documents (e.g. specific CDA forms)<br>messaging standards (e.g. HL7) | multiple "local" forms or very specialized ones (scores and scales)<br>clinical datasets, clinical indicators, infostructure |
| each Ptolemaic action line covers one operational sub-process (ePrescribing, eBooking, eReporting, etc) | each Copernican action line covers one healthcare objective (e.g. a disease-oriented network / chronic disease management; continuity of care) |

Co-operability among the clinicians (and with the citizens) on chronic conditions, involves:

1. The capture and the timely availability of the specific clinical data items needed by each clinician to perform her tasks in a particular moment, i.e. depending on the running context of the episode (condition of the patient, kind of facility, node in the clinical pathway, etc). The maximum of the benefit can be obtained when one deals with clinical situations that are considered as predictable.
2. The production of a "Baseline Profile" for each (chronic) condition of the patient, i.e. a minimum set of relevant, stable all-purpose data, to describe the background state of the patient (i.e. not reporting about a particular contact) with regards of a specific condition / health issue [Rossi Mori A, Mercurio G, Palumbo W, Paolini I, Ruotolo L (2008)]. For example, a Baseline Profile for an oncology patient (related to the stage of the disease), a profile specialized for the diabetic patient, a profile to describe the overall status of an elderly patient.

The above targets require an enabling infostructure [Rossi Mori A et al (2007c)], including:

- The toolkits to formalize, distribute and customize the authoritative care pathways (starting from the most relevant chronic conditions) to agree on the mutual responsibilities of professionals, to make explicit their expected information and communication needs along the nodes of each care pathway.
- The task-specific clinical datasets, i.e. explicit lists of the data items either to be captured and stored for a particular task, or to be communicated when transferring responsibility in a care pathway, or to compute indicators for audit / governance.

- Earmarked terminological subsets, i.e., clinically-oriented value sets (terms and codes) able to fit with each field of a task-specific clinical dataset, together with a toolkit to specify and maintain them, as well as to maintain the cross-relations with reference nomenclatures (e.g. SNOMED CT).
- Precise guidelines for a professional to uniformly perform the (new) clinical acts that generate the diverse variants of the Patient Summaries (e.g., the Baseline Profiles extracted from the patient record; the summary of an episode of care; the "letter to a colleague" on a particular health issue), to feed the Longitudinal her, or the Shared Social and Health Record to support the modern delivery of care.

# 3 eHealth services in Chronic Disease Management

The novelty of our approach lays within the systematisation of the available eHealth services into a comprehensive framework for ICT modular solutions. Through the example of the chronic conditions, we stress the need of a comprehensive review of the requirements for the different phases across the various care processes, looking for similarities among the patterns of care tasks involved by these processes.

## 3.1 A common Information and Communication substrate

Up to 5-10 years ago, in most countries the market and the initiatives of each healthcare facility were spontaneously facing the issues related to the diffusion of eHealth solutions and of the related organizational changes with a Ptolemaic attitude. That process of change management is made of many independent local decisions; it is completely different from the process involved by the Copernican approach for large-scale programs for the systemic dissemination of eHealth.

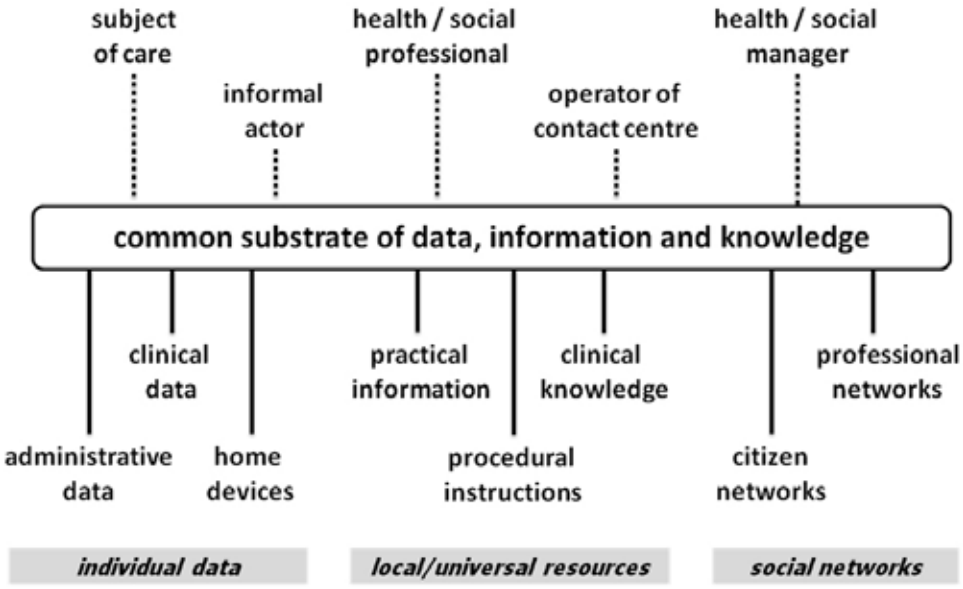
Nowadays a careful coordination is required, according to National and regional policies to promote new organisational models, calling for the cooperation of all the stakeholders, not limited to the deployment of the longitudinal EHR. This is particularly true when an objective is to create the "care networks" (of people !) on one or more chronic diseases.

In fact, all the information resources needed to integrate social and health care, should be developed with an appropriate coherence across a wide jurisdiction (see figure 1 below). Note that clinical data include e.g. prescriptions, diagnostic reports and patient summaries.

All the actors should rely on a common substrate for the Management of Information, Communication and Knowledge – MICK. In principle, this substrate will hold all the data, information and knowledge in a unique context, and may propagate "instantaneously" to the proper actors any modification in the informative resources of the care system.

This substrate should be designed taking into account the framework provided by the MICK landscape (as schematized in chapter 4), to support the new organisational models being promoted in the healthcare system. It should make a deep usage of standards and reference material, globally referenced in the previous chapter as the "infostructure" (definition of care pathways; data sets and governance indicators; earmarked subsets of coding schemes; guidelines about the production of new kinds of clinical documents).

In the rest of this chapter, we focus on two particular eHealth services (EHR and Telemedicine) that are evolving in a direction compatible with a decisive support to chronic disease management, shortly describing their potential structural role in the action plans on this topic.




### 3.2 From the longitudinal EHR to the support of shared care

The technological network that is asked to support the care networks in principle is not dedicated to a particular chronic condition, but should be seen as a unique resource for the jurisdiction, able to cover all the citizens and all the clinical conditions. Nevertheless, it can be built gradually, with an initial emphasis on a limited number of chronic conditions.

Many National and Regional jurisdictions are currently deploying their EHR infrastructures, mostly to make the operational documentation (i.e. of the second layer) available to authorized users. Our hypothesis is that the chronic disease management could be a major clinical objective for the EHR infrastructure, with relevant benefits for the professionals, the managers and, of course, the citizens [Rossi Mori A (2005)].

By observing the evolution of the strategies on the interoperability infrastructures, it is possible to perceive an overall trend to move from the original idea of longitudinal Electronic Health Record (i.e. a static collection of documents to preserve and make available the history of a citizen's health from birth to death) towards more operational tools, to support shared care and the synchronization of activities among healthcare professionals.

About 5 years ago, the vision in most countries starting to design the EHR infrastructure, was emphasizing the aspects of storing the information objects. The goal of the EHR was merely informative; the main use case was to provide a support to new mandates, by informing the new professional on the past history of the patient.

The attitude apparently gaining momentum nowadays is instead more devoted to a set of operational services for the healthcare provision, i.e. a Shared Repository also used for administrative purposes. This attitude, with proper extensions, may be also suitable for some needs arising from shared clinical pathways for chronic care management.

**Table 2: from the initial idea of longitudinal EHR towards a tool for synchronization of activities in shared care: consequences on clinical documentation and interoperability** (note - an asterisk marks the items further required for the shared management of chronic conditions)

| | initial idea on EHR | Current trend towards a Shared Repository |
|---|---|---|
| **main modality** | preserve historical data from birth to death | synchronize the activities with timely sharing of clinical data |
| **objective** | informative | operational, administrative<br>** also clinical care provision* |
| **needs** | consultation of past history | organizational and administrative purposes<br>** also for shared care* |
| **relation among mandates** | sequence of care mandates over time | subordinate mandates<br>** also a set of complementary care mandates (with partial responsibilities and simultaneously active)* |
| **functionalities** | safely store selected clinical documents and make them available to authorized users | manage the workflow of operational documents<br>** also processing of individual data items* |
| **ICT solutions** | basic infrastructure | also vertical applications (operational services to support the document workflow) |
| **constraints on the kinds of clinical documents** | any kind of document | only the kinds of documents specified in suitable agreements |
| **constraints on internal structure of documents** | any format | only documents structured according to suitable agreements (e.g. HL7-CDA level 2: structure of clinical statements for each section)<br>** also HL7-CDA level 3: specify which clinical data items should be transmitted in predefined contexts* |
| **requirements on Patient Summary** | [not foreseen] | ** several task-dependent variants of the citizen's profile* |
| **role of patient and informal care givers** | [not foreseen] | ** documentation of activities performed by patient and care givers*<br>** management of clinical data from home devices* |

## 1.1 Structural Telemedicine as a consequence of a transformation of care processes

Another opportunity for technological solutions, relevant for the management of chronic conditions, is the recent attitude to telemedicine [European Commission (2007), European Commission (2008), European Commission (2009)].

Telemedicine should be considered as one of the crucial components of the eHealth solutions to support the re-organization of (chronic) care delivery. The design of public or private Telemedicine services should be a consequence of a wider transformation of the processes of health and social care provision.

As far as chronic diseases are concerned, modern Telemedicine cannot be considered as an isolated resource, but it is inevitable to consider it in the context of the other eHealth solutions deployed in a whole jurisdiction, e.g. as in the VA's Care Coordination Home Telehealth – CCHT [The Joint Commission (2008)]. Moreover, it is important to consider the sustainability of the Telemedicine solutions, as well as their appropriate usage to support the care of chronic conditions [Schug SH, Editor-in-Chief (2008)].

The basic objective of Telemedicine is to move information and not the professionals and/or the patients. It may be characterized by four mandatory criteria:

an ongoing local clinical process of care provision ...

i. ... with the usage of clinical skills (by a professional) ...

ii. ... at distance (i.e. remotely with respect to the local clinical process) ...

iii.... by a decisive usage of the Information and Communication Technologies (ICT), with respect to the usage of paper, (voice) telephone calls or fax.

Regarding the organizational issues, we should consider how the Telemedicine services allow to support the re-engineering of the care processes and the re-distribution of the mutual roles and responsibilities among the actors within a facility and across the facilities. Those Telemedicine services may be considered as "structural", if they are fully integrated in the organization of the provision of healthcare services (with a clear subdivision of roles /activities), i.e.:

- When they require a deep involvement of the managers (how they organize the care services; how they achieve the proper involvement of the clinicians and the citizens; how they regulate the related fees and incentives; how they manage to have a suitable infrastructure in place; how they conceive the redistribution of benefits from the adoption of effective telemedicine solutions?)
- When they involve clear, explicit and irreversible organizational changes to reach the optimal redistribution of the human and technological resources in a jurisdiction, it is difficult to go back to a previous organizational pattern.
- When they are an intrinsic, essential and mandatory component of the care plans.

According to the above considerations, we propose the following definition of "Structural Telemedicine" in the context of chronic conditions:

"modality of care provision using remote clinical skills through ICT solution, considered by managers and professionals as an explicit component of reference clinical pathways and individual care plans".

Under this respect, it is remarkable the effort by a large number of industries and healthcare organisations on the standardisation of the interfaces of home clinical devices [Continua Health Alliance (2009)].

The interoperability of personal health solutions allows for plug-and-play installation, effective data transfer and remote control; it will thus facilitate the diffusion of the Remote patient Monitoring and Treatment (RMT). The Personal Health Systems (PHS, mostly based on home devices) will become a crucial component of chronic disease management because they foster independence, empower individuals and provide the opportunity for truly personalized health (and wellness) management [IPTS, European Commission's JRC (2009)].

Let us see in the next chapter how the various ICT solutions, including in particular the Shared Care Record (3.2) and the Structural Telemedicine (3.3), may be included in a comprehensive framework on chronic disease management.

## 2 Meta-situations and MICK requirements

As already mentioned, we want to characterize the requirements on the Management of Information, Communication and Knowledge (MICK) for a set of meta-situations.

Each meta-situation describes a particular phase in the evolution of the clinical and social situation of a chronic patient, with a stress on the common features across the phases of diverse chronic conditions. The related MICK is influenced by:

- the chronic condition(s) involved;
- the actors involved and the level of autonomy required for the subject of care and the respective informal carers;
- the actual organization of the care system (locally and in the wider jurisdictions).

By considering the MICK requirements for each meta-situation, we are able to work out the cluster of ICT solutions, which all together are supported by a fully comprehensive information substrate. We claim that the key criterion to gather together the clusters of ICT solutions is the similarity of the pattern of Care Tasks, from the point of view of the issues related to the MICK; the dimensions that strongly influence the care tasks are the severity of the condition and the clinical complexity of the management of the disease.

The analysis presented in this chapter may be further refined by any particular jurisdiction, in order to comply with the actual local context.

### 2.1 The dimensions of the MICK Landscape

The dimensions to be explored to describe a situation that determines a MICK landscape include, for example:

i. the clinical and social "background situation" of the chronic patient, that could be represented e.g. by means of a variety of multi-professional evaluation scales and the ICF coding scheme;

ii. the set of Care Tasks and of the actors that can be outlined in a more or less explicit and foreseeable care plan, including the expected role of the patient and of the informal carers;

iii. the kind of data (numbers, signals, coded entries, …) to be captured for direct care by formal and informal carers, to be shared among professionals, to be used by managers to produce the indicators for clinical governance;

iv. the local / universal instructions, clinical knowledge, practical information that could be useful for each actor to perform the care tasks;

v. how the information substrate may influence the decisions and the behaviour of each actor (in particular, the patient empowerment and the training of the patients and informal carers);

vi. the technological solutions (including the EHR infrastructure, the structural Telemedicine, the home devices, the social networking, etc) that could be used to cope with the Care Tasks and, in

general, with the particular clinical and social situation.

Within each phase of the evolution of the clinical and social situation of a patient with one or more long-term conditions, the performance of the care tasks requires that multiple formal and informal actors (organisations and individuals) interact for a common high-level goal; formal and informal carers must "behave as a coherent system".

For that to occur, they should be mutually aware of their roles, responsibilities, contacts, health issues taken into account, as well as of the status of any ongoing preventive, diagnostic and therapeutic activities (planned, scheduled, ongoing & performed). See for example the standard CONTSYS (EN 13940), on a system of concepts to support Continuity of care [CEN TC251 (2006)].

The requirements on the Management of Information, Communication and Knowledge (MICK) are similar for care tasks related to different chronic conditions. As the starting point of the development of the MICK landscape, here are the four meta-situations, with the possible high-level combinations of care tasks and MICK requirements.

## 2.2 Meta-situation 1. "regular attention", with minimal MICK requirements

The state of the citizen requires a systematic attention for a long period, because she is at risk for (a complication of) a chronic condition, or she is in an early, non-complicated phase of a chronic condition, or she is under a follow-up to monitor the effect of a previous treatment and to avoid new episodes.

"With the right support many people can learn to be active participants in their own care, living with and managing their conditions. This can help them to prevent complications, slow down deterioration, and avoid getting further conditions. The majority of people with chronic conditions fall into this category – so even small improvements can have a huge impact" [Department of Health, UK (2004)]

This meta-situation requires an intermittent, sporadic control by the health system. The citizen and the informal carers may have a relevant role in the change of life style and potentially dangerous behaviours. Part of the subjects of care will require social services.

Examples of care task may include:

- to maintain a register of citizens enrolled in a monitoring program and recall the citizen (up to a few times per year) to solicit for a new check of significant parameters;
- to perform periodic measurements or observations of sentinel parameters according to specific care pathways, a few times per year, for the early discovery of increasing needs;
- to organize the logistics of the provision of social services to frail persons, simplify the administrative burden;
- to coach /educate citizen and informal carers on the specific health issues, on the patterns of their evolution, on the optimal behaviour and life style to slow the evolution, on the recognition of the risks and the changes in the situation to be notified to the clinicians.

Examples of MICK requirements include:

- Healthcare professionals (GP, geriatrician, care manager): the registration of the citizen on a suitable list (e.g. a local register), with a synthetic description of the health issue and of a few

parameters to facilitate the periodic recall of the citizen and the prescription of periodic tests or visits.

- Social care professionals: assist in their coordination, support the logistics of provision of goods and services, assist in documenting the performed activities.
- Citizens and informal carers: the management of a Personal Health Record (e.g. web-based) to store systematic self-made observations and a log of the performed activities (e.g. measurements); the services to take part to a community of citizens with similar health issues to share information and experiences; the access to simplified administrative services (download / fill in of forms for requests, reimbursements, etc); web sites with authoritative clinical knowledge and the description of optimal behaviour with training exercises (and perhaps related eLearning services).
- Healthcare managers: the capture of data from the operative processes is straightforward, and the calculation of indicators yields a suitable tool to control the trend of the care phenomena.

### 2.3 Meta-situation 2. "stable care tasks" with additional systematic MICK requirements

The state of the subject of care requires the synchronisation among health (and social) professionals, and citizens and informal carers, ideally according to an explicit stable plan with precise roles. The evolution of the health condition is predictable and usually an authoritative care pathway is available, which describes the classes of clinical situations and provides a guidance, for each class, on the ideal tasks to be performed by each actor (including patients and their caregivers) thus suggesting their optimal roles and responsibilities (to be adapted to the actual context).

In spite of the mass of evidence-based documentation on the authoritative clinical pathways for most relevant chronic conditions, the actual deployment in real settings of the corresponding shared care plans is often unsatisfactory [Wagner EH et al. (2002)]; ICT can have a critical role in the success of a translational action plan.

This Meta-situation typically involves a single condition in an early stage. Multiple conditions and complications could be faced, if their interactions are predictable, i.e. if the care pathway for each condition is not significantly altered by the presence of the other conditions.

"Disease/care management, in which multidisciplinary teams provide high quality evidence based care to patients, is appropriate for the majority of people at this level. This means proactive management of care, following agreed protocols and pathways for managing specific diseases. It is underpinned by good information systems – patient registries, care planning, shared electronic health records" [Department of Health, UK (2004)]

In principle, the activities performed by all the actors should be orchestrated by a "Care Manager", i.e. by a care professional (preferably a suitably trained nurse) who in particular should help the patient and the informal care-givers to comply with the care plan: to manage the relationships with all the clinical actors and with the care system (booking, reimbursement, provision of goods and services); to promote the activities of self-care management; to let the patient and the informal care-givers acquire the suitable skills for appropriate management of the situation (by face-to-face training, social networks, elearning, etc.).

An important topic is related to the criteria to identify alerts when the situation potentially requires a temporary deviation from the stable care plan (for example, for interacting acute conditions), or the permanent migration to the Meta-situation 3.

The care tasks include most of those described for Meta-situation 1. Examples of additional care tasks comprise regarding:

- The care system: the multidimensional evaluation of the patient's situation, with the design and the deployment of a shared plan (goal, role, responsibility and activities for each actor, including citizen and informal carers).
- The citizen: periodic assessment (perhaps daily) of relevant parameters, also by home devices that may be directly connected to the network and to a contact centre; simple judgments on fine tuning of the therapy according to the parameters.

Examples of specific MICK requirements may include:

- On the side of the professionals: update of the evaluation of the patient's situation and of the shared plan, timely communication - as appropriate - to other clinicians (notification of contacts and other relevant events, assessments or other clinical data), management of a common agenda of planned care activities, assessment of the patient's situation to decide for potential changes in the ongoing care plan.
- On the side of the patient: management of home devices and of their connection to the network, advanced modalities of communication with the professionals (tele-presence, email, filling in web based forms, etc.).
- On a contact centre: management of the contacts with the patient and the informal carers, monitoring the data from the patient or from home devices and issuing potential alarms to appropriate specialists, simple advice to the patient as a basic triage.
- On the healthcare managers: the stability of the care tasks and their compliance to evidence-based clinical pathways allow characterizing well-defined clinical data sets [Maggini M, Raschetti R, Rossi Mori A et al (2008)]; thus the capture of data from the operative processes and the calculation of indicators may be very effective.

### 2.4 Meta-situation 3. "continuous adaptation of variable care tasks" involving additional non systematic MICK requirements

The state of a subject of care involves the interactions of multiple chronic conditions with severe complications and acute co-morbidities. It requires multiple activities with "parallel responsibilities" of various actors, perhaps operating in different facilities.

The course of action is strongly dependent on the "daily" evolution of the situation: it is difficult to orchestrate all the assessments and decisions by all the various actors into a coherent comprehensive care process, i.e. to foresee which activity should be performed each time, to plan its trigger and to realize when the situation requires new assessments and decisions (and by whom). Therapy is complex and should be continuously adjusted according to its actual effects. This situation suggests an opportunity for ICT solutions to support the organizational aspects of shared care and cooperative decision-making.

Normally the combined situation is really unique; the results of the clinical trials and the evidence-based clinical pathways are seldom directly applicable to the particular case (also because they are usually based on studies which are performed on single controlled conditions and exclude elderly people) and the experience on a patient cannot be directly re-applied to another patient.

"As people develop more than one chronic condition (co-morbidities), their care becomes

disproportionately more complex and difficult to them, or the health and social care system, to manage. This calls for case management – with a key worker (often a nurse) actively managing and joining up care for these people" [Department of Health, UK (2004)]

The coherent management of the complete care process requires a "Case Manager", i.e. a professional (a nurse, or – in more complex cases – the GP or a specialist) who should support the health "system" to properly cope with the patient's needs, i.e. to involve and synchronize health professionals, providers, patients and informal carers.

The Management of Information, Communication and Knowledge is more demanding of professional skills and less foreseeable, i.e. less suitable for structured representation for further systematic processing. In fact, a large amount of ad hoc clinical variables is captured for each case, but an effective professional communication requires a just small, context-dependent subset of data (different each time) for each peculiar task-related communication. Therefore, the detailed clinical data are less re-usable and statistical processing may be inappropriate.

However, once the decisions are made and an actor or a team starts a particular sub-procedure, it follows its regular path with a predictable MICK, until a new assessment takes place and a different decision is made. Within the boundaries of this sub-process, the situation is under control and suitable ICT solutions can be effectively activated.

The care tasks for this Meta-situation imply:

- for the care system: complex activities, with interaction among therapies and difficult planning over a long temporal span;
- for the citizen: decisions and responsibilities of citizen and informal carers are limited: clinical care is mostly delegated to professionals.

The MICK requirements are less suitable for highly structured ICT solutions; they include:

- On the side of the professionals: support to data capture and storage, support to decisions (access to up-to-date specialized knowledge, alarms on drug interactions & tele-consultations).
- On the side of the patient: support to the informal carers in performing complex procedures, also with permanently operating home devices;
- On the healthcare managers: the systematic capture of data from the operative processes is very difficult because the clinical situations are too unique and not comparable; often there is a lack of reference evidence-based clinical pathways to be taken as guidance. The calculation of indicators is often not effective because they are not able to assess the appropriateness of the decisions with a statistical significance.

## 2.5 Meta-situation 4. "support to tasks about the daily activities"

The subject of care may present a reduction of autonomy in daily activities, up to the point that they become completely dependent on certain types of function.

From the practical point of view, the technological solutions may be able to alleviate the dependency of the subject of care and reduce the burden for informal carers, providing a major improvement in the (quality of) daily life of the subject and of the informal carers, thus facilitating the move from institutions to home.

We can define here the MICK requirements within a scale to describe the interaction of the informal user with respect to the technological services:

- passive user – generic domotic devices are able to send data to a remote centre, without a local intervention (e.g. fixed webcam, sensors of presence, movement, pressure, water, gas, …); permanent measurements (on the patient in bed, wearable devices);
- reactive user – device setting and measurement are guided step by step by the device (perhaps after training and with printed / web based instructions);
- user interactively guided by a professional – the procedure is performed by the user, interactively guided by a remote professional (e.g. video consultation on skin lesions)
- proactive user – the procedure is managed by the user, with limited decisions (perhaps after a significant training, or using interactive instructions – help line);

This meta-situation is only partially related to the three "clinically oriented" meta-situations, because it is mainly determined by the actual loss of functions, which may be a consequence of the age or of any disease or accident.

## 3 Conclusions

We developed a comprehensive framework to deal with ICT solutions for chronic disease management, in order to develop a coherent approach across the different diseases.

The technology can influence the evolution of the organisational models about chronic conditions by a mix of mechanisms, including, for example:

- By changing the mutual roles of the professionals and of the informal carers, allowing each of them to perform tasks currently performed by less skilled individuals (and thus moving the burden from specialized facilities to less specialized ones and eventually to the home). This phenomenon also includes the potential creation of new professional profiles, e.g. care managers, and new jobs (e.g. increasing the number of non-medical professionals in the territory).
- Optimizing the organization of care, by better synchronizing the activities of the different formal and informal carers involved, increasing the awareness of each other, reducing the time of their communication (and thus providing better care with less resources, with a positive influence on the evolution of the subject's status).
- Optimizing the accuracy of the care processes by better monitoring and more timely reactions to the events happened to the subject of care (again improving the quality of care and the subject's status).

The final effect is usually to reduce the burden of care on the (public) system, in two major ways: by increasing the efficacy and the quality, but also by transferring the burden to the individuals (the subject of care and the informal carers).

The specific influence of eHealth services may be cross-related both on the care provision issues and on the eHealth issues.

### 3.1 The strategic and organizational aspects

The main strategic and organizational goals of a health system may be achieved with the assistance

of “sustainable” eHealth services:

1. Quality of life, by providing assistance to patients at home, also by proper clinical equipments (devices or video-communication), with a suitable connection to remote clinicians.
2. Equity of access to social and health services, by increasing the decentralisation and the flexibility of the supply of services (i.e. offering new services to the citizens).
3. Internal optimization of the work organization within the care facilities, e.g. by locating the human and technological resources where most appropriate and using Structural Telemedicine services for communication, modifying the care processes and the usage of resources as required (i.e. offering the same services to the citizens, by a modified organizational model to increase the quality of services and/or decrease the costs).

Even in apparently simple cases, our generic schema (based on the four Meta-situations) needs an accurate adaptation. In particular, each type of actor manages a diverse target group of citizens; e.g. a diabetologist limits the mandate to the patients with diabetes in various stages, while for a GP the target group involves the patients with the various chronic conditions, and for a nurse acting as a care manager it includes chronic patients from various GPs.

Analogously, the modalities to communicate with the patient are very different, especially if the activity on a disease has to be synchronized with other ongoing contacts for the same patient on other health issues.

## 3.2 Consequences on the eHealth Roadmaps

Previous considerations also have a consequence on the national and regional eHealth plans (Roadmaps) [Rossi Mori A et al (2008)]. In fact an optimal eHealth Roadmap should:

- be coherent with the healthcare policies;
- support a synergy between the healthcare world and the technological world;
- be balanced among the 4 layers of intervention (enabling factors, operational workflows, care processes, governance).

On the technological side, the programs on public infrastructures (regional and national) are already being deployed in several European jurisdictions. They involve the adaptation of the electronic systems in public and private healthcare structures, the wide integration of the Master Registries of citizens, professionals and facilities. Moreover, they have already faced the issues of standards and regulations.

On the healthcare side, the major bottleneck regards the influence of the healthcare policies on the organizational models and, therefore, on the eHealth solutions. From the point of view of the info-structure, it is necessary to collect, make usable and disseminate the definitions of the reference clinical pathways for a diffuse routine use, in addition to the clinical datasets for the cooperation among professionals and detailed indicators for the clinical governance, derived from the clinical pathways [Maggini M, Raschetti R, Rossi Mori A et al (2008)]. Moreover, it is necessary to collect, compare and feed into the system the experiences that in each Country already faced the topics in the third and fourth layers (i.e. about the care processes and the governance).

The change process may be optimised by the creation of a network of (regional) support centres, to promote the local participation and the exchange of know-how, through: a proactive documentation

service; a collection (and a comparison) of systematic descriptions of best practices; the production of reference technical, strategic, educational material; the management of forum, newsletters, thematic workshops for dissemination and consensus making.

In addition, an intense activity of training and promotion must be set up, towards the opinion-leaders, the professionals, the population in general and the specific classes of patients.

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# Six Steps to Electronic Health Records Interoperability

Storing and providing patient-centric health-related information is a common idea and there are many implementation projects targeting electronic storage and supporting remote access. However, wide acceptance and common understanding of an electronic health record (EHR) as successful as IT-successes like mobile phones or ATMs seems to be far away. This paper discusses solutions for the six main challenges of an interoperable EHR: responsibility of EHR entry authors, privacy of personal data, identification of the patient, quality of content, architecture, quality of infrastructure.

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Interoperability, Electronic Health Record, Privacy, Identification

> “Solutions for the six main challenges of an interoperable EHR: responsibility of EHR entry authors, privacy of personal data, identification of the patient, quality of content, architecture, quality of infrastructure”

# 1 Introduction

Multiple EHR projects are being designed or implemented at this time - most of them on a national, regional, or even enterprise level - and these projects more or less run into similar issues. Many of these issues are not related to the enabling technologies themselves, but they are more in the realms of politics -- both in the governmental and regulatory sense and in the internal corporate sense -- and economics. Most people with a global view of healthcare agree, however, that there is a substantial economic case for wide scale use of EHRs. Starting with the assumption, therefore, that these non-technology-related issues will be overcome, and therefore assuming that medical professionals are willing to enter data into IT-systems, we found the following six challenges which have to be dealt with in any EHR-system:

1. responsibility of authors for EHR entries
2. identification of the patient covered by an EHR
3. privacy of personal data
4. quality of content
5. architecture
6. quality of infrastructure

Because there are many existing definitions, let us characterise an EHR as (MRI, 2009)

- patient-centric computerised healthcare data;
- possibly collected from multiple different and often unaffiliated organisations;
- designed to cover more than one encounter;
- potentially accessible from different locations (a key characteristic for most effective use of EHRs).

# 2 Liability

The whole idea of an EHR is that the healthcare professional currently treating a patient somehow can rely on what has been written into the patient's EHR, so that the "EHR reader" transfers some of his liability to the "EHR writer".

A prerequisite for believing in the content of an EHR entry would be to know the identity of the author of that EHR entry. As a consequence similar identity requirements as for patients are also valid for healthcare professionals entering data into an EHR.

Users of existing IT-systems in health care are often not technically authenticated, i.e. one authorised person logs into IT-systems in the morning and a group of professionals and assistants share either the sessions or the credentials. Data entering processes are sometimes unclear and the data sources are not separated with respect to data authenticity. Furthermore, there are no common regulations addressing the validity of EHR entries. For each of these reasons, doctors cannot really rely on the authenticity of an EHR. As a result, in a critical situation, a healthcare professional would not base vital decisions on an EHR.

Physician orders, exams and test reports, as well as medical summaries are medical records, and as

such they are legal documents, which must be authenticated by the creator and be kept in unaltered form. Based on further (legal) regulations, technical means for identification/authentication (such as cryptography) may serve as a base for a limited transfer of liability from the reader of an EHR entry to its responsible author, who should be distinguished from the data enterer, the observer (of the clinical findings being reported) and the scoping organisation (legal entity).

The authors of EHR entries must rely on the authenticity and availability and longevity of their entries into the EHR, because they might want to use these entries as evidence in legal disputes. So authentication of authors is only one aspect, but there also has to be a legal frame which accepts authenticated EHR entries (and the very small risks of forging them), as evidence in a court suit.

A detailed process clarification of EHR data entry, regulated by a cross-organisation contract or by legislation, would be needed to effectively transfer liability from the current medical performer to some EHR author(s).

Based on "information self-governance" (under current discussion), patients may be enabled to see their EHR entries and even hide certain entries from medical staff. In a so-called "patient-driven EHR" (no practical implementation yet), a patient may enter, control, hide or even modify and delete entries. Both approaches once more raise doubts on liability. Although the author's identity would be quite clear for each visible entry, the medical foundation of the information entered may be questioned. In the case of the patient-driven EHR, the omission of selected pieces of information could actually change the overall context in which a physician or other care-giver would interpret the information, which could potentially result in erroneous care decisions.

Health professional identification has received a lot of attention recently at a European level. This is not related only to EHR writing and reading but also to verification of eligibility and status in a cross-border free and mobile Europe.

The main political document behind it in the EU is the European Directive 2005/36/EC on the recognition of professional qualifications. Identification for professionals mainly serves as i) a certification means of eligibility (which is also supposed to protect citizens from unauthorised practice; the case of Radovan Karadzic being the most recent spectacular example), ii) a logging mechanism and iii) an access mechanism (both to physical areas as well as virtual spaces).

The preferable identification token choice at the moment seems to be a smartcard (HPRO, 2009; SCA, 2006).

## 3 Patient Identification

Uniquely identifying patients is an absolute prerequisite to operating an EHR which should correctly store and retrieve patient-related data.

**Mapping:** The patient identification in this section is needed to match a person to a file (or multiple instances of a file). Identification under different settings may mean different things and may require different organisational and technology solutions. We refer to the type of identification dealt here as back-office identification, following the definition in [M403]. Another functioning of identification is authorisation; this is discussed in Section 4 dealing with Privacy issues. The patient identification is required as a mapping from the individual to its related EHR-entries; neither that mapping nor the identifier does necessarily have to be part of these EHR-entries (front-end identification). Mapping can be done through direct attributes (biometric features such as iris scan, fingerprint & visual image) or through indirect attributes (e.g. demographics or tokens, like a smartcard).

**Unique:** An identification can be managed to be unique (i.e. be issued for a single person) either globally, or within a certain scope, which is the overall organisation/area in which that identifier is unique. Implementing a unique identity therefore requires some authority operating a scheme to create unique identifiers, one or more identity issuers and one or more directories for lookup purposes. The scope of that authority is the maximum scope of the related EHR. However, using a globally unique scheme like the ISO Object Identifiers allows creating globally unique patient identifiers, composed of the authority-specific ISO-OID root and a patient-specific extension.

**Invariant:** Any EHR has to be based on a unique patient identification, which ideally – but not necessarily - is invariant over the patient's lifetime. That patient identifier only needs to be unique for a given set of patients being managed by that EHR-system (back-end identification).

As an example, the current german KVK (patient card issued by health insurers) is unique within Germany if used together with the identifier of the related health insurance ("Krankenkasse"). However, the KVK & Kassen-Nr. are not invariant, since the insured person may switch the insurer. In the same way, ISO 21549 and the European Health Insurance Card (EHIC) are based on identifiers derived from the health insurance contract. So, the numbers taken as potential identifiers are not invariant though they provide a simple scheme to unique identifications. The recently approved eEHIC CWA (eEHIC, 2009) has provisions for unique citizen identification, although from a political point of view it is not meant to be an identification card, but rather an entitlement card.

**Exclusive:** Note that "unique" may also be understood in a way that there shall not be two identifiers referring to the same person, which is an aspect that takes organisational measures to enforce. If different applications issue or use separated identifiers – but each of them uniquely – such separated identifiers for the same patient can be linked through a "master patient indices" anyway (IHE, 2008).

**Eternal:** Provided that a unique, exclusive alphanumeric patient identifier is invariant and will never be used again (e.g. after the patient's death) such a patient identifier can be used as the primary key in an IT system.

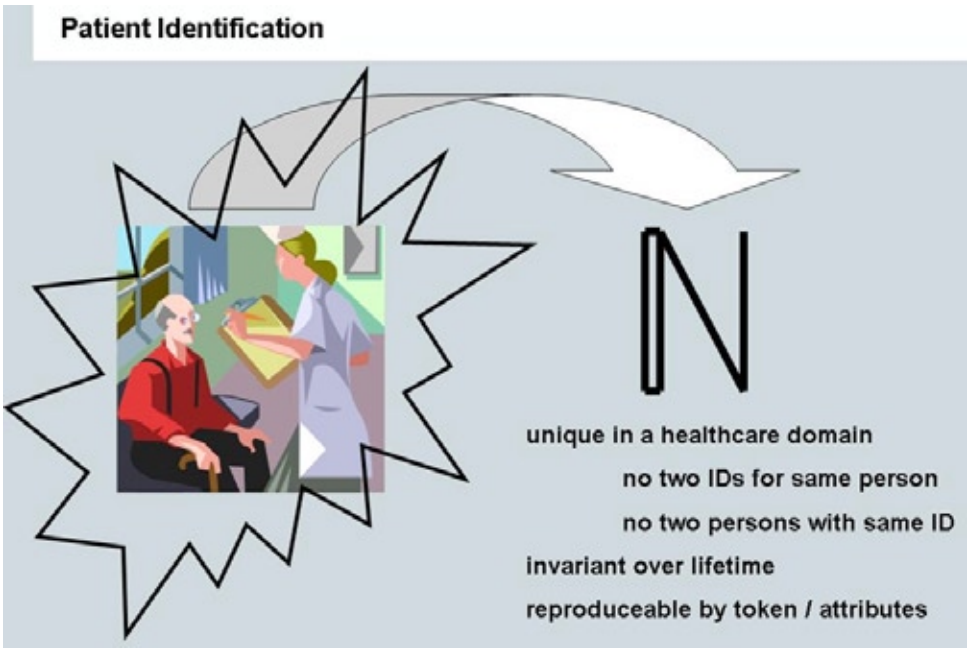


*Fig. 1: Properties of a Patient Identification*

Note that most regulations somehow limit or even prohibit the use of personal identifiers with global (not scoped by a single contract) applications and/or long term storage.

Smart EHR systems also store so-called external identifiers – generated temporarily or by offline systems - as an attribute to each entry so that if the join (between primary and external identifier) later turns out to be wrong, these entries can be split away and the join can be undone. In a hospital, query, split and join use a considerable amount of resources, and this is one of the economic deterrents to optimally effective use of information technology in healthcare organisations.

## 4 Privacy

The organisations and individuals charged with the management of EHR information are required to ensure that adequate protection is established and that access to the information is granted only to authorised parties.

It is worth mentioning that paper-based health-data have always had risks regarding privacy; computers may however give sensitive data into wrong hands

- at a higher speed
- over a long distance
- without any hint to the information source or the patient

Due to regulatory requirements (e.g. Healthcare Insurance Portability and Accountability Act (HIPAA), Directive 95/46/EC) and similar regulations, providers and operating organisations have to implement appropriate measures, document and assess them. In many cases, directors and leading executives are personally liable for IT safety and security.

Privacy of personal health data is supported by authorised access to data and functions, plus secure and safe storage of the EHR.

Authorised access needs authenticated identities of the patient, as well as the healthcare professional wanting to have access to that patient's EHR. Assuming that the patient identification has been authenticated, the healthcare professional accessing data and functions of an EHR must also be authenticated.

Healthcare professionals obtain permissions to access and perform by personal login and group membership. One foundation of secure EHR-Systems is individual healthcare professional ("login") accounts and their assignment to groups which may both be the basis for granting permissions to access health-related data and to use healthcare-IT-services processing such data. Like the implementation of patient identification, either biometric or symbolic information or a token (hardware) can be used as the "personal secret" required for a login, as previously discussed.

Authorising healthcare staff to use data and services can be achieved by permissions of the underlying operating system or plugged-in directory services communicating with the computing platform through standard protocols (like e.g. LDAP).

Though privacy discussion catches much public attention, it should be handled by sober minds using procedures and resources related to the respective risks. In secure environments, technical protection can be relaxed.

Protecting the privacy and ensuring authenticity of health-related data is currently supported by

local signature/encryption algorithms in a public key infrastructure, both being implemented using established means of the underlying computing and communication systems. Since an identity infrastructure is needed anyway for both patients and healthcare professionals, a public-key infrastructure (PKI, certificate and private key-issuers and public key-lookup) can be added, as an extension to that identity infrastructure.

Separating organisations handling data which only taken together make up sensitive information is another measure to increase security, since it is more unlikely that employers of different organisations collaborate in unlawful plots.

Recent work on the European Interoperability Framework (EIF,2007) and in CEN/ISSS Workshop on Data Protection and Privacy (WS/DPP) provides pointers to the way in which organisational co-interoperability, between sector specific standards and requirements, can be accomplished.

Note that the privacy concerns of the medical professionals and other entities involved in providing and paying for health care, deserve the same attention and need similar measures. Doctors frequently prescribing regulated substances or implementing expensive procedures mostly have a medical reason to do so, and it is not the EHR system's responsibility to find persons prescribing such substances for other reasons.

## 5 Quality of Content: useful meaningful information – how to model it, store it and present it

Quality of the content being stored in EHR entries is related to topics like "structuring" the data, information sources, modelling & encoding, and consolidating redundant data.

### 5.1 Granularity of Entries

Up to now we have assumed that it has always been clear what an entry in an EHR is and that some schema or the author determined when to start and when to finish placing data into a single entry. These are the possible scopes of a single entry of an EHR:

- "Liability": whenever a medical professional - writing data into an EHR - releases and signs a healthcare statement related to a single patient, a new entry can be created and since there is a point in time of signature, a total ordering of all entries can be defined. Unsigned, uncontrolled data might as well be submitted as entries provided that the respective markup indicates the origin of such entries.
- "Encounter" the whole longitudinal set of data collected for a single patient and potentially describing multiple encounters can make up a single EHR entry. A (partial) ordering in time can be defined based on "begin" and "end" dates of each respective encounter.
- "Point of care" the whole longitudinal set of data collected for a single patient and potentially describing multiple encounters can make up a single EHR entry. Such entries would not have a predefined ordering in time, since the patient might go on receiving care from different sites and organisations.

### 5.2 Data Maturity

Multiple doctors typically diagnose different diseases, even for the same symptoms. As long as these doctors keep their own paper records, this is fine. With the use of EHR, however, these doctors will aggregate redundant (if not superfluous) data into the EHR. How do we protect future care-givers from masses of data containing only limited amounts of real information?

Regarding a life-cycle of health-care data, maturity of EHR entries can be described by an additional attribute for which we see these typical values:

a. chronological collection, that has not yet been consolidated or reduced ("chronological", machine-generated or entered without release/signature)

b. longitudinal, encounter-related collection of clinical information ("encounter-based", signed and released in a local context)

c. "eternal", redundancy-free, consistent diagnoses and procedures ("valid", condensed, long term information which has been selected and validated in the context of all previous EHR entries)

This scheme allows for any unauthorised sources, like external entities, devices, non-medical staff and patients to enter data into the EHR, which would however describe this as "maturity level a)". Only after review by medical professionals - possibly eliminating redundant data - such entries would be promoted to b) and only after global review placed to level c).

### 5.3 Medical Terminologies

Controlled medical terminologies allow for representing medical statements in a formalised way and are required for implementing automated search and medical processing (e.g. drug interaction check, medical/workflow guidance, reporting, reimbursement, search/index/query).

A medical terminology is a set of classes each representing a concept in the medical domain. A class may also be called a term. The meaning of each term is a medical concept assigned via its semantics. The pure set of terms - without regarding semantics - is called vocabulary. The incarnation of a class in a specific statement (e.g. an EHR entry) is called an instance. Different caveats must be taken into account when using terminologies:

1. A terminology should be independent of context (time, location, organisation), at least within the scope of the EHR system using that terminology.

2. Using a term should identify the terminology where it is originated so that the receiver knows from which vocabulary the given codes are.

3. Terminologies typically evolve by keeping old entries and just adding more new terms, but in some cases, old terms have been removed or even reused for a different concept. The German pharmacology central number PZN, for example, reuses deprecated terms but with a different intended purpose which may cause severe misunderstandings and risks to patients. A version number along with the terminology identifier help to detect such conflicts.

4. A "small" terminology with only few terms may not be precise enough to capture the physician's intention. The rather "general" terms provided by small terminologies might each have to be extended by a plain text statement. Such a situation moves a part of the information to be stored / transferred into the "unstructured" world while the "structured" world does not carry all the information.

5. Terms of an existing terminology in some cases can be refined with modifiers. E.g. ICD has modifiers for the site of a findings (Both, Left, Right, but also V for "suspected diagnosis", Z for "no symptoms of this diagnosis" and even an A for "this can be excluded"). Modifiers for negation are really risky, because systems receiving an E10.3A but not understanding the A would assume a "diabetes with eye problems", the opposite of what was intended.

6. A fine-grained terminology (with a large number of terms) may present different codes for the same medical situation, so that multiple terms for a single medical finding are listed in a given patient's EHR. In reality, multiple medical doctors might diagnose different findings based on the same symptoms, so that one complaint may be the root of multiple entries in the patient's EHR.

7. Fine-grained terminologies (with a large number of terms) tend to having synonyms (as well as "meaningless" nodes). Synonyms reduce interoperability and may lead to redundant (multiple, yet different) documentation of identical medical concepts.

8. Optionality (e.g. ICD modifiers or some SNOMED dimensions) restrict compatibility.

9. Some medical terminologies can be used for expressing cause-symptom-relationships, and many clinicians see a need to express causality between instances. Here is one example based on SNOMED without any cause-symptom-relations: A patient was brought as an emergency case "P00300" into hospital. He complained about fever "F03003", shivering/ague "F03260" and diarrhea "F62400". Doctors first found an acute inflammation "M41000" of the stomach "T63000" and the duodenum "T64300", later the cause Salmonella cholerae-suis "E16010" was found so that the final diagnosis "gastroenteritis paratyphosa" "D01550" could be documented. If multiple of these terms are stated in an EHR entry, one would like to express the relation between these terms, because it should be expressed that these have not been separate complaints. Special coding guidelines try to address this, but do not give a comprehensive easy solution. E.g. ICD has a cross symbol for the main cause and an asterisk for symptom terms. The asterisk can only be used, if it is presented together with a "cross"-code.

### 5.4 Semantic Interoperability

Not only syntactic compatibility at its interfaces but also its ability to keep and transfer semantics makes an EHR-system useful for exchanging meaning (semantic interoperability). A common conceptual model is always the foundation of representing semantics in a computer. Terminologies (sets of terms and meanings) are an important part of such conceptual models. SNOMED CT (www.snomed.org , ed. by Coll. of American Pathologists, www.cap.org,), LOINC, ICD, OPS, ICF, ID-MACS are important examples of such terminologies.

Up to now, we have explained how to represent healthcare data in a structured way. Since we need to make sure that readers of EHR entries understand what the authors have intended, we need semantic interoperability. Using and understanding symbols in a common way requires to support common use and interpretations of symbols for instances and concepts. Note that this means not only to provide registries, catalogs, master-patient-indices but also to teach the meaning of each identifier and each term to the humans using them. Within the scope (i.e. the geographical and organisational area) of an EHR system, all humans involved need to know the meaning of identifiers and terms. Such an understanding cannot be achieved with purely formalised and technical material. Instead, plain text definitions supported by examples and training material are required.

A wider range of possible expression plus a defined interpretation - both supporting longevity of EHR entries - can be achieved through model-based interpretation, where all entries are mapped

to a common domain-model known (plain text definitions and also examples) to both producers and consumers of the EHR. The meaning is then derived from the model and not directly from the syntax of the entries. The formal part of this domain-model is the reference information model (RIM).

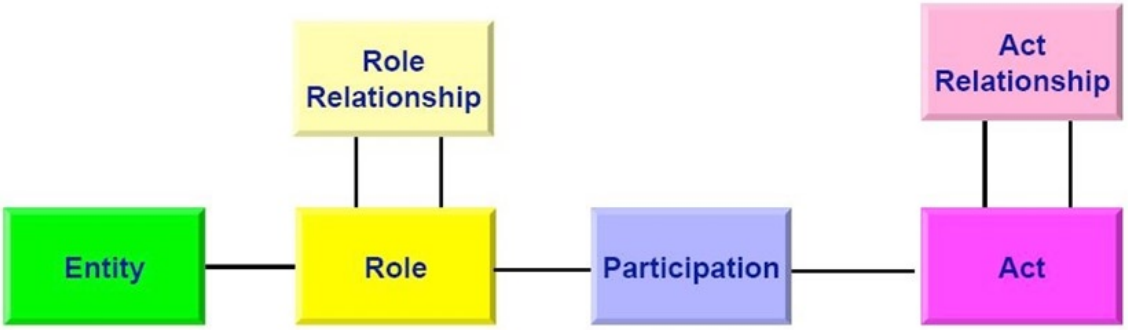


*Fig. 2: The superclasses of the HL7 Reference Information Model (RIM) [(c) HL7 Inc.]*

An innovative such approach with high expressiveness is the HL7 v3 RIM (ISO 21731) originally invented for messaging clinical events. Each situation is mapped onto fundamental concepts like "Act" (compare to "use case"), "Participation" (compare to "actor"), "Role" (compare to "appearance") and "Entity" (compare to "essential nature") which are connected by relations. That very basic model has to be refined in multiple steps, in order to form specific messages and to derive computer source code. By 2006, 16 application (plus 10 technical) domains have been published under HL7 v3, which in turn are refined into approximately 600 single messages each reflecting a use case in a respective domain.

The broad foundation of the RIM and its derived messages are both the strength and the weakness of HL7 v3: unparalleled expressiveness and elegance, versioning of documents, workflow aspects and even a meta-view can be represented. On the other hand, each implementation requires large and detailed guidelines on how to use and interpret the elements of HL7 v3.

While these messages may express any situation in healthcare, it is not clear, which messages and what part of these messages should be recorded by an EHR. Again, a conceptual model - based on these RIM classes - of the domain to be covered by an EHR must be derived from well-defined processes in order to model the set of possible entries and to map from a "message sender" domain into the EHR domain.

Optionality/Cardinality in the model as well as in its external representation reduces interoperability, because it leads to different, incompatible messages. Therefore, Implementation Guidelines are needed to constrain the use and representation of model elements so that NO optionality is left over.

To sum up, plain text definitions and explanations of the respective information models seems to offer the only solution for semantic interoperability, i.e. for migrating or mapping encoded data based from one conceptual model to another. A generic converter between two information-models is called an ontology mapper. There are approaches to use SNOMED CT (or similar systems) to build common ontologies and to use these as an anchor point in such mappings.

## 5.5 Presentation of EHR data

Now let us consider an EHR system with all above issues solved: the system grants access to credible

structured medical data of a single identified patient to an authorised user. It soon will happen that long lists of entries e.g. for diagnoses or medication will be shown to each reader, who - in most cases - only had a specific question regarding a certain encounter or complaint. User acceptance will decrease, if medical doctors feel that they are drowning in a sea of irrelevant data whenever they access an EHR-system.

Instead of copying bulky medical records down to client IT-system, a custom-view has to be created, which shows a reduced subset of references into the respective patient's EHR. Based on metadata and keywords either a human expert, or a query interface creates such a custom-view and then provide links to the original EHR data.

While client IT-systems (in the GPO or hospital) may help in constraining the results of querying an EHR-system, it takes a medical professional to judge on skipping (ignoring) past events which he/she considers irrelevant versus highlighting important facts recorded in the EHR system, as part of the patient's relevant medical history.

## 6 Quality of Infrastructure

Providing a so-called virtual EHR which can be seen as just a collection of references into decentralised systems actually storing the medical content requires those decentralised base systems to be up and available and performing with requirements that are proportional to the overall system requirements. The solution lies in differentiating different types of information and defining the respective non-functional requirements.The infrastructure for EHR systems needs to provide a certain level of performance, a defined availability at remote locations and long term storage of the EHR.

### 6.1 Performance

The number of point-of-care workplaces able to access an EHR system together with the number of patients having EHR entries stored in that system plus the size of these EHRs determines the potential load which an EHR system must handle. Taking into account the required response time of the EHR system, one can deduct the computing power needed for the servers in an EHR system plus the required networking bandwidth. Cryptographic measures for encryption and authentication take another toll both on computing power and bandwidth.

### 6.2 Availability

Typically some kind of 24/7 availability of EHR functionality is needed, which can only be provided by professional hosting organisations. With decentralised systems, the probability of a single server - the one you needed for sending you an important EHR entry - is higher but the overall availability is better via redundancy.

### 6.3 Long term Storage

The "long term for storage" is defined by the EHR usage time interval: Depending on the EHR business model, EHRs may be distinguished by how long they are supposed to be used and what time interval of the patient's life is covered:

- encounter

- insurance coverage time
- disease
- lifetime

Available servers, long term storage, a safe and secure archive need an experienced and reliable IT-service provider. Such a provider can be the IT-department of a hospital or a regional healthcare information organisation (RHIO), or a trusted commercial hosting service.

### 6.4 Area of use

How large is the geographical area, in which the EHR can be accessed / edited? How good is the coverage rate, i.e. the percentage of healthcare providers that actually have access or may even edit entries in an EHR?

## 7 Centralised or Decentralised?

Experience from studies and EHR projects shows that from a semantics point-of-view maintaining nationwide - or even larger - centralised EHRs would be less useful than connecting federated systems and allowing queries for patient-related data across multiple EHR systems. A centralised EHR (UK, NPfit) store would have to translate data from decentralised systems into a common representation prior to storing it. The responses collected from federated stores as a result of a query may be translated as well, but this translation would happen per query and can be done in the context of the query. The receiving system can decide how to present the information collected from a federated EHR system responding to a query. Thus the decentralised approach helps preserving original information even if there are issues with integrating content represented in different formats and encoded using different vocabularies.

So the ever-ongoing "(de)centralisation battle" should be replaced by a local/regional/global decision that has to be made for each type of information based on its respective properties and usage:

1. Clinical documents: big memory footprint, highly security sensitive, persistent, identified, invariant, attested/signed collection of clinical information, typically related to a certain encounter or disease.
2. Registry entries: security sensitive, persistent, identified, invariant: attributed references to clinical documents.
3. Indicator of existence of some information: persistent, identified, invariant, - possibly attributed - document reference, minimal EHR entry.

Fig. 3 shows how different types of content can be provided in different scopes and using different types of storage location (Donelly, 2006).

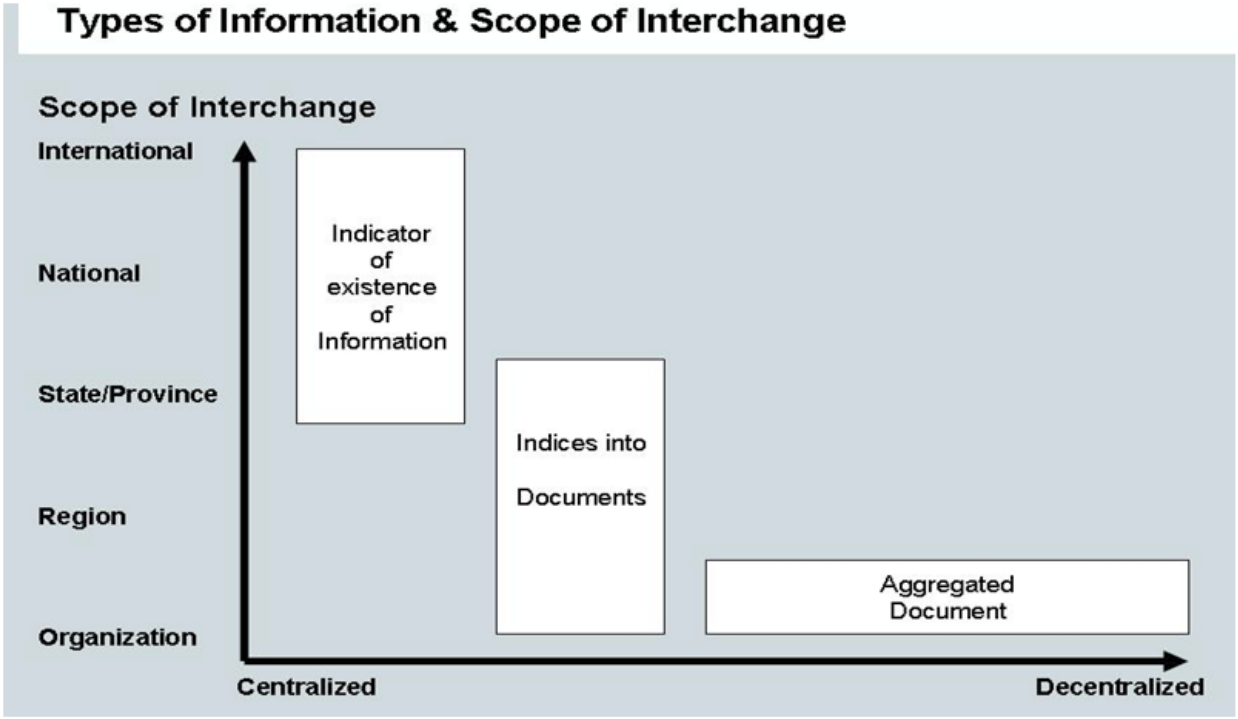


*Fig.3: Scope of Interchange implies different organisation of content*

From an IT point of view, there may be more different types of information in an EHR entry which are appropriate for different types of "decentralisation":

1. Dynamic workflow artifacts: short-term, identified, volatile status description of a workflow instance (e.g. of an order workflow with the steps entering, processing and completing), may reference items of 1.), 2.)
2. Just-in-time views: transient, unidentified, volatile descriptions of situations, like e.g. results of "canned queries"
3. Event notifications: persistent, identified, invariant, description of a transaction at one single point in time.

The "data maturity" mentioned before is also related to the question where to keep certain EHR entries. Since the setting - the geographic/organisational scope - of potential readers is mostly local for "chronological" data and rather local (maybe regional) for "encounter-based" data but surely global for "eternal" data, these maturity types of EHR entries are related to the architecture as well.

## 7.1 A Decision Table

Having in mind that there are aspects and elements which are handled rather locally than centrally and vice versa, we examine several elements of an EHR system with respect to the question of centralisation vs. decentralisation. Note that the intention of the table is not to absolutely determine where to manage certain elements of an EHR system. Architects will first map table's columns to a

given topology (legislative / organisational structure) and then map elements - described in the cells of the table - into that topology. The left column lists elements (data and functions) for which there are good reasons to have them locally managed. The right column lists elements that rather should be centrally managed. The middle column ("scoped") lists elements that may be managed at some level depending on the specific topology. Rows with an asterisk (*) are indicating the column which should provide a guideline to architects.

**Table 1: Elements of an EHR system with respect to Topology**

| | LOCAL | SCOPED | CENTRAL |
|---|---|---|---|
| **PID Requirements** | Unique<br>AND qualified | unique<br>AND invariant<br>AND qualified | unique<br>AND invariant<br>AND eternal |
| **PID Solution** | PID as secondary key | Identity Source<br>MPI | Identity Source<br>MPI |
| **Security Solution** | Decryption<br>Signature<br>Private Keys | Encryption<br>Signature Validation<br>Token Generators<br>Public Key Registries<br>Key Issuers | Trust Center<br>Service Directories |
| **(*) Validity of Content** | transient / draft | released | summarised / validated |
| **EHR Entry Maturity (see: Content)** | Chronological | Encounter | Eternal |
| **Terminology / Modelling Support** | Terminology Client<br>Communication Server | Impl. Guidelines for Specific Vocab./Models<br>Terminology Server<br>Communication Server | RIM / Ontology<br>Terminology Server |
| **Instances / References** | Internalise/ Externalise | Instance Registry (Role) | Instance Registry (Entity)<br>Instance Registry (AET) |
| **Terminology** | local vocabularies | classifications e.g. ICD | Ontology supported by e.g.SNOMED |
| **(*) Communication** | Directed | undirected / addressed | Broadcast |
| **Object Type** | Modality Report<br>Lab Report<br>Vital Signs | Prescription<br>Progress Note<br>Discharge Letter | Emergency Data Set<br>Payor Coverage Stmt<br>Medical Summary<br>Medical History |
| **Workflow Mgt.** | Workflow Artifact (Task, Worklist, Alert) | Workflow Template<br>Selected / Temp. View | Event Registry |
| **Object's Memory Size** | Medical Source Data | References w Attributes<br>Key Objects | Patient-related Indicators |

| | LOCAL | SCOPED | CENTRAL |
|---|---|---|---|
| **(*) Gov. Organisation** | GPO / Lab / Department | Hospital Regional/State Provider Payor | (Inter)National Provider Payor |

## 8 Summary

Taking a step back and looking at all these issues, one will find that precisely determining governance of an EHR can be seen as a prerequisite to solving the open issues mentioned above. Let us assume that a regional healthcare information organisation (RHIO) owned the EHR. Then, the RHIO ("provider") and the individual care contracts would provide the legal and business foundation to:

i. identify the patient (the RHIO has a care contract and/or person number);

ii. clarify the responsibility for the medical content (the legal entity providing healthcare is responsible for the information provided and therefore will setup a scheme to authenticate authors and content);

iii. set the rules for ensuring a patient's privacy (the RHIO will set up a privacy policy and accordingly establish a scheme to authorise access);

iv. define an information model and all terminologies as well as other rules as content quality including "cleaning up" (the RHIO might want to cooperate with (inter)national bodies to get guidance from and submit requirements to standardisation experts);

v. establish levels of an architecture and determine where to manage what types of EHR entries and references (The RHIO company defines an architecture for services and data, depending on its size);

vi. define the requirements for performance and availability (the RHIO company might e.g. sign a contract with hosting/service providers on operating an adequate infrastructure within their region and for their customers).

Likewise, if we assume that a RHIO or a similar regional health network takes governance for an EHR, the above-mentioned EHR challenges can be mastered in the context of the contracts and legislation for that respective network.

### Acknowledgements

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# Reflections on a Decade of eHealth The Second Stage in Healthcare Transformation

This article provides some background from the early days before there were any convenient labels for this segment, looks at where we are today with eHealth (successes and failures, gaps in understanding and in the value business case, strategic acceptance and lessons learnt) and then takes a view forward for the next decade looking at how we can expect eHealth to evolve in the real world, why it is important, what are the critical success factors, and a brief view of the world of eHealth at the end of the decade.

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President
EHTEL

Keywords
Health, care, eHealth, Telematics, ICT, market, deployment, vision, transformation, driver, stakeholder, roadmap, collaboration

> “A lot of progress has been done over the last decade about what can eHealth do, but visions are needed now about the “how” and who should be empowered to make it happen.”

## 1. Introduction

This paper is inspired by the 10th anniversary of EHTEL (European Health Telematics Association) an organisation that has been active in eHealth from the beginning, providing a unique forum for all eHealth stakeholders across the European Union (and beyond).

eHealth is the current label used to describe interaction between healthcare and information technology. We can already identify three clear stages of eHealth evolution as discovery, acceptance and deployment – and also postulate a fourth stage when all labels become redundant, and what we now call information technology is accepted as an integral part of the care process - just like telephones, scanners and bedpans. But this would be to run before we can walk (a not infrequent characteristic of eHealth and its precursors).

The underlying theme of this address is to derive some practical conclusions to support the process of 'making eHealth happen', to look at some of the aspirations and in particular to consider how to make progress towards the fourth stage. To do this we have to go back and paint a picture of how we got to where we are (and where we are not) with eHealth, looking at the interrelationship between health and information technology. Then we need to take a realistic look at the status quo, what is already on the table, what evidence already exists and what are the gaps, the areas which have as yet not received a great deal of attention. Finally we need to build on existing templates for the next decade and consider the factors that will create a constructive obsolescence roadmap for eHealth.

## 2. The first age of Discovery (1989-1999)

The first stage of discovery (1989-1999) was heralded by the European Commission's recognition that their Research and Technology Development (RTD) programme should also tackle issues within vertical sectors despite the difficulties involved in interpreting the governing rules which were predicated purely on a research and technology base. This eventually led to the AIM programme specifically designed for health. The major achievement here was to enable and support a community across the European Union of people committed to working together, exchanging ideas, information and experience. This did not exist in the health IT world, only within the clinical community but with increasing access through email, this new community developed around EC projects and associated conferences, workshops and other 'European' activities. Even then the governing rules made it extremely difficult to avoid the 5 year research model which often meant that, by the time the project was complete, any useful results had often been overtaken by events. Despite the difficulties this was the baseline for eHealth and by the end of the decade, this was a vibrant and active community (though still rather introspective and technology oriented).

These were the days of "magic solutions", "silver bullets" and "paradigm shifts" – not to mention a somewhat impractical commitment to the imposition of wide ranging standards. Like many similar new communities, it spent huge amounts of time and money talking only to itself, with little direct connection to healthcare professionals and not enough contact with the real world of clinical practice. The constraints of the EC RTD programme, the disconnect between Health ministries and IT, wide ranging ignorance of eHealth and its potential, and the enthusiastic pursuit of interesting technologies all made this a frustrating time. Pilots were everywhere and achieved things locally but almost none of it was consolidated, and most of it was lost in silos, conference proceedings and budgetary inflexibilities. There was also a significant reluctance, sometimes downright opposition, to change - quite apart from the transformation that was becoming an evident necessity. The paternalistic model has a proven track record all the way back to Hippocrates. But there were (and

still are) conflicting interests involved.

There have been some important signposts along the way. With the AIM programme - a turning point for what we now call eHealth – which ran between 1988 and 1994 under the direction of Niels Rossing, Health Informatics had come to be viewed as Health Telematics. Also, one of the first major gatherings of this community was in Geneva at MEDINFO in 1992. A foreword from the Chairman of the Scientific Programme Committee, Salah Mandil, was entitled - "From EDP in Health to Health Informatics" and the first keynote speech was by Roger Penrose of Oxford University entitled – "What computers can and cannot do!!" In the same year, the European Commission, at the highest level, was considering a proposal to establish common base networks for open health information systems in Europe.

Project scope expanded dramatically, as also did the eHealth community itself as ideas about specific applications of information technology to healthcare began to develop across care settings and health communities up to a global level. By the end of 1999 it was clear that to bring together technology and healthcare, the academic and technology emphasis would have to be rethought. Some way of building bridges and achieving active collaboration between the various stakeholders would be a prerequisite for success.

## 3. The second stage of Acceptance (1999-2009)

The second stage of acceptance (1999-2009) began with recognition by the eHealth community that nothing was going to happen by osmosis or just because of the enthusiasm of that community alone. There would need to be vision and structure, stakeholder involvement, some high level encouragement and a lot of hard work on the ground. Once again the European Commission took the initiative to support a number of activities to tackle these transformation factors. One of these was the establishment of the European Health Telematics Association (EHTEL) to provide a forum for all key stakeholders. The drive for this came partly from SMEs looking for ways to get connected to EC programmes, and to become involved with the health IT community with other stakeholders. The challenges were evident – there was no main stream credibility for health IT within the technology sector or indeed within healthcare itself; there was no voice for innovation and new ideas; there was no business case, no evidence base and among the major players, there were few who were aware or listening to the health telematics community.

In contrast, the opportunities were beginning to open up. The health IT community was beginning to gain momentum and credibility in some areas. New technologies were maturing which had relevance to healthcare and particularly there were a lot of small companies actively working with innovative local health groups and clinicians. The growing pressures of demography, medical advances and patient empowerment were all in sharp contrast with finite resources available to address a growing demand from citizens and patients for more health attention. The impact of increasing incidence of chronic disease, evidence based medicine, and early glimpses of personalised care, information based management and control, economics of transformation through technology support and development of strategic ideas from European markets were changing perceptions, priorities and the choice of health business models. In addition, as opportunities emerged, stakeholders began to be more aware of the opportunities and threats associated with ongoing change.

During this decade, some forward progress was achieved. But often, time seemed to stand still, and much of the tactical movement was either sideways or even backwards. Key progress centred around consolidation of various IT 'labels' into the term 'eHealth'. Again, it was the European Commission

that took the initiative,holding held the first high level conference on eHealth in 2003. This provided official endorsement for eHealth - and since then, the label has stuck. In February 2009, the seventh of these conferences will take place in Prague. The key next step was to increase the level of understanding of the importance and value of eHealth. Today, there are few dissenters, and most stakeholders are happy to acknowledge this state of affairs. In January 2008, the EC launched its Lead Market Initiative programme with eHealth as one of the significant components. In an interview in January 2009, Ilias Iakovidis put forward the proposition that eHealth could be a key to future European industrial growth, with the current economic crisis possibly offering a huge opportunity to invest in eHealth, to stimulate jobs and to drive economic growth.

The European Commission's continuing support for eHealth will be crucial in the next stages of evolution, but one of the things we have learnt is that the Commission alone cannot do all of this on its own. Its key responsibilities and priorities are declared, but eHealth is not just a top down affair. There are some components which can be dealt with at European level but these are rather restricted since there is currently no European market for healthcare or for eHealth. The financial crisis will emphasise this – for all the European and national support for banks and economies, the crisis will hit local communities hardest, and has to be tackled locally on a day to day basis, not just at a macroeconomic or national level. This makes it difficult for politicians who will have to delegate in order to be effective locally (and more so in health than other parts of the public sector).

In this second stage, much attention has been paid to issues of healthcare transformation and to the role of eHealth, but the results have been disappointing, particularly where excessively centralist strategies have tried to impose 'one size fits all' solutions. Issues of scale and complexity in healthcare are only just beginning to be understood in relation to eHealth, although this was highlighted early on in the decade1. Even now, it seems evident that working with population groups above 5 million involves a major shift in complexity which is still beyond the practical application of today's IT technology in a healthcare environment. This is not just a European phenomenon. Even the USA Veterans Administration, a world leader in health IT with common systems plus a 'command and control' culture, has experienced problems with multiple different implementations of the same (apparently identical) systems. Experience with the UK National Programme for IT serves to underline this issue and now risks causing of a serious 'disconnect' with the supply side of IT industry, both large and small. The National Care Record service, as originally envisaged, is now regarded as impractical and non-viable. Experience with medical records in France, the demise of GIP-DMP, and the smart card programme in Germany all endorse these difficulties with over ambitious projects. Even in the Netherlands, for so long a pioneer in health IT, the national programme is struggling to deliver against the original objectives.

What about healthcare users – how do they view eHealth? The simple answer is that they do not yet see it as an immediate priority. The prevailing perspective is rather limited and varies significantly depending on different user categories. On the one hand, many users are clinical professionals across a range of specialties and functions from paramedics and nurses to hospital consultants. In their own private lives, most will be IT users at some level. Yet, when they go to work, corporate IT capabilities often don't extend to supporting and enabling them to do their jobs. Indeed, there is even considerable frustration, centred on the view that medicine is a personal relationship between clinician and patient, which needs to be kept that way. On the other hand, for patients and increasingly citizens, there is a parallel frustration, but reflecting the paradox of a perceived special relationship with GPs and the medical profession which is often at odds with reality.

1 Report written for UK DTI (Department of Trade & Industry) Understanding the Market for eHealth October 2001

But on the other hand, the work EHTEL has done with patients groups leading up to the publication of the Patient's Charter2 highlights very real concerns about quality, access, convenience, and confidentiality as well as the sustainability of present prevailing models of care. Choice and empowerment sounds good - but is it any practical help when you are seriously ill or coping with chronic disease? But looking ahead for users, the prognosis is good – they will be better informed, and more notice will be taken more notice of their individual preferences. They are likely to be given more responsibility for their own health, but there is still a large gap in understanding between them and other stakeholders that will have to be addressed at local as well as at national level.

Much of what we have learnt in the past decade is not actually new, but rather a more pragmatic reflection of the difference between popular perception and prevailing reality.

Healthcare is about people and if eHealth is to make a major contribution, as the eHealth community and its stakeholders believe, then it must be more people oriented. Not just for government or politicians; not just for clinical professionals, nor indeed for health managers or civil servants. We have learnt that the paternalistic model of healthcare is breaking apart at the seams under growing pressures of demand, demography, choice, public health and patient safety.

New business models are now required where the citizens are given both choice and responsibility; where this is encouraged and informed; where clinical professionals, as just one part of a strictly finite set of high quality resources, are supported and informed to be more effective, to work as part of broader care teams looking towards more personal and personalised care; where regions, national governments and politicians are confident enough to allow the principle of subsidiarity and delegation to be applied; and for common sense to break out in healthcare. This is not going to happen overnight but more likely over an extended period of time in order to release the full benefit potential of eHealth.

There are already some clear signposts for the way ahead. For example, the progress being made in Sweden based on the national eHealth strategy. There is a bewildering array of different telemedicine projects, mostly small scale and locally focussed, but with the potential to be deployed more widely given the right supporting infrastructure, reimbursement and political will. There is already some genuinely innovative thinking typified by the multi-award winning Virtual Ward Disease Management Project initiated by Croydon Primary Care Trust in the UK. The initial concept is now well proven and accepted, and local community strategic thinking is focused on second phase issues about how eHealth can effectively add value and support new models of care.

We have learnt that eHealth is no longer subject only to RTD, and that support must now come from different funding programmes and initiatives. The Lead Market Initiative (LMI)3 and the recent ICT Policy Support Programme are both examples that are moving the focus towards local deployment. There are many good initiatives just started, with projects such as Calliope (Call for Interoperability in eHealth)4, epSOS (Smart Open Services for European Patients)5 and Commonwell6 notable leaders. The focus is now on interoperability, telemedicine, personal health systems. But the real potential for connecting to care episodes, consultations, patients and citizens is still far from fulfilled.

We have learnt that healthcare is not just about politicians, ministries and clinicians or even just patients and citizens. It is a complex joint working collaboration between many stakeholders all of

2 The briefing paper "A Patients Charter for eHealth Information System" is available at https://www.ehtel.org
3 To read more about the Lead Market Initiative, see http://ec.europa.eu/enterprise/leadmarket/leadmarket.htm
4 To read more about CALLIOPE, see http://www.calliope-network.eu/
5 To read more about epSOS, see http://www.epsos.eu/
6 To read more about Commonwell, see http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=4589

whom are beholden to different pressures, agendas, external dependencies and codes of conduct which conflict at as many points as they converge. We have also learnt that collaboration is only effective when it is underpinned by active commitment and involvement of all the various parties.

We have learnt that, despite considerable investment, industry does not yet have the capability to apply itself to health as it has done to most other industries; there is no effective global market and still no common solutions. Everything remains bound up with existing interests, politics, resources and essentially insular thinking. But we have seen some progress here too, with Microsoft and Google both taking major initiatives. We have seen Intel come forward to initiate chip level standards, working hard with many other companies in establishing Continua as a practical and down to earth initiative to overcome some of the discrepancies among technology components. We have seen the inexorable rise of Open Source as an alternative model for reducing the constraints of technology 'lock in'. Perhaps most importantly we have now seen the beginnings of convergence between IT, telecoms, medical equipment and medical devices.

What we have still not seen is any truly scalable collaboration model to overcome the silos and protective interests in healthcare. Historical 'legacy' models are still there, as are ongoing turf wars between primary and secondary care, between specialties, against change, and against the citizen-centric service model. Somehow, eHealth is still buried underneath all of this, struggling to extricate itself and prove that it really has the potential to help address the demographic problems that lie ahead.

What we have also not seen any clear and unequivocal business case for eHealth, or even for its component parts; we have not seen clear explanations of what eHealth can do, for whom – and how to go about using it. Where are the good practice examples?, What sort of collaborative models work for which stakeholders and addressing which operational objectives? How can the results and lessons learnt be presented to a wider audience so that people in local communities can understand how they, too, can implement ideas and proposals to deliver better, more effective, more personal care with better value for money. We have known for some time that existing cost savings model are too simplistic for eHealth7, but we will still need to spend time and effort finding answers which are honest, and clear but also effective in a practical local care environment.

The third stage of Deployment (2009 – 2019)

The third stage of deployment (2009 – 2019) will be a challenging one for healthcare. Many of the issues that have been a feature of this sector over the last twenty years will come home to roost. Cost will as ever be the prime one – how will Europe and its Member States cope with the rising cost of healthcare provision (and the financial crisis will not make this any easier). The prognosis from the US is not encouraging with costs already at 14% of GDP and projected to go on rising towards 20%.

Demographic patterns across Europe clearly show an ageing population with more and more people in the age groups associated with higher proportional costs. Widespread increases in the incidence of chronic disease are a testament to our growing ability to avoid premature death – but also an economic millstone that demands changes in the way chronic disease is managed. Diabetes is only one example where there are already insufficient clinical resources to meet current clinical guidelines – incidence is forecast to double over the next decade, but specialist clinical resources are likely to reduce in real terms. New drugs, new procedures, new equipment are emerging to help, but unit costs are rising rapidly. This is only a snapshot of how existing health infrastructures are already struggling to cope.

7 Pttation given by Tom Jones ACCA at the first high level conference on eHealth organised by the European Commission in Brussels May 2003

Beyond this, there are new opportunities and challenges – the concept of personalised medicine, the use of stem cell technology, genomics and proteomics and many others will develop and provide new ways of protecting and preventing disease. But in doing so, we risk radically changing the balance and economics of healthcare. Alongside all of this are ongoing societal developments – the politics of choice and delegation of responsibility; location of management and control; increasing concern about safety and quality; and moves towards self-management (seen by some as the only way to constrain rising cost and meet the expectations of voters). It is a faint hope indeed that the healthcare sector will become less complex, or that there will be simple answers to the demands being made. While much can still be done by organisations like WHO and at European and national level, the hard reality of healthcare will increasingly be evident at personal and community levels - and it is here that information has to be the lubrication for real progress.

Prior to the current financial crisis, the European context for IT was already moving in the right direction, with increased interest from major players and SMEs alike along with movements to bring IT along side medical equipment on the supply side. However, recently it has started to look as if Europe (traditionally strong in the healthcare technology field) may be beginning to lose its competitive edge. Traditional IT suppliers (many of them now operating as services suppliers) have had a mixed time recently in the UK and elsewhere, while small specialist suppliers have been decimated in some markets. This financial crisis will hopefully help to focus minds within the IT industry. But healthcare does not necessarily offer straightforward options to replace declining financial services revenues. Some of the reasons for this are that health is a difficult market to engage, often not knowing what it wants or what is likely to be realistic. There is no effective hierarchy of decision making, and still considerable suspicion and mistrust between healthcare and IT industries. This is evident in the adversarial procurement and contract management typified by the National Programme for IT in England, where Local Service Providers are struggling with Cerner and iSoft to deliver effective care record solutions. But behind this there is a more serious issue – that of encouraging smaller suppliers with existing healthcare solutions or new technologies and technical innovations. If, as we have said before, successful deployment of eHealth depends on collaboration between stakeholders, then we have to find a way to bring along industry, both large and small, and it has to be a way that provides both opportunity and motivation. Most importantly, it also has to allow them to identify with (and share) wider strategic goals for healthcare service delivery.

Given these contexts and the current economic crisis where we are now with eHealth? We know there are no simple answers or panaceas, no single immutable way forward. We know that eHealth is just one (albeit a key one) enabler for healthcare transformation. We are close to having the technology we need, including interoperability of information and the systems that share it, but not yet the transformational change mentality nor the flexibility of approach to collaborate and share. But we are beginning to see an awakening stakeholder awareness of the true potential value of eHealth. As yet the eHealth community is still too small, too narrow, still talking to the converted, not inclusive enough and not yet identifying with fundamental grass roots of healthcare transformation.

So we are still only at the threshold of the third stage, where healthcare is facing huge challenges from all sides. eHealth is accepted as an idea but not yet as a practical, valuable and essential support tool for facing many of these challenges. Now we have a global financial crisis which will inevitably impact, and exacerbate, many of the problems facing healthcare. For eHealth, the crisis underlines the challenge of investing now to keep our heads above water - and taking bold steps forward towards 21Century care.

The direction of travel is towards information based care, built on evidence and collaboration; towards more informed self-management and responsibility for both patient and citizen. The role

of technology will increasingly be to provide and support this information from the lowest level upwards, deriving management, public health and research information gathered at the point of care and as an integral part of the care process. Critical success factors will be based on effective local working, together with mechanisms to share, inform and educate across the wider continuum. Technology has to become the servant of care, delivering eHealth as close as possible to citizens and patients, bringing subsidiarity into healthcare and enabling results that people on the ground want and need rather than what others in the chain think they want, and being able to assess value by outcomes within the care conversation.

We will only begin to make real progress by learning the lessons of the last two decades, putting them into practice wherever they are effective, by understanding the complexity of the healthcare process following good practice by decomposing the complexity into manageable components and managing at that level. We have to work harder to bring stakeholders together looking for synergies and common purpose. We have to find ways to bring initiatives at all levels into a form that makes sense and where conclusions, good practice and advice can be generated and shared. We have to find ways to bring industry on board, and get them involved, in learning where best to invest, with whom and why successful partnerships are so important. We also need an informal infrastructure of collaboration and communication, so that everyone who needs to know can find out who is doing what and where, and with what results.

Our aspirations for 2019 should include a much more common community care model, irrespective of funding sources, where information is an automatic by-product of the care process, eHealth becomes just an integral part of care, and where IT and medical technology converge at the level of usefulness and value. Innovation has to be encouraged, rewarded and deployed, reducing not just 'time to market' for products and services but also 'time to generate value' in successful user deployments. Most of all, a pragmatic information base is needed to enable an improved balance between quality, access and convenience of care.

We recognise this as "one of the grand challenges facing mankind" as described by the US National Academy of Engineering8 but we are confident that Europe will rise to the challenge.

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8 News article e-health-insider.com/News/3480 February 2008

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# Medical Informatics 2040: Reengineering & Transforming Healthcare in the 21st Century

## 1. Introduction

Management Strategies. In their recent book entitled "Medical Informatics 20/20" published by Jones & Bartlett, the authors talk about key management strategies and selected health information technologies that healthcare executives should be focused on over the coming decade. The management strategies include Collaboration, Open Systems, and Innovation (COSI).

HIT By 2020. The key health information technologies (HIT) to be deployed over the next decade include Electronic Health Record (EHR), Personal Health Record (PHR), and Health Information Exchange (HIE) systems. The authors have projected that by 2020 –

- 80% of health care provider organizations will have implemented EHR systems in the U.S.; approximately 20% will still lag behind and not quite be there.
- 80% of the general population will have started using PHR systems in the U.S., and 20% of the population will not.
- 80% of EHR and PHR systems in the U.S. will be linked via HIE networks; 20% of these systems will still not be connected.

Emerging HIT Solutions. While the fact achieving those objectives will lay the foundation for dramatically improving healthcare, radical reengineering and transformation of health care will start to come about when the following emerging health information technologies are eventually implemented in the coming decades.

- Genomic Information Systems & BioRepositories integrated with EHR Systems
- Nanotechnology & Implantable Health IT Systems interfaced to EHR and PHR Systems
- Advanced User Interface Solutions, e.g. Wearable Systems, Health Apps, and eGame Technologies
- Health Information Exchange (HIE) with other Industries/ Sectors, e.g. Banking, Security, Manufacturing, Pharma, etc.
- Televideo & Home-based TeleHealth solutions interconnecting patients with health care providers

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Keywords

Health information technology 2040; health informatics 2040; medical informatics 2040; eHealth 2040

"This article is aimed at shifting the discussion of Health information technology (HIT) solutions and management strategies that may be dominate our attention in the 2040 timeframe.."

- Medical Robotic devices interfaced to Health IT (HIT) systems
- Complementary & Alternative Medicine (CAM) information systems modules integrated with EHR systems

By 2020, these emerging solutions may only be used by 20% of healthcare providers and patients in this country. However, the time has come to start focusing our attention on these cutting edge technologies, their development and on how they will be effectively employed to further transform healthcare over the coming decades. Many of these emerging solutions are heavily attuned to serving the needs of individual citizens. There are still many technical, legal, ethical, social and other issues that must be addressed before widespread implementation of these systems occur in the 2020 – 2040 timeframe.

## 2. Future Scenarios – 2040

Genomics, Preventive Care, and Public Health. By 2040, it is conceivable that every U.S. citizen will be required to have an entry in a national biorepository and genomic information system. This will be needed for a wide range of reasons from national security, public health, immigration control, citizen identification, resolution of crimes and more. Genomic information systems will be integrated with EHR and PHR systems and will allow for early identification and treatment of individual disease/ healthcare issues. Hard data will be yielded from these systems allowing providers to better treat their patients and government and researchers to target time and resources on specific diseases/ conditions. Medical schools and provider organizations will be able to train and employ the right mix of specialists to treat their patient population. The focus of health care will dramatically shift to preventive health practices instead of the current practice of treating patients after the fact.

Nanotechnology and Implantable Systems. By 2040 most citizens will have made the choice to have an implantable nanotechnology device that will be tailored to meet a number of their personal health and medical care requirements. For example, these interactive implantable medical devices could be used to more accurately identify patients who are unable to communicate, for some reason. The device could be programmed to contain key clinical information about a patient in an emergency care situation. It could also be programmed to be used as a tracking device for Alzheimer patients. Based on one's genomic information, the implantable device could be programmed to monitor specific conditions, and to dispense medication as needed while simultaneously alerting one's healthcare provider. The implantable medical device would be able to wirelessly communicate or interact with the more robust, 'smart' EHR or PHR systems of the future.

Health Apps, Robotics, and Wearable Systems. By 2040, a number of other emerging technologies such as medical robotics, health gaming technologies, and wearable health IT systems will have evolved and be widely deployed. Complementary & Alternative Medicine (CAM) information modules will be incorporated into more robust, 'smart' EHR and PHR systems of the future as healthcare goes global and embraces knowledge and effective healthcare practices from other cultures. These technologies and solutions will complement and further support the continuing evolution of healthcare in this country, especially as it becomes more citizen-centric in its focus.

## 3. Conclusion

New Management Strategies. It is time for the more forward thinking health IT executives, clinical informaticians and citizen/consumer advocates to begin the process of shifting the emphasis of

their strategic thinking out to the 2040 timeframe. We all need to embrace the transformational management strategies needed to be operate successfully in the 21st century - Collaboration, Open Solutions, and Innovation. It is time to move beyond dated management strategies that emphasize authoritarianism, secrecy, and convention.

Transformational HIT Solutions. Radical reengineering and transformation of health and healthcare will not occur solely as a result of acquiring and implementing EHR, PHR, and HIE solutions. These solutions are currently attracting 80% of our current investment and attention and will be largely in place by 2020. It is when we couple the innovative, cutting edge technologies (e.g. genomics, implantables, nanotechnology, robotics) with the EHR, PHR, and HIE systems that radical changes will really start to happen. These emerging technologies currently garner less than 20% of our investment and attention, yet, looking ahead, they will provide 80% of the expected tangible benefits to be reaped from embracing new solutions over the long term.

Leading healthcare provider organizations should seriously consider collaborating with other organizations on pilot projects utilizing these innovative, cutting edge health IT solutions.


***This article has barely touched upon the future. What health information technology and related solutions do you think we need to focus on as we extend our horizons and start to look out to 2040? Please send your ideas or comments to the editors of this journal or Peter Groen (groenpj@cs.com), Director of the Shepherd University Research Corporation (SURC) and the Virtual Center for Collaboration, Open Solutions, and Innovation (COSI) in Health Care - see http://www.shepherd.edu/surc/cosi***

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Health eGames – http://www.iconecto.com and http://www.gaming4health.com/ COSI Web Site – http://www.shepherd.edu/surc/cosi/

[Also, see http://www.hhs.gov/myhealthcare/news/phc-report.pdf

This HHS report, "Personalized Health Care: Opportunities, Pathways, Resources," presents a long-range plan for achieving more individualized treatment for patients, especially by using genetic information and healthcare information technology.]

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# Decision Support Systems in Health Care: towards a Simulated Health System

## Decision Support Systems in Health Care: towards a Simulated Health System

### Executive Summary

Computer-based decision support in health care with the application of simulation methods is receiving attention at European level as the indisputable advantages of these methods are getting widely recognized. Managerial and policy decision support however, have still to find their way into the forefront of the European developments. Relevant attempts remain fragmented and introvert, resulting in reportedly slow adoption rates by real practice.

This paper draws upon a framework of two interlinked practical cases, one from the private and one from the public sector, to portray its message. The first case follows a typical approach, where mainstream methodology and traditional implementation hinders the realization of a wider value proposition. The multidisciplinary collaborative approach of the second case responds to these identified limitations and is used to demonstrate the 'openness' of such tools and the array of potential results that can be achieved.

Inspired by the Virtual Physiological Human research objective, we extended this practical set of cases to a wider framework for collaborative and multidisciplinary multi-scale decision support. This framework aims to spark new directions in line with the EU ehealth agenda to better target and assist health authorities and managers.

The paper identifies lack of simulated-mass and simulation interconnectivity as a significant and underemphasized adoption barrier and recommends practitioners to turn to 'open' interoperable models as a mean to address the systemic complexity of high level decisions and to add sustainability to their work.

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Keywords

Decision support systems, simulation modeling, interoperability, impact assessment, epidemiology

> "Taking under consideration the complexity of executive decision making in the case that these systems were to be used, one could not help but wonder on how these decisions are currently being taken, when such systems are largely ignored."

## 1 Introduction

Information and communication technologies in health (also referred to as eHealth) are receiving reasonable attention, as their beneficial impact in the quality, access and efficacy of healthcare is getting widely recognized. The need to increase the adoption of these systems is well established both in the European and the US health agenda, as the health industry is growing more and more knowledge intensive. Medical practice is steadily embracing innovative ICTs to enable better cures and better means for early detection of diseases, although some scepticism exists about whether this process could be faster. Cutting edge European eHealth research has led to significant technological achievements, covering a wide range of health services, which have nevertheless failed to reach sufficient deployment in real practice. The adoption rate of technologies that focus on better practice management and administrative needs is reportedly (Wickramasinghe & Geisler, 2007) slower than that of the other eHealth applications.

Current European research in eHealth focuses on three eHealth aspects: Personal health systems, patients' safety and the virtual physiological human. Computer-based modeling and simulation are largely applied in two of the three priorities, indicating the potential of these methods and the recognition they enjoy in supporting medical decision making. These methods, however, have a significant history of application in numerous decision support health cases, where the objective is of a managerial or policy nature. Decision support systems (DSS) have shown moderate potential (and systemic weaknesses) in solving managerial problems that highly correlate to those that the European eHealth agenda sets forth as highest priorities, yet are somehow treated as a future issue, with health related data quality to be considered a primary burden.

In this paper we build upon a set of two recent practical cases, developed successively, to stress both why and how we could change health care decision support. The first case is a typical simulation application for a private health center, member of a leading corporate group, which although technically successful, comes short in achieving a larger value effect. The second case, developed with the international collaboration of the Medical school of Aristotle University, the Skin Cancer Center of Charite Berlin and the Erasmus MC, Department of Public health, answers to the weaknesses of the first case. An overview of both studies is presented here to serve as a basis for an extended framework of a multidisciplinary DSS. The functionality and the main features of this wider framework are discussed along with the potential of this type of initiatives over its limitations and shortcomings.

This paper aims to:

- Provide a practical example of the limitations of traditional decision support.
- Provide a good example of real collaboration and good multidisciplinary DSS development to respond to these limitations.
- Present a basis for discussion on future collaborative tools with application on the crossroads of policy making, patient management and technology.
- Contribute to the European eHealth agenda by providing new knowledge to support health authorities and health managers and utilize eHealth evolution and potential for better health care planning.

## 2 Developments and challenges

The demand for health care services is on the rise, as the European population is ageing and constantly seeking better and more access to health. It is estimated (Braun et al, 2003) that in 40 years, 65-year-old Europeans will account for 40 % of the population. Ageing however is not the only determinant of demand increase, as modern lifestyle and the rising prevalence of diseases due to increased risk factors, further contribute to this demand boom. On the supply side, health care providers face scaling costs and competition over both customers and resources, while investment risks are growing and legal frameworks are getting tougher. The stress-equation that is shaping over the health system is reflected on the underlying challenge to provide the best health care under the limited budgetary conditions. The use of eHealth applications is believed to bring a beneficial impact on both sides of this systemic problem, but its adoption is so far slower than expected.

### The European eHealth Agenda

According to the European eHealth agenda, health authorities and managers responsible for the proper organization and running of health systems are hindered by the limitations of today's paper based aggregation and data processing in facing the increased budgetary pressures against the rising patient expectations (An action plan for a European eHealth Area, 2004). These limitations however are placed within a data quality spectrum, which although is very likely to be correct, represents only part of the problem. Timely, directly comparable data and infrastructure for collaboration are believed to empower health authorities to manage public health. The eHealth agenda further stresses the need for information processing in dealing with the complexities of health related information and knowledge without, however, realizing in full the implicated difficulties.

### Supporting decisions

Providing the right data to health stakeholders is undoubtedly a big challenge. It is also undisputed that eHealth has contributed to the collection and storage of health information that is vital for a knowledge-based domain -such as health care- to thrive. Aggregation and analysis of these data into meaningful information is however, still lagging in progress as we move from database management to model-based management technologies (Tan, 1998 and 2005). Decision support and data utilization are falling short of our expectations, not only because of incomplete or non-comparable data but also due to the lack of a systemic multi-disciplinary approach to their analysis. DSS are not widespread (Kuljis et al, 2007) and usually fragmented to the extent of a single model or specific solution, with little re-usability or extensibility.

It is our belief that eHealth will in time be able to provide data as it is described within the agenda, but even then we will still be in need of efficient methods to be able to utilize them. Health stakeholders are facing ever-rising decision complexity with stale tools. The truth is that there is only scarce and fragmented effort to point out and work through this particular problem. Such foresight research could fasten the eHealth uptake and shed some light on what exactly we need to be collecting and how.

## 3 Decision support systems in health care

DSS supply managers with information and they propose solutions in semi- or unstructured decision-processes. DSS consist typically of repositories for data (i.e., databases or data warehouse), methods and models as well as sequence control systems. Health Decision Support Systems (HDSS) have been following the developments of mainstream information processing with a small time gap. From the

isolated diagnostic systems for research and training and the pioneering clinical decision support tools of the mid 50's to the clinical and administrative integration systems of the 70's to the 5th generation formal model technologies such as fuzzy logic Neural Networks and Graphical User Interfaces, HDSS has been widely applied to the health sector (for a more detailed reading in HDSS historical development see Tan, 1998).

Long application history, short success track

In this paper the method proposed and used is simulation modelling. Simulation has been used for modelling health care systems for over forty years. Health system simulation, simply put, is the application of modelling and computer simulation methods to study the interactions between individuals and/or components of a system and how these interactions over time produce the behaviour observed in the healthcare system (Lyell et al, 2008). Simulation has been applied to a number of health care areas (Homer & Hirsch, 2006), as can be seen in the table below. For a solid and consolidated reading on simulation applications in health care, a non technical reader can consult Fone (2003).

| Application Areas in Health Care |
| --- |
| • Disease epidemiology: heart disease, diabetes, HIV/AIDS, cervical cancer, chlamydia infection, dengue fever, and drug resistant pneumococcal infections<br>• Substance abuse epidemiology: heroin addiction, cocaine prevalence, and tobacco reduction<br>• Patient flows in emergency and extended care<br>• Health care capacity and delivery in areas such as population health planning, dental care, and mental health, as well as how the health system will be able to cope with natural disasters and terrorist acts<br>• Interactions between health care or public health capacity and disease epidemiology (Hirsch G, 2004 and 2005, Homer J, 2005)<br>• Performance management<br>• Evaluation of the performance and impact of information and communications technology applications on health care (Anderson, 2002), including Computerised Physician Order Entry systems and electronic prescribing systems designed to reduce medical errors leading at adverse events. |

***Table 1 Simulation applications in health care***

Despite the long history of application and the wide range of areas it covers, simulation is not widely used in practice. Indeed, simulation is in many respects the ideal approach for addressing healthcare issues, yet the relatively small number of successful implementations suggests that it has been underused in the health sector (Brailsford, 2007). The gap between "suppliers" and "customers" is rather big, and in a sense demand never met supply. Simulation experts are failing to understand customer's perceptions (Robinson & Pidd, 1998) and are still pretty much trapped in an obsolete "manufacturing" approach.

It is clear that simulation practitioners need to put new practical and innovative ideas on the table, try out new multidisciplinary and "open" models to combat fragmentation, and pay attention to their after-sales efforts to better support their results. The need for interoperable simulation modelling is surfacing, as stakeholders begin to realise the systemic inter-connection of the health system. It is on these identified gaps that this paper aims to contribute by adding a new perspective through the two-case framework presented in the rest of the paper.

## 4 The Corporate Health Group Case

This first case can be characterized as a typical simulation application in health care. By typical we mean the business-as-usual approach that is largely followed by decision support studies with simulation. Mainstream methodology is applied in a project-oriented attempt to enhance managerial decision making, and the main results as well as post-project findings are outlined here, to help showcase the limitations of the overall approach and to prepare the ground rationale of the second case.

### 4.1 Scope and methodology

The subject of the case study is a health center, member of a leading corporate health group, in the process of relocating to a more strategic location. The health center has been operating successfully for many years, and enjoyed a good reputation and stable growth. Under this opportunity, management decided to launch a simulation project to assess the old status, and project the current model to the future structure of the center, just before final arrangements were to take place at the new facility. The center's management is particularly interested in addressing three issues:

- Current status assessment (in terms of resource utilization, quality of service).
- Modeling of the new center and performance assessment.
- Performance test in situations of increased service demand.

Corporate management, however, is overly interested in a tool to assist its decision-making at operational level. Management reports, resource lists, and financial results are not adequate to facilitate precise and effective decision-making on higher levels of management, yet they are still considered the main tool for operational analysis.

**Overview of Methodology**

The methodology implemented in this study was based on commonly accepted Discrete Event Simulation methodology (Banks et al, 2004). An action plan was designed to break down work, to assign the work among the study team and to time-schedule the project. Below are the main methodological steps that were followed:

- Problem formulation and study plan
- Requirements specification
- Data collection Model definition
- Draft basic model and pilot run
- Basic model modifications and validation
- Design of the new center model, validation and acceptance
- Experimentation (What-if scenarios)
- Results (Performance assessment / comparative analysis)
- Suggestions/conclusions, management report

## 4.2 Implementation and results

Implementation was carried out by a single team of simulation modellers and was completed with the involvement of the centre's management in most of its development phases. Two main conceptual models were developed and tested for a number of validation tests. Data was primarily fed by the centre's ERP system and the operational manager's expert opinion. Computer modelling was assisted by a commercial simulation solution. The figure below illustrates a part of the conceptual model used in the simulation.

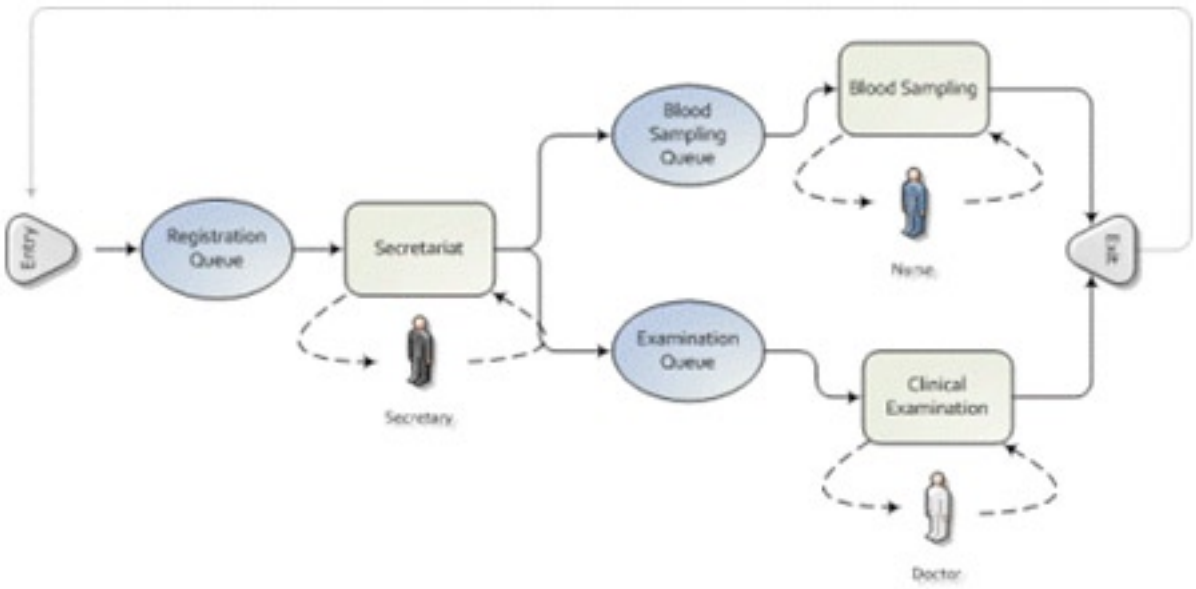


*Figure 1: Snapshot of "Floor Two" conceptual model*

Three main experimentation scenarios were elaborated with the respective results grouped under each. The experimentation results provided support in:

- Assessing the old center format and provide meaningful analysis of the workflow and resources, that checked with the knowledge and understanding of the manager.
- Formulating the new format out of the old and identify key implications of the layout change. Detailed workload balance analysis and recommendations were given.
- Anticipating repercussions of a given future demand rise in the new setting and a potential reduction in staffing.

## 4.3 Project implications

The results were presented to the centre's management and they were accepted as rational, credible and very helpful. The company implemented the study's main suggestion and did not reduce its staff. One year after the launch of the new center the manager was asked to verify and assess the impact of the results and recommendations that were given to him. The new center was launched with remarkable success and its management enjoyed a staggering increase in demand for its services. This resulted in a "bloom" in the center, which added a series of new services, and numerous new personnel to service the growing demand. All these "unexpected" changes made most of the

simulation recommendations obsolete, greatly reducing the study's impact.

This post-project assessment reveals a series of serious limitations to this typical approach that are shared by similar cases. The poor predictions, which provided the basis for experimentation and rendered the whole study irrelevant, should not be viewed as bad methodology, but rather as a lack of a multidisciplinary focus on implementation. The discontinuation of post-project support and the limited time scale, for which the study was intended, further limited the opportunity to add value through a more service oriented approach. The lack of openness or connectivity or a post-utilization plan drastically limited the post-project value, and all the work effort encapsulated within the model remained largely unutilized. Consequently the possibility that the group further adopts such methods is and will remain fairly small.

# 5 The Skin Cancer Center Charite Case

In this chapter a real case of particular interest is presented: an international multidisciplinary consortium collaborates to design a tool to assist in the strategic decision making. Traditional epidemiological modelling is combined with discrete event simulation for empowered experimentation. The objective of this chapter is to use this case outline as an (good) example, upon which a wider framework will be built in the next chapter.

## 5.1 Scope and methodology

Based on the identified weaknesses presented earlier in the first case and within the already established collaboration among the Skin Cancer Center of Charite Berlin (SCCC), the Aristotle University Medical school and the Public Health department of Erasmus Rotterdam, a research plan was created to guide the actions aiming to design a decision support method/tool to facilitate strategic planning and short-term capacity assessment. The physical simulation objective was the SCCC and the final tool user is SCCC executive management.

The initial objectives set early in the plan included the following:

- Develop a tool that applies forecasting methods to predict long-term demand changes and simulation to test if these changes can be serviced by the current infrastructure. If these changes cannot be supported, pinpoint the pressure points and produce strategic planning recommendations.
- Assess the current SCCC 'system' and recommend potential improvements.
- Provide Charite management with a powerful tool to:
    - assess their capacity, resource utilization, and Customer service and,
    - experiment with what-if scenarios and get strong response results.

### A new methodological approach

The methodology deployed to reach these objectives was divided in two components, 'forecast' and 'simulation'. The first component is devoted on the management of the development of the epidemiological part of the study that aims to predict future demand for skin cancers.

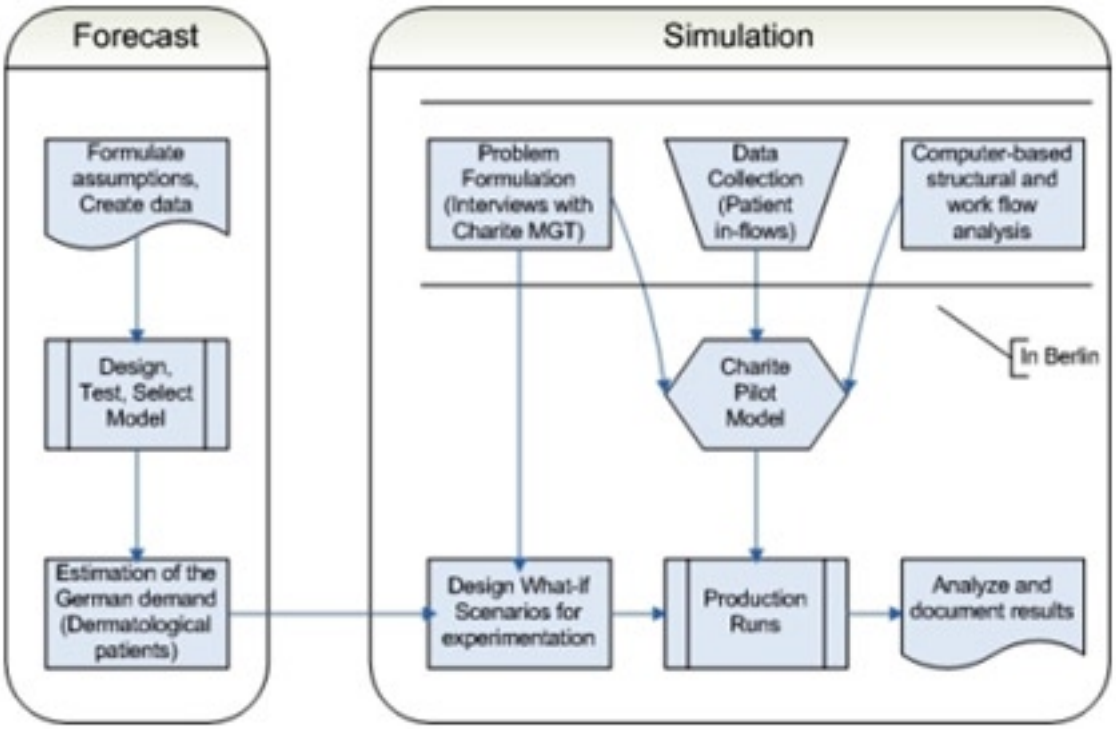


***Figure 2 Methodology of the research plan***

In the second component, a typical DES methodology is followed and executed in three levels – Data collection, modeling and experimentation. As can be seen in the figure above, component 1 feeds the experimentation scenario design module of component 2.

In this scheme, using the predicted number of incidents on the basis of population projections and risk factors, we design a specific experimentation scenario: what if the current center had to deal with the future (10 years horizon) demand? Then with the simulation model, we test that scenario and assess the center performance and move on to corrective actions. After this experimentation, the results are validated and analyzed to provide meaningful recommendations.

## 5.2 Implementation and overview of the results

The project was developed according to the above methodology. The forecast was based on Berlin population projections for 2018 and Dutch skin cancer incidents as collected by two cancer registries. With the use of simulation software the actual SCCC was modeled and the experimentation scenario was used to assess the center's capacity in increased demand. Below is a figure of the SCCC activity diagram used in the simulation.

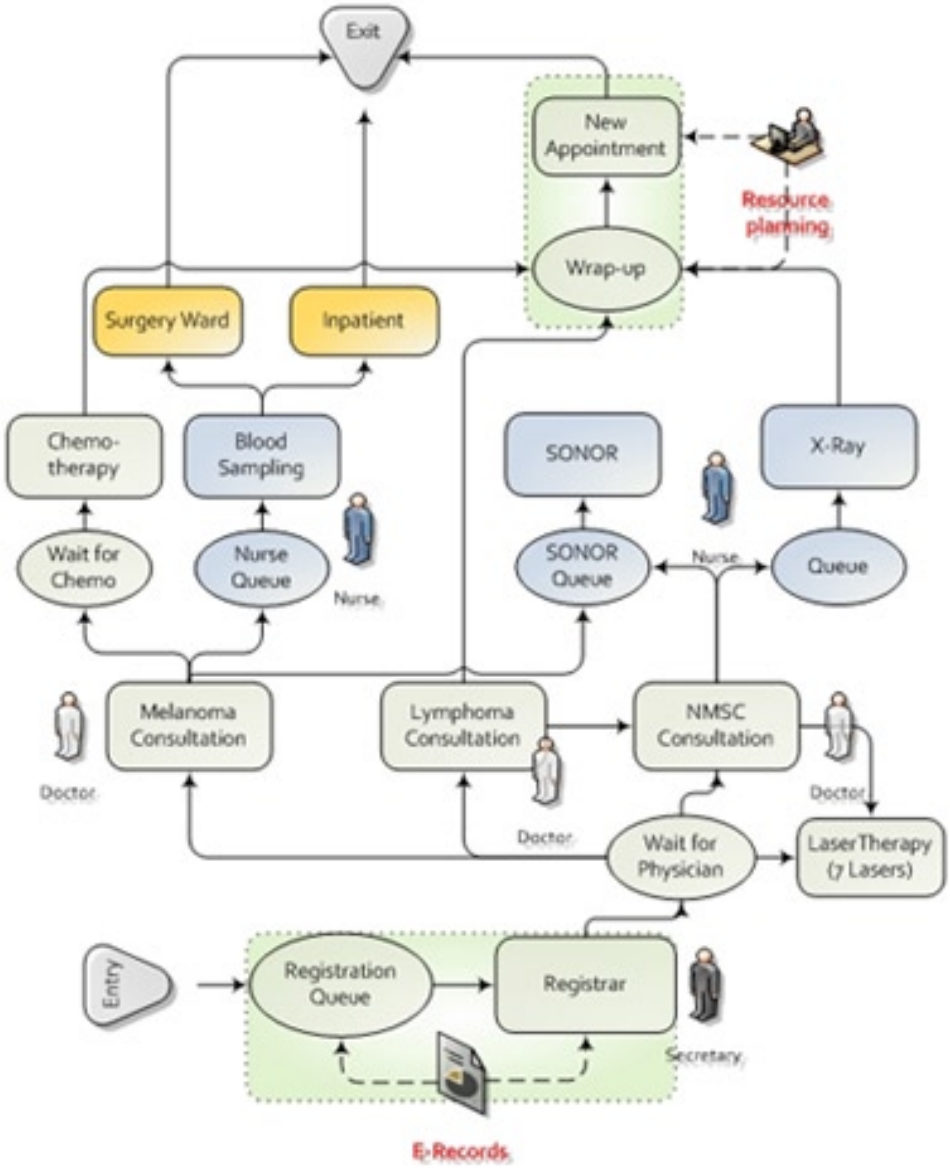


***Figure 3 The SCCC cycle diagram***

The project implementation was successful in:

- Assessing the current quality of customer service (in waiting times, time in system), resource utilization (percentage of working vs. idle) and identifying potential bottlenecks and corrective action.
- Assessing the ability to service the increasing demand without decreasing the current quality of service (as reflected by time physician allocates to patient) and identifying the human resource needs in a 10 years time-frame to meet these conditions (increased demand under the same quality).
- Presenting an open model for reuse of the SCCC layout. SCCC is considered a rather unique skin cancer center in European dermatology, and it is important that its model is open for anyone to get insights on its operation.

### 5.3 Post project utilization

The project is considered complete in meeting the initial objectives, although, as we were taught by the first case, there should always be a safe time before a study of this kind can be considered successful. One of the most important achievements remains the fact that this tool, if maintained updated, will be able to feed on identified changes in skin cancer prevalence to always be proactive in assessing and addressing the impact of these changes on the center's operational performance. Connecting epidemiology to operational management, however, is only a part of the bigger picture. The conceptual framework as presented here could be a receptor of more horizontal 'add-ons' like innovation diffusion models to include the technology evolution effects.

**Empowering assessment**

In addition to the use of the tool as intended in the original research plan, the tool can be flexibly used to assess numerous other possibilities. The model architecture is open to meta-analysis and experimentation on practically anything that has something to do or can be linked to either epidemiology or operational function. Interventions that aim to improve the operational performance by simplifying or facilitating administrative procedures could be easily assessed by the tool that is already developed. Inspired by two good European eHealth practices (RPS2 -Resource Planning System, and FLOW- national health care network), for instance, we could easily answer questions as to what would happen if the SCCC management would adopt similar solutions, or better put, what the operational impact of such an intervention would be.

In Figure 3 we isolated and indicated (with light green) the area of operational impact that would be affected by the implementation of an appointment facilitation system (like RPS2) and an E-record system. These systems will have a real impact on actual performance time for managing the patient records (at the moment they are hard-copy files) and they would probably diminish the time taken to schedule new appointments and manage all the follow-ups. The organisational changes that these interventions will assert are possible to model and concrete performance results can be obtained to support a decision about whether this investment will have a significant impact operationally.

The added value to the approach of this method is in the dynamic and analytic nature of the results it provides. Mainstream operational impact assessment is most of the times limited to a simplistic static numerical estimation of effect (e.g. percentage of decrease in administration time needed per file, aggregated to the number of files and average time of files processed). This method however simply gives a static preface of the ramifications of effects this might have in a system of thousands of interactions.

## 6 Towards a simulated Health System

The two cases presented above have shown how a logical reparative progression can lead us to new ideas to understand and exploit the value map. So far we have been able to connect epidemiology as a forecasting method to simulation modelling as an operational performance assessment tool, and we also provided a theoretical extension example with two interventions of administrative nature. Epidemiology, however, uses risk factors and historical data to forecast future incidents. Many public health interventions aim directly to the improvement (lowering) of risk factors that are causing disease. A health programme aiming to lower specific risk factors will result in fewer incidents (at least less than those that would have been expected without this action) and our model would be able to assess the operational impact that this programme will have. For instance, a promotional campaign about the dangers of sun exposure aiming to reduce skin cancer could well be assessed

beforehand on what impact this intervention would have on an operational level, in addition to its social impact.

**Widening the framework**

The ambition of this paper is to present a wider framework of decision support and include policy making for the whole health system (local, national or European). The biggest motive and challenge in widening the 'SCCC case' framework is creating critical 'mass'. The health system is a very complex set of heavily interconnected subsystems that altogether operate as a whole, and an intervention in one small part will have an effect on other parts as well. The biggest problem with simulation is exactly this; it is scattered, unconnected, and most of the times abandoned soon after the first results were made public.

In this manner, even successful simulation cases usually model a very specific area, which represents a tiny fraction of a small health subsystem. The SCCC case for example is good for in-house recommendations, but its scope is extremely limited to that of a clinic in a dermatology hospital in Berlin. And if we just think outside Berlin, or the skin cancer treatment, or even the hospital point of view, we will need to have much more of a simulated reality to model and address policy decisions. The same is true for corporate level decisions in the context of the health group and its operational network of 40 business units.

**Ambition and inspiration**

It is clear that the complication of a project simulating, a health system (or a subsystem) would be very costly to implement centrally. The perception of the difficulty of interconnectivity runs so deep that some experts have come to consider it unrealistic (Salt, 2008). Inspired, however, from the impressive Virtual Physiological Human research objective (translate all functions of the human body into a coherent set of multiscale computer models), where the emphasis is given on the integration of existing models rather than on development of new models (ICT Work Programme 2009-10), we propose to share the same view for the simulated health system.

The level to which integration in simulation modeling is possible practically dictates the percentage and scale-depth of the health system we could actually model. If local simulation models of physical or electronic health systems are to interoperate, mass could be built, and a central system could provide a test-bed for large effect analyses down the interactions chain. It seems more feasible to develop, maintain and update such local systems and try to connect them, than actually design and support a huge health system simulator. Once such a multi-scale integration is achieved, we could well support policy makers in assessing managerial aspects. Adding more multidisciplinary simulation objects will allow combinational decision support (clinical and operational). The above framework is presented in the figure below.

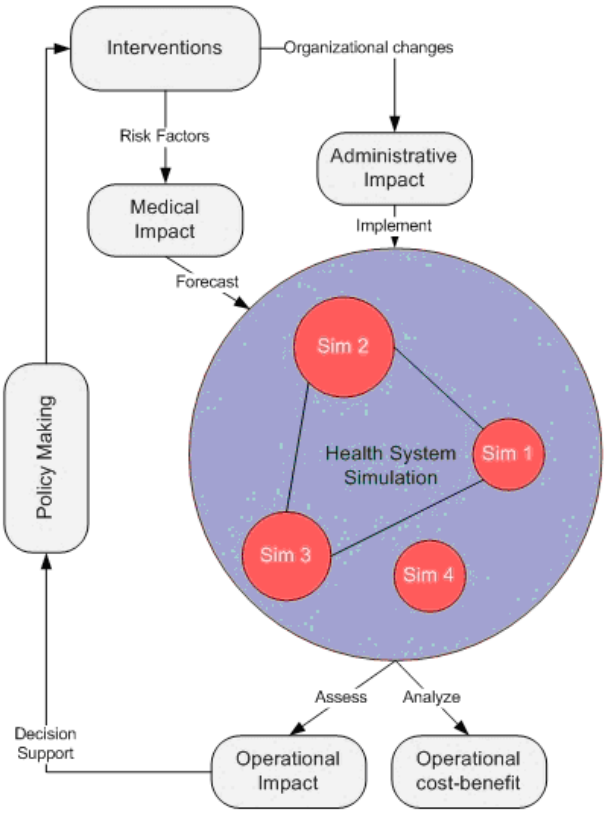


***Figure 4 The extended health system simulation network***

The figure above contains the essence of the methodology that has been developed for the SCCC case. In reality however, it is very difficult with our current knowledge to assess the feasibility of the proposed framework for a number of reasons since we lack the knowledge of how many simulation tools are operable at the moment; there is very little research on simulation modelling interoperability, and 'translating' the medical impact of intervention can be quite problematic due to poor epidemiological data management.

## 7 Conclusions – Lessons Learned

The framework presented in this study aims mainly to provide a new approach to health care management and policy making with the help of ICT tools and ideally spark some new collaborative efforts on the matter. As data collection is becoming comparable and more precise, we believe that these frameworks will not only become more feasible, but they will be part of the everyday decision support practice. The most promising finding so far is that simulation modelling is quite flexible and open to other disciplines and applications and can suitably serve as a basis for other components to connect on. Our team managed is to identify limitations, to experiment with two disciplines, traditional epidemiology and simulation modelling, and come up with an open prototype tool that can be further developed.

We strongly believe that Europe is not utilizing the potential of such eHealth tools, and as a result its health sector is slow in innovation adoption as decision making is rather weak and consequently risk-averse. Decision support in health management and policy making is currently not a priority for the European Union and research is too fragmented to achieve significant penetration into real practice. Regardless of funding and prioritizing this type of methods, we learned that perhaps the most vital

element for successful development is collaborative work. It is therefore important for health researchers to focus on 'open' interoperable models rather than introvert one-shot projects.

Taking into consideration the complexity of executive decision making in the case that these systems were to be used, one could not help but wonder on how these decisions are currently being taken, when such systems are largely ignored.

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# Cameras in your living room, the next step in e-homecare?

## Executive Summary

Although the positive effect from the use of cameras in eHomecare on patients has been demonstrated, it also makes care more privacy intrusive: capturing us on film in our most personal, most intimate environment, our own home. This paper examines the protection of the patient, on the one hand, and occasionally filmed persons, on the other, when using video monitoring systems in eHomecare. Three protective mechanisms will be discussed in this specific setting: the right to protection of personal data, the right to privacy and the right to personal portrayal.

First, images and sounds from a patient made with an observation camera are protected by the Data Protection Directive. There is, however, discussion going on with regard to the protection of occasional visitors. Discussion also arises with regard to the protection of the processed data as sensitive data. The patient's data are likely to be qualified as health data, and thus protected more stringent. Data of occasional visitors are, in contrast, most likely not to be thus qualified. Secondly, the patients themselves will undoubtedly also be protected under the broader right to privacy, but occasional visitors risk to fall by the wayside. Last but not least, the images will also be protected by the right to personal portrayal when the captured persons are recognizable.

Due to these three protection mechanisms, the use of cameras as a next step in eHomecare will currently have to be based on the consent of the patient. Whether or not occasional visitors need to be warned about the use of cameras is, however still open for discussion.

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Keywords

Cameras, health data, privacy, data protection, portrait rights

> "When cameras are placed in people's homes, the images made can be protected by three different legal mechanisms: the protection of personal data, the protection of the right to privacy, and the protection of the right to personal portrayal."

## 1 Introduction

Our society, including our health- and homecare, is more and more confronted with visualization. In hospitals we use high definition x-rays, 3D scanning and observation cameras. In homecare, it has been announced that the use of digital imaging, interactive webcams and even camera-nursing will be soon introduced. There are many benefits brought by this increased use of visualization. However, it also makes care more privacy intrusive. Operating cameras in and around homes is often seen as one of the most privacy intrusive practices, since it captures us on film in our most personal, most intimate environment.

The Belgian IBBT project TranseCare1 is currently developing a video monitoring system, as part of an ICT platform, which can assist people under care and their family and health professionals. The overall objective of the TranseCare platform is to support people suffering from a chronic disease and/or from degenerative disabilities due to age through the aid of an ICT platform. The TranseCare project wants to take the concept of "independent living systems" a step further by among the use of other components, the use of a video monitoring system. Already in the early stages of the project, the consortium came up with two different kinds of systems that could be used. We could opt for a system with cameras that can only be switched on in emergency situations, or a system, which monitors continuously. Within the project, the consortium decided not to develop continuous monitoring. This choice was made, not so much for technological or legal reasons, but mostly with the social acceptance in mind. Legally, specific questions with regard to privacy and the protection of personal data arise in both cases.

This paper will elaborate on the protection of personal data, the right to respect privacy, and the right of personal portrayal, currently being the main legal mechanisms, which protect our privacy, when cameras are installed in our homes.

## 2 Data protection

In Europe, personal data are protected by the Data Protection Directive 95/46EC (hereafter DPD), which has now been implemented by the member states. In Belgium, the implementation of the directive resulted in an adjustment of the Data Protection Act of December, 8, 1992 (hereafter DPA). This paper will however be restricted to the discussion of the DPD, and thus European Law, as much as possible.

As always, the first main question to be asked is whether the DPD is actually applicable to the use of cameras in peoples' homes. Data protection laws are only applicable when "processing" of "personal data" takes place. So to answer to this question, the first issue to explore is the interpretation of those essential terms used by the DPD. It has to be verified whether or not "personal data" are being "processed," when using a video monitoring system in a homecare setting.

In a second stage, a distinction will have to be made between the protection of "normal" personal data and "sensitive" personal data, including health data. It will be examined whether or not the personal data captured by the video monitoring system are protected under the stricter regime of

1 "Transparent ICT platforms for eCare" is a Belgian project supported by the Flemish Institute for BroadBand Technologies (IBBT). IBBT is an independent research institute that stimulated innovation in ICT by order of the Flemish government. IBBT brings different partners, from the industry, universities, non-profit organizations and governments together in multidisciplinary research projects, such as TranseCare. More information on the project and the partners involved can be found on the following website: http://project.ibbt.be/transecare.

sensitive data.

In both stages a further distinction will also have to be made between the protection of the patient and the protection of occasionally or incidentally filmed persons.

### 2.1 Essential terms in the DPD: "processing" and "personal data"

As indicated above, the Data Protection Directive is applicable to the "processing" of "personal data".

The term "processing", according to the Directive, means "any operation or set of operations which is performed on personal data whether or not by automatic means such as collection, recording, organization, storage, adaptation or alternation, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction" (article 2, (b) DPD). This includes any form of handling of personal data, regardless of whether automated processing is involved or not, and from the very first stage of its collection. Given the Directive has opted for a broad definition, reinforced by an extensive interpretation by the Article 29 Working Party2, capturing images with a camera, whether these images are stored or not, clearly has to be regarded as some kind of data processing.

Next, the DPD defines "personal data" as "any information relating to an identified or identifiable natural person, the data subject" (article 2, (a) DPD). Given, again, the very broad definition, both on the European level and, at least in the case of Belgium, on the national level, it is acknowledged that images, just like texts, sounds and even radiofrequencies, can be are personal data, at least whenever they refer to identifiable individuals3.

The DPD does not define when an individual is identified, but since it allows for identifiability, it does not require the last and highest degree of identification, that is, unique identification as for instance by a DNA profile. An individual can also be identifiable when he can be identified, directly or indirectly, by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity. To determine whether level of information is high enough to be qualified identifiable, account should be taken of all the means likely reasonable to be used to identify the said person (Recital 26, Bullesbach et al., 2006). This will have to be assessed case-by-case according to a proportionality criterion. It follows that what is of legal importance is the capability or potentiality of identification rather than the actual achievement of identification. However, whenever the process of identification requires the controller to deploy disproportionate efforts, data will not qualify as "personal" (Coudert & Dumortier, 2008; Bygrave, 2002).

## 2.2 Applicability of the DPD to the use of a video monitoring system

Though the DPD thus has a very broad scope, discussion arises when applying the definitions of "personal data" and "processing" to the use of a video monitoring system and more specific with regard to the images and sounds captured by this system. This is not so much the case with regard to

2 See for instance, Article 29 Data Protection Working Party, Opinion n° 4/2007 on the concept of personal data, WP 136, 20 June 2007.

3 At the European level, this was acknowledged by the Article 29 Working Party in its opinion 4/2004 on the processing of personal data by the means of video surveillance of 11 February 2004, 5 and in Recital 14 of the DPD. In Belgium, this was acknowledged by the Belgian Privacy Commission in both its advice nr. 14 of 7 June 1995 and advice nr. 34 of 13 December 1999.

specific patients, but certainly is with regard to incidentally filmed persons, like the patient's wife or husband, visitors or the cleaning lady.

With regard to the patient who is being observed by the video monitoring system, whether this is a continuous monitoring or not, the applicability of the DPD is clear and generally agreed upon. The camera processes – captures on tape – personal data – the image of the patient. The patient is easily identifiable on the images and the images are made with the intention to identify the patient and his health situation. With regard to occasionally or incidentally filmed persons however, there is no unanimous stand4.

Applicability of the DPD to images of occasionally or incidentally filmed persons

Some, like the Belgian Privacy Commission, are convinced that images of natural persons cannot be qualified personal data when made accidentally or incidentally5. This is because they argue that the purpose for making the images is decisive.

Others, however, do not take the purpose of the processing as a starting point, but rather evaluate the images according to their identifiability. They argue personal data are being processed every time a person is filmed, accidentally or not, at least when this person can be identified without unreasonable means or effort.

Although no explicit statement on the issue has been made, the Article 29 Working Party tended to agree with this second opinion. In its latest opinions, however, the Working Party seems to be mainly aiming for a flexible and usable interpretation of the DPD, and therefore now considers the purpose of the processing as a possible criterion. The Working Party interprets "data relating to a natural person" as data concerning that person. Therefore, one could argue that images of identifiable persons, accidentally made, are not personal data, since these images are not used to evaluate or influence the filmed person, and thus does not concern these persons6. Two examples can be given to clarify the differences between both opinions.

The first illustration is what has been called the "pond and ducks example". A camera is set up in a park to observe ducks on the pond, but passersby are also captured on tape. According to the first opinion, the images of the passersby do not have to be considered as personal data, since the purpose of the filming was the observation of the ducks and not of people walking nearby. According to the second opinion, however, these images are personal data when the passersby are identified, or identifiable without unreasonable means or effort.

The second illustration concerns the monitoring of a barrier in a car park. The barrier is filmed not to observe the people in the cars, but to make sure cars can easily get in and out. According to the first opinion, no personal data are being processed even though people are being filmed, since the purpose of the monitoring is only to ensure smooth traffic flows. According to the second opinion, however, personal data are being processed simply and solely because the faces of the people in the cars are filmed as well. This, of course, unless the tape is so unclear that people cannot be identified without unreasonable means or effort. The second opinion only takes the purpose of the processing into account at a later stage, when assessing the lawfulness of the data processing.

4 For the sake of completeness it has to be added that this discussion does not only rise in healthcare scenarios, but for instance also with regard to surveillance cameras. See Bullesbach, Poullet and Prins, Consise European IT Law, Kluwer Law International, The Netherlands, 2006, 32.

5 Advice Belgian Commission for the Protection of the Privacy, June 7th 1995, n° 14, 2; Advice Belgian Commission for the Protection of the Privacy, December 19th 1999, n° 34, 2.

6 Opinion 4/2007 Article 29 Data protection working party, June, 20th 2007, http://www.ec.europa.eu/justice-home/fsj/privacy/index-en.htm, 10.

Coming back to the use of cameras in a living room of a patient, the discussion is the same. When using a camera to observe a patient, the first opinion implies only personal data of the patient are being processed (and therefore protected by the DPD), and not the images of occasionally filmed persons. The second opinion on the other hand, implies that not only the images of the patient will be protected, but also those of these other persons. This is, again, at least when these other persons are identified or identifiable, which is exactly what the discussion will then be all about.

Both opinions make valid points, which means that it will eventually be up to the sovereignty of the judge to make a choice between the two. Next to that, I am convinced that the choice will not be purely legal, but will also be influenced by business strategies. I would, however, want to stress that the consequences of the choice are extensive, as this decision implies the choice for the protection, or hardly any protection, of accidentally filmed persons. However, as it will be elaborated below, this is not the end of the story as there are two other protection mechanisms apart from the DPD.

Applicability of the DPD to sounds

The Council of Europe has explicitly recognized that sounds can be qualified as personal data, at least under the always present condition of identifiability7. This is also acknowledged in article 33 of the DPD.

With regard to the use of cameras in people's homes, this implies that also recorded sounds may be qualified as personal data. Furthermore, when images and sounds are captured together, the level of identifiability rises. However, with regard to sounds captured from occasional visitors, the same discussion as described above will arise.

## 2.3 Protection of health data and the use of a video monitoring system

The DPD makes a distinction between "normal" personal data and "special categories" of personal data. At the European level (unlike on the Belgian level), these special categories are mentioned, but not defined. One of those categories is the data concerning health data. In the recommendation of the Council attached to the DPD, it is stated that data concerning health require "a strong and clear link" to the health of the person8. The European Court of Justice, however, held in the Bodil Lindqvist case that "the expression 'data concerning health' […] must be given a wide interpretation so as to include information concerning all aspects, both physical and mental, of the health of an individual" (Bullesbach et al., 2006).

In Belgium, health data are defined as "data concerning health", which implies that the health (or a health condition) must be directly shown. This seems a bit stronger than the interpretation of the Council and the ECJ9.

However, the essence of the definition is often illustrated with a picture of a man in a wheelchair at a park. In the picture, you can clearly see the man is handicapped, but the picture was not taken for the sake of the handicap or health of the person, so the picture itself does not have a direct

7 See Opinion 4/2004 Article 29 Data protection working party, February 11th 2004, http://www.ec.europa.eu/justice-home/fsj/privacy/index-en.htm, 5; Convention No. 108/1981.

8 R (97) 5 on the Protection of Medical data, European Council, February 13th 1997, http://www.1.umn.ecu/humananrts/instree/coerecr97-5.html, 2.

9 For the sake of completeness, it has to be stressed that, although there might be a slight difference between the Belgian and European interpretation, due to the member states' freedom, when transposing directives into national law, it must not be forgotten that in the case of lack of clarity one must always take into account the original intention of the directive.

connection to the man's health. Whereas, when the same person is photographed, e.g., at a disability examination and this picture is added to his health record, the picture does connect directly with the man's health and will be qualified as health data10.

When applying this reasoning to the use of cameras in a homecare setting, we are, again, faced with a dilemma. At this stage, however, the dilemma arises with regard to the patients and not so much with regard to the occasional visitors / incidentally filmed persons.

With regard to the monitored patient, it could, be argued images made in the different rooms of the patient's home are not health data because they do not relate directly to the health of the patient. Though information about the patient's health can be derived from the images, the images were primarily not taken for the sake of healthcare, the purpose of the video monitoring system not being continuous or occasional monitoring of the health status of the patient, but rather being support for daily life or allow quick and efficient response in an alarming situation. On the other hand, the camera often will be placed in the home specifically because of the high risk for health problems. In that case, the images will only be viewed for health purposes, and therefore it could also be argued that they are health data. This second interpretation is reinforced when the monitoring system does not monitor the patient at all times, but only when an alarm is activated, indicating a health problem is occurring.

However, it must be stressed the qualification of the images made by the video monitoring system will require a case-by-case approach and evaluation, much depending on the purposes of the video monitoring system.

As already announced, this reasoning also needs to be evaluated with regard to occasionally filmed persons. As indicated above, it is plausible to argue that personal data are being processed when persons are occasionally filmed by a video monitoring system. However, considering the images of occasional visitors as possible health data is, at least in my opinion, a step too far. It is possible that the existence of a health condition can be established from the image, for instance that a person has a broken arm. However, the image will never refer directly to the health of this person and even more important, there should be no intention what however to monitor their health via the camera.

## 3 Protection of the right to privacy

The protection of personal data is only one part of the protection of the right to privacy. Since, as described above, some argue that occasionally filmed persons are not protected by the DPD, when using a video monitoring system, it need to be researched whether they might be protected under the second protection mechanism: the right to privacy (article 8 European Convention on Human Rights).

The right to privacy is, like the right to protection of personal data, interpreted very broadly by the European Court of Human Rights (ECHR). Moreover, it is one of the fundamental rights called upon most frequently. When assessing an alleged violation of the right to privacy, the ECHR takes into account the kind of information and the level of intimacy involved. As a consequence, the ECHR, in contrast to the DPD, makes a distinction between privacy sensitive and non privacy sensitive information. Therefore, not all data are equally protected. Seeing this distinction, I fear that the protection of occasionally filmed persons on the basis of right to privacy should not be taken for

10 See also Advice Belgian Commission for the Protection of the Privacy, June 7th 1995, n° 14, 6.

granted, despite the broad interpretation. This is because, although the images made do refer to the personal lives of the filmed persons, they might not be so intimate and might thus not so quickly be regarded as an unreasonable infringement as would with regard to the patient himself.

Furthermore, the ECHR also takes into account the doctrine of reasonable expectations of privacy. This doctrine originates from the US, where it was introduced in 1967 by Justice Harlan11. According to Harlan, privacy only needs to be protected, when there is an actual expectation thereto, and this expectation is regarded as reasonable by society. The reasonable expectations doctrine is, however, not interpreted in the same way in Europe as it is in the US: the ECHR has e.g., at least for now, only used this doctrine in cases of public privacy. With regard to the use of cameras, the ECHR has already decided that a person cannot call upon his or her right to privacy when filmed by surveillance cameras in a place where one could expect this to happen12. However, as it is typical for the concept of reasonable expectations, this is subject to change. The future will thus have to show how this concept will be interpreted, when cameras are used inside homes and of course each individual situation will necessitate a case-by-case approach.

## 4 The right of personal portrayal

The right of personal portrayal means that every natural person has the right to his or her own images and the right to keep them. This means that permission must be granted to create any human portrait, and for every use of one.

The right of personal portrayal is in fact part of the right to a private life, which in turn is part of the right to privacy. The right of personal portrayal is protected by article 8 of the European Charter on Human Rights, article 17 of the International Covenant on Civil and Political Rights, and by many Constitutions such as Belgium's (article 22 Belgian Constitution).

### 4.1 Scope of the right to personal portrayal

The scope of the right to personal portrayal is fairly broad.

First of all, the right to personal portrayal is both an individual and a family right. On the one hand, the individual right protects the personal portraits of all natural persons just because they are human beings (Dierickx, 2005). On the other hand, the familial privacy or familial integrity right protects the fellow humans of the portrayed person (Gukdix, 1980-81). However, an infringement of the familial right of personal portrayal is often not accepted in the jurisprudence. The cases in which such an infringement has been accepted were always sexually orientated.

Secondly, both the image and the portrait of a person are protected. This implies that both the physical features and the behavior of a person are included. Among examples from the jurisprudence of what is protected are the special way of clothing, the general conduct of a person, and memories of certain habits. Examples of what is not protected by the right to personal portrayal are the

11 in the well known Katz vs. United States case ruled by the U.S. Supreme Court.

12 Lódi v Switzerland, EHRM June 15th 1992, http://cmiskp.echr.coe.int/tkp197/view.asp?item=27&portal=hbkm&action=html&highlight=&sessionid=10078018&skin=hudoc-en;
Halford v United Kingdom, EHRM June 25th 1997, http://cmiskp.echr.coe.int/tkp197/view.asp?item=1&portal=hbkm&action=html&highlight=&sessionid=10078018&skin=hudoc-en;
See also Loermans, 2004.

characteristics of a person or his or her voice. The voice of a person is, however, protected by a different right, namely the personal right to the voice (Senave, 2004).

Thirdly, an image or portrait can be made with all kinds of different technologies: two-dimensional photos and films, as well as three-dimensional sculptures, are protected. Furthermore, it is of no importance whether the portrait exists in a physical form, or is immaterial (e.g. live stream of a camera).

Apart from these three broadening elements, there is one limitation to the right of personal portrayal, namely, that the person is only protected when he or she is recognizable. How the term "recognizable" must be interpreted depends on the sovereign opinion of the judge, but it is advisable to take into account the same rules as used in the DPD. Recognizability must always be regarded from the point of view of others, and not the person in the portrait; however, being recognizable to friends and / or family is sufficient to invoke the protection (Dierickx, 2005).

## 4.2 Protection of the right to personal portrayal

When a person believes that his or her right to personal portrayal has been infringed, he or she can invoke his or her right against every person, who "makes" or "uses" the portrait without consent. This is what is called the erga omnes effect.

What comprises the "making" of a portrait has already been cleared out above: it concerns every image made by no matter what technology, and captured in no matter what way. However, what comprises "using" a portrait is less clear. In the legal doctrine, there is, e.g., discussion whether or not the use must have a commercial purpose. In the Belgian jurisprudence, the need for a commercial purpose has, however, not (yet) been accepted (Dierickx, 2005).

All actions considered as using a portrait can only be rightful after obtaining consent. Naturally, of course, whatever is not considered to be using a portrait can be done without consent. It has to be stressed that consent to make a portrait is not the same as consent to use a portrait, nor to reuse a portrait. So, in the case of the use of cameras inside people's homes, different consents need to be obtained in order to monitor the patient, in order to store the images made, and in order to transfer the images, e.g., to a health professional. In addition, a presumed consent will never be accepted in the case of the reuse or reproduction of a portrait.

For the consent there are, of course, certain conditions on how this should be obtained and on what information it should be based, but this issue goes beyond the subject of this paper.

# 5 Conclusion

When cameras are placed in people's homes, the images made can be protected by three different legal mechanisms: the protection of personal data, the protection of the right to privacy, and the protection of the right to personal portrayal.

Images and sounds from a patient made with an observation camera are protected by the Data Protection Directive. There is, however, discussion about the images and sounds of occasional visitors. Some people regard the purpose of the filming as the decisive criterion. Others, on the other hand, only take the purpose of the processing into account when assessing the lawfulness thereof, and regard every image of an identified or identifiable person as the processing of personal

data. Discussion also arises with regard to the qualification as sensitive data. The processed data of the patient are most likely to be qualified as health data, and thus protected under the regime of sensitive data. Data of occasional visitors are, in contrast, most likely not to be thus qualified.

The protection of personal data is however only part of the protection of the right to privacy. For patients, the right to privacy will undoubtedly be part of the game. With regard to occasional visitors, however, this is not so likely due to the interpretation of the right to privacy by the ECHR.

Last but not least, the images will also be protected by the right to personal portrayal when filmed people are recognizable. The right to personal portrayal is interpreted in a fairly broad way.

Due to these three protection mechanisms, the use of cameras as a next step in eHomecare will currently have to be based on the consent of the patient. Whether or not occasional visitors need to be warned about the use of cameras in the homes they are visiting, though, is still open for discussion. However, in my personal opinion, I tend to say this would be necessary too. In what way this warning must be given and how realistic this is, are two further questions to which the answers will most likely depend on the national laws of the different member states.

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# Acceptance of Virus Radar

## Abstract

Communicable diseases are a perplexing problem in the operation of healthcare facilities. We outline the advantages of an automated warning system that inhibits the spread of infectious agents. The User Device is based upon Wireless Local Area Network equipped mobile telephones. Acceptability of the virus radar User Device and the associated Contagion Vigilance Service was investigated. A survey was distributed describing the Device and Service, and the functions of an operational system, including warnings of contagion risks and privacy protection methods. Fifty-nine persons, both employees and patients, indicated their willingness to pay and their status. The most representative individual was willing to pay €50 a month for the Service and €150 for the Device, out of a monthly salary of €300. Many persons with lower education/income responded inconsistently, indicating poor understanding. These persons tended to respond with lower values, which, however, still indicated a substantial willingness to pay. Thus, we conclude that acceptability will be high, particularly among those with higher education/income.

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Keywords

Preventative health services, patient data privacy, real-time systems, distributed data bases, epidemiology

> “The level of support indicated could justify a System of this type, even if the installation and operational expenses had to be supported by user payments alone.”

## 1. Introduction

Healthcare Associated Infections (HAIs) are a growing global health issue. Certain resistant organisms, initially characterized in the care environment, such as Methicillin-Resistant Staphylococcus Aureus (MRSA), have become an increasing problem in the community as well. MRSA is now considered as an accelerating pandemic[1]. While healthcare environments have become breeding grounds for such resistant organisms (The proportion of Staphylococcus Aureus that is MRSA in American intensive care units increased from 2% in 1974 to 64% in 2004[2]), more effective translation of basic discoveries into clinical application could not only prevent this, but could also make these environments the first line of defense against these emerging threats. However, this requires resolving knowledge gaps in implementation. Peters[3] has pointed out that one of the unresolved questions is, "Why can't we control Hospital Associated - MRSA despite knowing how to do it?"

The proposed Vidar virus radar User Device is a cellular and Wi-Fi (Wireless Local Area Network) mobile telephone with supplementary functions. It periodically notifies a location database of its position. If its position has been marked as adjacent to a contaminated area, the user receives an alert on the phone. This permits the user to take evasive or protective actions, thereby reducing the risk of infection. Security features of the Contagion Vigilance Service make tracking of users impossible. The Vidar virus radar User Device and the associated Contagion Vigilance Service is a more advanced version of a proposed Contagion Management System[4], since it includes location-specific tracking. While this permits localization of infectious agents transmitted independently by direct person-to-person contact, it also increases privacy concerns and complicates needed security technologies. (The term "Vidar" was selected as the short name for our proposed Project, since it was a convenient contraction of "virus radar" and it was also the name of an old Nordic god.)

There is organized resistance to radio frequency identification (RFID) tracking technology among the general public. Computer users are known to limit their online purchasing activity considerably due to security and privacy concerns. On the other hand, both RFID/Wi-Fi tracking and collection of sensitive data are routine activities in some hospitals. Given the unique combination of these two technologies in the Vidar Project, it was important to estimate acceptability of the procedures and the effectiveness of our educational materials.

The objective of this study was a preliminary evaluation of acceptability of the Vidar virus radar User Device and associated Contagion Vigilance Service[5]. Subsidiary objectives were to test educational materials and gather marketing information. By estimating willingness to pay for the Device and the Service, we establish the economic feasibility of virus radar for a hospital, independent of the saving generated by preventative actions and increased awareness of infectious disease in the hospital environment. Our null hypothesis was that hospital users and personnel would not find the Vidar Project acceptable. This would be indicated by a lack of willingness to pay for the User Device and the associated Contagion Vigilance Service.

1 Peters, G. (2008, April 20). Epidemiology and resistance mechanisms of Methicillin-Resistant Staphylococcus Aureus. MRSA: the changing epidemiology of the epidemic, Pfizer Integrated Symposium. Eighteenth European Society of Clinical Microbiology and Infectious Diseases Integrated Symposia. 19-22 April 2008, Barcelona, Spain. URL: http://www.sessions2view.com/eccmid08c3_library

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3 Peters, G. Idem

4 Stodolsky, D. S. (1997). Automation of Contagion Vigilance. Methods of Information in Medicine, 36(3), 220-232.

5 Linköping University, Institute for Social Informatics, and Stefan S. Nicolau Institute of Virology. (2007, 8 May). Virus Radar. Unpublished research proposal. Abstract, etc. available at URL: http://virusradar.org.

# 2. Method

## 2.1 Materials

An information sheet and response slip were prepared. The English version is presented in Appendix A.

## 2.2 Procedures

Ten survey information sheets and twenty response slips were distributed by a staff person on each of the three floors of Pavilion B2 at the Infectious Diseases Hospital, which is adjacent to the Stefan S. Nicolau Institute of Virology in Bucharest, Romania. The questionnaires were delivered between 9 AM and 12 AM and retrieved by the same person, at the same hours (9 AM to 12 AM), 24 hours later. This availability sample was taken during the week of 9 April, 2007. Each subject completed a response slip with a blue pen. All response slips were returned completed, except for one which was lost.

## 2.3 Results

**Distribution of Respondents**

Responses were highly skewed, therefore the data was log transformed to achieve a more normal distribution. This also has the advantage of transforming the data into a scale more closely corresponding to perceptual differences. That is, the distance between €30 and €40 is equal to the distance between €300 and €400 after this transformation. With a base 10 log transformation, the value 1 equals €10 ($10 = 10^1$), the value 2 equals €100 ($100 = 10^2$), etc.

We then performed an outlier analysis to trim extreme values[6]. A jackknife distance analysis revealed four persons who had responded 1€ to both questions. They were removed from the data set. Three missing values result from transforming data values of zero, which are undefined after a log transformation. Thus, we retained 52 records of transformed values. Responses remained from several employee categories [graduate nurse (20), doctor (13), nurse (7), cleaner (4), other (5)] and from patients (10).

Finally, we performed a nonparametric bivariate density plot (Figure 1, Appendix C) to identify clusters within the payment data. This plot shows the highest density at €150 per Phone ($10^{2.176}$) (range €100 to €200) and €50 per month ($10^{1.699}$) for Service (Cluster 12). A less well defined Cluster (9) appears around €50 per Phone ($10^{1.699}$) (range €50 to €250) and €10 per month ($10^1$) for Service. Another poorly defined Cluster (8) appears with the same value for Service, but a lower value for the Phone, €20 ($10^{1.301}$) (range €10 to 30€). Between one-third to two-thirds of the data points are visible in the graphs, because many responses had identical values thus overlapping others. A mesh plot (Figure 2) gives another view of the data, clearly showing the peak at the higher values. The Modal Clustering Table (Appendix B) shows that 11 persons are included in the high-value Cluster (12), while only 9 appear in each of the others (Clusters 8 & 9). If we are to choose a single value to exemplify our results, it would be in this higher value Cluster, since it is the largest Cluster and also the best defined one. Thus, the Graduate Nurse who appears in the center of this Cluster is our most representative individual.

6 SAS Institute. (2000). JMP (R) Version 4 (Release 4.0.4). Cary, NC.

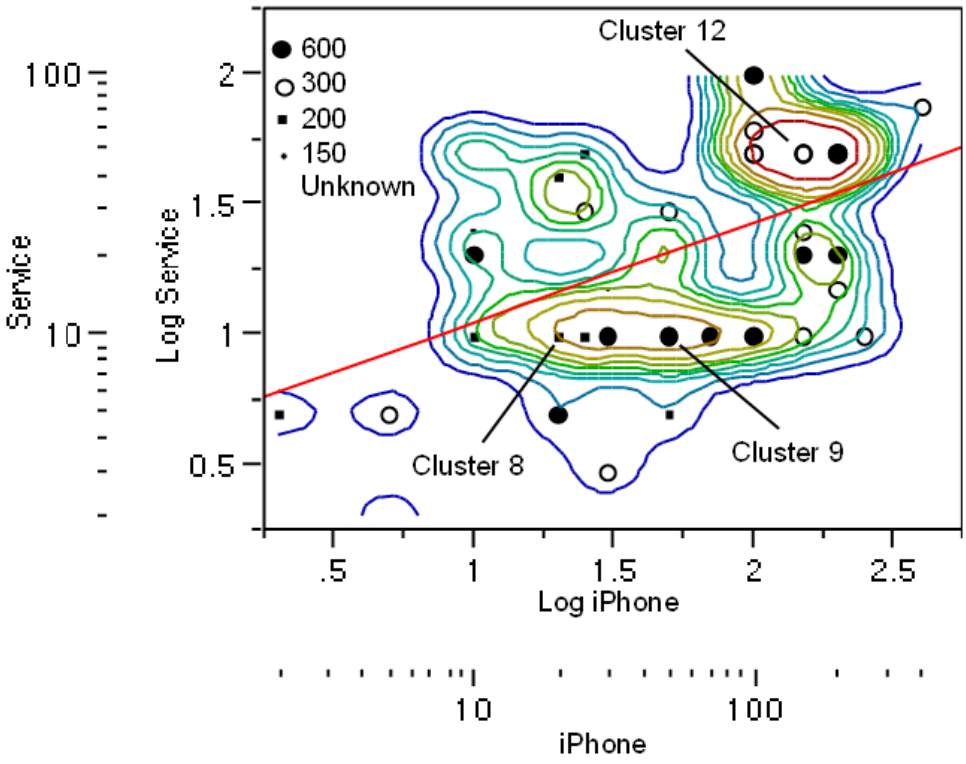


*Figure 1. Nonparametric Bivariate Density Plot Showing Incomes and Cluster Centers*

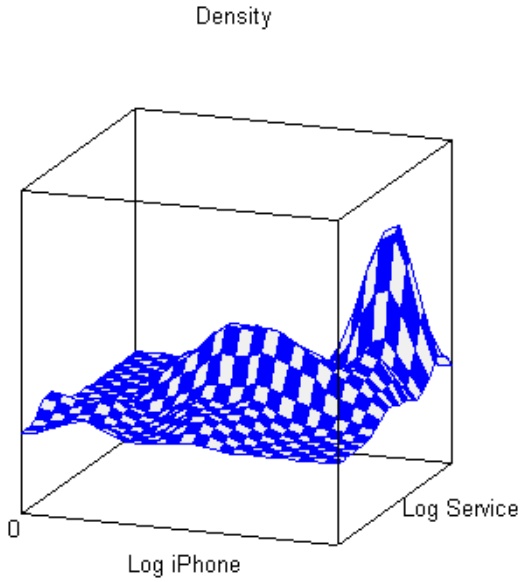


*Figure 2. Mesh Plot of Densities*

**User Acceptance**

User Acceptance was estimated based upon willingness to pay for the Vidar User Device and the Contagion Vigilance Service. A one-way analysis of variance (ANOVA) was performed upon the responses to the payment amount questions. The income data was treated as ordinal, minimizing any risk that imprecision in income estimates would effect the results (If salary levels are in the correct order, our analysis is unaffected.) Finally, power analyses to identify sample sizes needed in

future studies were performed.

The mean (numerical average) response to the question "How much would you pay for a new Phone performing these functions?" was a bit over €60 ($10^{1.8}$) (Figure 3, Appendix D). The difference in payment willingness among groups was highly significant [F (3, 41) = 5.28, p < .0038] (Appendix D). The mean comparisons show that the two high-income groups (€600 [doctor] and €300 [graduate nurse] and the two low-income groups were indistinguishable (Appendix D). The lack of a difference between the highest income groups, appears to reflect a leveling off of willingness to pay with higher income. Thus, we can assume a perceived value of the Phone of about €91 ($10^{1.96}$), regardless of income, once income passes a threshold between €200 and €300. A possible confounding variable was pre-existing ownership of a mobile phone.

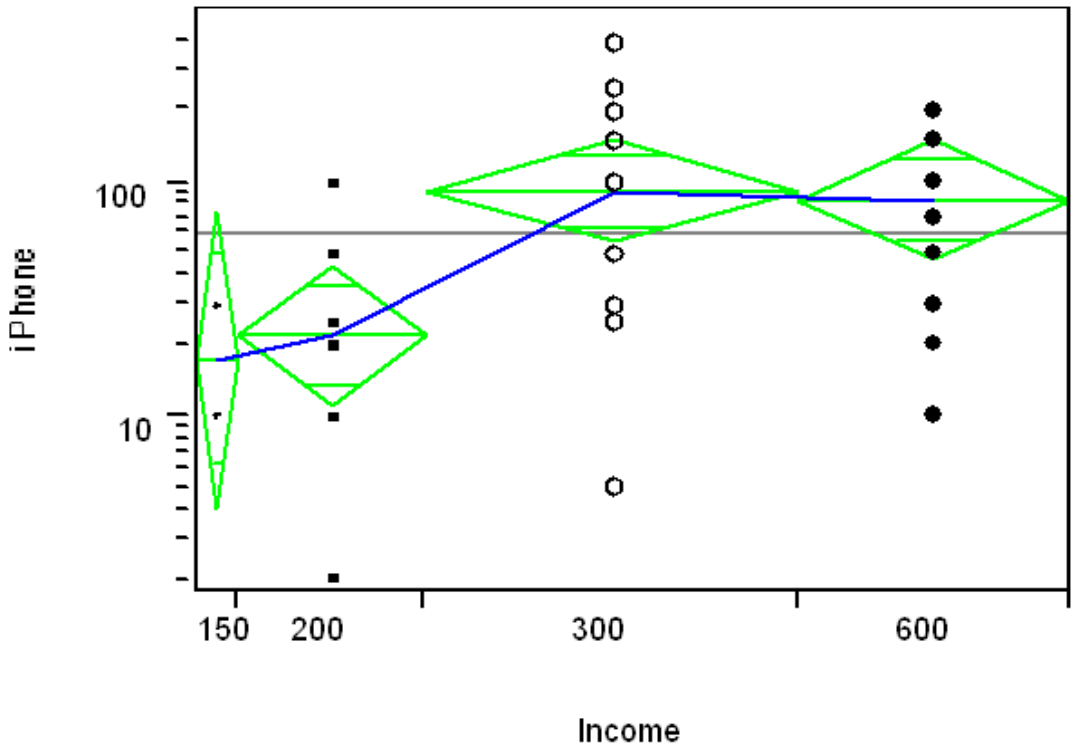


***Figure 3. One-way Analysis of Log iPhone By Income***

On the average, respondents were willing to pay €20 ($10^{1.3}$) per month for the Virus Radar Service (Figure 4, Appendix E). The differences among the groups are not significant [F (3, 41) = 1.5099, p < .2275] (Appendix E). However, the data again appears to reflect a leveling off of willingness to pay with higher income. Thus, we can assume that the perceived value of the Service is about €30 ($10^{1.39}$), regardless of income level, once it passes a threshold between €200 and €300. The power analysis showed that we need at minimum 76 respondents to achieve significance at the .05 level (Appendix E).

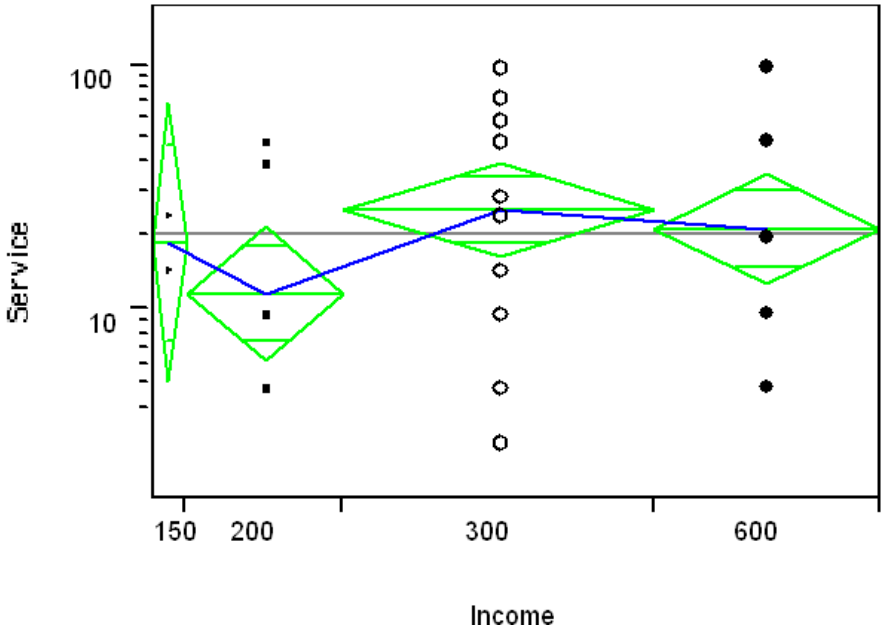


*Figure 4. One-way Analysis of Log Service By Income*

If we compare willingness to pay for the Service as compared to willingness to pay for the Phone, we can see (straight line in Figure 1) that these are significantly correlated (Appendix C) [maximum $R^2 = 0.54$, $p < .003$]. This supports our assertion of a similar pattern in the data for the two types of payment willingness. Thus, our estimates of a rising level of willingness to pay with income up to a threshold between €200 and €300 is supported, as is our estimate of constant perceived value above that threshold.

## 3. Discussion

This study investigated acceptance of both the virus radar User Device and the Contagion Vigilance Service by surveying willingness to pay for the Device and willingness to pay for the Service. While participants answered two willingness-to-pay questions, their acceptance was assessed within the context of an integrated System. The main finding was that potential users were willing to make substantial payments to achieve the protection the System provided.

There are at least two groups in terms of willingness to pay revealed by the nonparametric cluster analysis. The higher paying Cluster is well defined and tends to agree on both the value of the Service (€50) and the value of the Phone (€150). The other Cluster chooses a much lower value for Service (€10) and doesn't agree on the value of the Phone. This disagreement on the value of the Phone could indicate that individuals in this lower paying Cluster didn't understand the Survey Information. Therefore, taking an overall sample average could result in misleading values. Thus, the mean response of €60 to the question, "How much would you pay for a new phone performing these functions?" could be too low. The fact that the higher education/income groups choose the value €91, also throws suspicion on the lower value. The overall mean value for Service, €20 may also be too low, since the higher education/income groups choose €30. If we must choose one representative individual from the data set, it is the Graduate Nurse who was willing to pay €50 a month for the Service and €150 for the Phone, out of a monthly salary of only €300. Our best estimates, therefore, place the perceived value of the Phone between €91 and €150, and the perceived value of the monthly Service between €30 and €50. In terms of our application, even the lower payment values

indicate a substantial willingness to pay for both the Phone and the monthly Service, considering the monthly income levels in the sample (€150 to €600).

If either the User Device or Contagion Vigilance Service was not acceptable, this would have been indicated by participants not being willing to pay for either the Device or the Service. We also asked them to indicate their patient status or personnel category, thereby permitting us to evaluate how educational background and estimated income would mediate the responses.

We attempted to counter ethical concerns about the tracking technology by explaining the anonymity of location data and alerts, and by offering compensation for possible losses associated with a potential breach of confidentiality. Similarly, we attempted to allay concerns about privacy by ensuring participants that their data remains under their control at all times and can be completely withdrawn from the experiment upon their demand. We list benefits of the Vidar technology and advantages of Internet Protocol telephony within the hospital environment, assuming a mature system. By placing the technology in an operational setting and presenting both risks and benefits, we hoped to achieve a realistic assessment of the Vidar virus radar acceptability and usability in the hospital environment. This pilot study was a test of our procedures and also permitted us to determine the sample size needed to obtain definitive results.

There are two possible explanations for the split between the main willingness-to-pay groups revealed by the analysis. One is the income level and the other is the education level. These two variables are confounded in our data, since income was estimated from employee category. Thus, it is difficult with this data set to distinguish between a failure to understand the questionnaire, due to a lack of education, and the effect of income. However, when one examines the differences in how well Clusters 12 and 9 were defined in the modal analysis (a factor of 2 versus a factor of 5 in range on the Phone values), the educational level explanation appears to be favored. This is because the lower value Cluster (9) was so divergent in terms of willingness to pay for the Phone. There is a trend in the data indicating that those with lower incomes tended to concentrate in the low value Cluster (9) as opposed to the high value Cluster (12).

Since the two monetary variables were significantly correlated, we would expect to see better defined low value Clusters if there was adequate understanding. This correlation also supports the common trend in the data concerning a rise in willingness to pay with increasing education/income up to a threshold level between €200 and €300 in monthly income.

**State of the art**

Real-time location systems (RTLSs) are used in hospitals now in order to reduce the amount of staff time spent locating movable equipment and to reduce equipment inventories, thereby yielding substantial savings. Movable equipment, such as wheel chairs, is often monitored with alarm systems, which have been effective in reducing equipment losses. The "[r]esearch firm IDTechEx of Cambridge has released a report on the real-time location systems (RTLS) market and its growth prospects over the next decade. They estimate that the RTLS market will explode over the next ten years, growing from an 'esoteric niche market' to one worth $2.71 billion in 2016"[7]. Thus, we expect an increasing number of healthcare facilities to have this technology installed. Our infection control strategy can then be employed with minimal additional expense.

Reminders and warnings can be automatically triggered, if a violation of a management strategy enforcing contact precautions is detected. For example, if a certain room that has been set aside

7 Rfidupdate (2006). Report: RTLS Market Worth $2.7b in 2016. URL accessed 8 Nov 2008: http://www.rfidupdate.com/articles/index.php?id=1065

for a patient known to harbor a resistant organism is approached by a user not authorized to enter that room, an alert can be issued. Failure of the person to respond to the alert could lead to a warning sounding at a nursing station, so that the situation could be immediately investigated. In this example, the surveillance system yields a second layer of protection against risky contact. This technology is now used to track patients who may become confused and leave their ward inappropriately. However, Torchia[8], in a report from the Yankee Group, stated, "Individual privacy concerns will stall human asset tracking in European markets and union-represented industries."

There is no state of the art in automated identification and management of contagious disease. However, there is prior work in syndrome identification. Typically, the first sign of an epidemiological outbreak, due to a novel agent, is a communicable syndrome. Current syndrome surveillance methods are complex manual procedures requiring highly trained persons. Delays in data collection and agent identification seriously impede the ability to control infectious agents[9]. The first steps toward automated syndrome identification have been taken, but they have been limited by manual data-collection methods[10].

**Advances expected with an automated system**

The failure of current HAI control methods is indicative of the unsatisfactory tradeoffs available in practice. For example, one approach to preventing the spread of resistant organisms is to test every new patient and then take contact precautions which minimize the chance of a resistant organism spreading to other patients. In many situations, however, this approach is not economically feasible. Similarly, while the hygienic procedures for controlling HAIs are well known, it has proven very difficult to maintain compliance, due to the constant educational and motivational campaigns that appear to be necessary. The introduction of an enhanced location-based services management strategy allows the alteration of the cost-benefit tradeoffs, while improving the ability to identify new agents.

Accumulated data from System operation allows for the identification of specific points of failure in current techniques and technologies. It also permits the comparison of the effectiveness of different strategies for the application of such techniques and technologies, and the optimization of such strategies. While traditional evaluation methods are typically applied to an entire ward or hospital, and have trials that may run over weeks, months, or even years, the proposed method allows greater source specificity and much better time resolution, permitting the very rapid identification and quantification of risk-related events.

Since the technology operates in real-time and can identify individual sources, patient self-management becomes possible. For example, a patient with reduced immune response could choose to avoid an area being used by other patients under treatment for infection. Similarly, if such a patient was discovered to have had such contact, a prophylactic dose of an antibiotic might be appropriate and, in fact, could be an optimal strategy for drug delivery. Similarly, this type of information facilitates dynamic risk-based surveillance and thereby optimal targeting of laboratory tests.

8 Torchia, M. (2005). RTLS Market To Exceed $1.6 Billion by 2010, URL accessed 8 Nov 2008: http://www.rfidupdate.com/articles/index.php?id=949

9 Smithson, A. E. & Levy, L.-A. (2000, October). Ataxia: The Chemical and Biological Terrorism Threat and the US Response. Washington, DC: Henry Stimson Center. URL: http://www.stimson.org/pubs/cwc/atxchapter7.pdf

10 Brossette, S. E., et al. (2002). A data mining system for infection control surveillance. Yearbook of Medical Informatics (pp. 332-9). Stuttgart, DE: Schattauer Publ. Co.
Fricker, R.D., Jr., Hegler, B.L., Dunfee, D.A. (2008). Assessing the Performance of the Early Aberration Reporting System (EARS) Syndromic Surveillance Algorithms, Statistics in Medicine, 27, pp. 3407-3429.

While discrete contact precautions are typically reserved for specific agents that can justify their added management complexity and effort, the System described here permits a graded response to the range of agents typically encountered. Thus, for example, the alerting system could warn of the type and degree of risk at a given location, thereby permitting users to respond appropriately. For example, if it was known that a specific patient was infected with an agent that could colonize a healthy person, a user might decide to use gloves to reduce the risk of contacting the infective agent. This graded range of risks would also maintain an increased awareness of the problem of healthcare associated infections and thereby ensure greater compliance levels. It could further make more effective use of facilities possible, by taking advantage of preexisting isolation options. For example, a ward could be structured so that patients known to be infected with similar agents could be placed together, reducing the risk of other patients becoming infected. Where several nurses shared responsibility for such a ward, contact with patients could be organized to minimize the inadvertent spread of an agent, by ensuring that different sets of patients were served by different nurses. Thus, the more sophisticated use of existing facilities could lead to greater patient safety with little or no additional expense.

In summary, the objective of the Vidar Project was to demonstrate the feasibility of a contagion management system based upon networked mobile devices. Information retrieval facilitates syndrome identification and the issuing of alerts to those at risk in real time. The focus is on tracking transmission within the hospital and notifying at-risk persons once an agent has been localized. State of the art is also advanced in the collection of sensitive personal data and security for mobile devices.

**Analytic approach**

Within the hospital environment, infectious agents are expected to be well characterized and carriers easily identifiable. When an individual's laboratory test is positive, we trace the likely source and forward transmission paths in the location database. Characteristics of different transmissible agents, and levels of immuno-competence are integrated into the analysis, as are sympoms presented by suspected new carriers. An objective is to adjust the sensitivity of the tracing algorithms so that carriers can be rapidly isolated, without excessive clinical laboratory tests.

Syndrome identification is supplementary to tracing of identified agents. In this case, data is limited to patient symptoms, immuno-competence, and other personal factors. Automated syndrome surveillance can be evaluated by its ability to identify carriers prior to the appearance of symptoms and by overall reduction of in transmission of infectious agents.

**Specific Impact**

The Project would employ advanced information and computer technologies to assess risks of infection and improve patient safety, without compromising user privacy. It would facilitate identification of common patterns in safety-relevant events and trigger alerts designed to stop the spread of infectious agents. This alerting and management support System incorporates new tools for prediction, detection, and monitoring of infection risks directly impacting patient safety. The solution depends on innovative data mining and integration with the present electronic health record system. It provides decision support to both users and the infection control officer, and allows prediction of adverse events.

The privacy-protection advances remove a major barrier to the deployment of real-time location systems in the multi-billion dollar European market for RTLS technology[11]. It is expected that the

11 Torchia, M. Idem.

management of contagious disease will be extended from the healthcare facility into the community, as our strategy proves its effectiveness. This is essential in the long run, since, for example, Community-Associated MRSA is becoming a widespread problem[12] and more effective hospital management of these agents requires prior knowledge of patients' exposure.

## 4. Conclusion

The main finding was that potential users were willing to make substantial payments to gain the protection that the proposed virus radar System provided. The most representative individual was willing to pay €50 a month for the Service and €150 for the Device, out of a monthly salary of €300. Many persons with lower education/income responded inconsistently, indicating poor understanding. These persons tended to respond with lower values, which, however, still indicated a substantial willingness to pay. Thus, we conclude that acceptability will be high, particularly among those with higher education/income. The level of support indicated could justify a System of this type, even if the installation and operational expenses had to be supported by user payments alone.

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# 5. Appendix

## Appendix A

**Vidar (virus radar) Project - General Information**

The principle Project objective is the protection of Hospital Personnel and Patients from Flu infections using a Phone with supplementary functions. In case of an outbreak, the Phone will sound an alert when you approach a high-risk area. One appropriate response is to avoid entering the area. Another is to wear a protective face mask and disinfect your hands after leaving the area. All measures considered can be taken at any time for protection against infections.

You will be able to use your current mobile service with the Phone. Cost-free communication with other users will be possible, while both are in the Hospital area. At the end of the three-year project, you will be able to keep the Phone or return it for a full refund.

In order to function correctly, the Phone must update your location every few seconds (location updates are a normal part of mobile phone operation). Your identity is not linked to this location information. In case of a warning being issued, it will be transmitted to all Phones. Only one Phone will be able to decode the message and sound an alert. Other Phones will silently discard the message. Therefore, other users will not be disturbed in any way by the message received.

You will receive a thousand Euro compensation payment, if any confidential information is released. If a breach of confidentiality causes greater damage, the Hospital's insurance will compensate you. You will be able to withdraw all information at any time.

You are required to participate in up to four tests of the alert system each year. The test may require you to put on a face mask and report to a Hospital laboratory. The test may require that you provide a throat swab or may use another biological sampling method. You may also be asked to load data from your Phone into a computer (this provides technical support, if it is necessary) that can transmit alerts to other users. You may refuse. No identity information is transmitted with the data. These procedures will take less than 10 minutes.

Please enter your responses:

:How much would you pay for a new Phone performing these functions?

(0 - 500 Euro) _____

:How much would you pay for the Service, assuming it protects you from some communicable diseases? (0 - 100 Euro / month) _____

I am a (check one) Doctor _ , Graduate Nurse _ , Nurse _ , Food Service Worker _ , Patient _ , Cleaning persons _ , other _.

Observations _____

## Appendix B

*Largest Modal Clusters including Most Representative Members*

| Category | Count | iPhone | Service | Income | Log iPhone | Log Service | Cluster |
|---|---|---|---|---|---|---|---|
| graduate nurse | 11 | 150 | 50 | 300 | 2.17609 | 1.69897 | 12 |
| doctor | 9 | 50 | 10 | 600 | 1.69897 | 1 | 9 |
| nurse | 9 | 20 | 10 | 200 | 1.30103 | 1 | 8 |

## Appendix C

Nonparametric Bivariate Density

| Variable | Kernel Std |
|---|---|
| Log Phone | 0.135664 |
| Log Service | 0.107032 |

### Linear Fit

Log Service = 0.6612939 + 0.3841518 Log Phone

### Summary of Fit

| | |
|---|---|
| RSquare | 0.237088 |
| RSquare Adj | 0.22183 |
| Root Mean Square Error | 0.364822 |
| Mean of Response | 1.311088 |
| Observations (or Sum Wgts) | 52 |

### Lack Of Fit

| Source | DF | Sum of Squares | Mean Square | F Ratio |
|---|---|---|---|---|
| Lack Of Fit | 13 | 2.6693707 | 0.205336 | 1.9063 |
| Pure Error | 37 | 3.9853995 | 0.107713 | **Prob > F** |
| Total Error | 50 | 6.6547702 | | 0.0621 |
| | | | | **Max RSq** |
| | | | | 0.5431 |

### Analysis of Variance

| Source | DF | Sum of Squares | Mean Square | F Ratio |
|---|---|---|---|---|
| Model | 1 | 2.0680872 | 2.06809 | 15.5384 |
| Error | 50 | 6.6547702 | 0.13310 | **Prob > F** |
| C. Total | 51 | 8.7228574 | | 0.0003 |

## Appendix D

Oneway Analysis of Log Phone By Income, including Means Comparisons and Power Analysis

**Oneway Anova**

**Summary of Fit**

| | |
|---|---|
| Rsquare | 0.294544 |
| Adj Rsquare | 0.23885 |
| Root Mean Square Error | 0.446578 |
| Mean of Response | 1.783501 |
| Observations (or Sum Wgts) | 42 |

**Analysis of Variance**

| Source | DF | Sum of Squares | Mean Square | F Ratio | Prob > F |
|---|---|---|---|---|---|
| Income | 3 | 3.164157 | 1.05472 | 5.2886 | 0.0038 |
| Error | 38 | 7.578410 | 0.19943 | | |
| C. Total | 41 | 10.742567 | | | |

**Means for Oneway Anova**

| Level | Number | Mean | Std Error | Lower 95% | Upper 95% |
|---|---|---|---|---|---|
| 150 | 2 | 1.23856 | 0.31578 | 0.5993 | 1.8778 |
| 200 | 9 | 1.34410 | 0.14886 | 1.0428 | 1.6455 |
| 300 | 18 | 1.96275 | 0.10526 | 1.7497 | 2.1758 |
| 600 | 13 | 1.92334 | 0.12386 | 1.6726 | 2.1741 |

Std Error uses a pooled estimate of error variance

## Appendix E

Oneway Analysis of Log Service By Income, including Means Comparisons and Power Analysis

**Oneway Anova**

**Summary of Fit**

| | |
|---|---|
| Rsquare | 0.10651 |
| Adj Rsquare | 0.035971 |
| Root Mean Square Error | 0.396524 |
| Mean of Response | 1.314818 |
| Observations (or Sum Wgts) | 42 |

**Analysis of Variance**

| Source | DF | Sum of Squares | Mean Square | F Ratio | Prob > F |
|---|---|---|---|---|---|
| Income | 3 | 0.7122301 | 0.237410 | 1.5099 | 0.2275 |
| Error | 38 | 5.9747763 | 0.157231 | | |
| C. Total | 41 | 6.6870064 | | | |

**Means for Oneway Anova**

| Level | Number | Mean | Std Error | Lower 95% | Upper 95% |
|---|---|---|---|---|---|
| 150 | 2 | 1.28702 | 0.28038 | 0.7194 | 1.8546 |
| 200 | 9 | 1.07766 | 0.13217 | 0.8101 | 1.3452 |
| 300 | 18 | 1.41952 | 0.09346 | 1.2303 | 1.6087 |
| 600 | 13 | 1.33830 | 0.10998 | 1.1157 | 1.5609 |

Std Error uses a pooled estimate of error variance

**Means Comparisons**

Dif=Mean[i]-Mean[j]

| | 300 | 600 | 150 | 200 |
|---|---|---|---|---|
| 300 | 0 | 0.08122 | 0.13251 | 0.34186 |
| 600 | -0.08122 | 0.00000 | 0.05129 | 0.26064 |
| 150 | -0.13251 | -0.05129 | 0.00000 | 0.20935 |
| 200 | -0.34186 | -0.26064 | -0.20935 | 0.00000 |

Alpha=0.05

Comparisons for all pairs using Tukey-Kramer HSD

| q* |
|---|
| 2.68648 |

**Abs(Dif)-LSD**

| | 300 | 600 | 150 | 200 |
|---|---|---|---|---|
| 300 | -0.3551 | -0.3065 | -0.6615 | -0.0930 |
| 600 | -0.3065 | -0.4178 | -0.7578 | -0.2013 |
| 150 | -0.6615 | -0.7578 | -1.0653 | -0.6234 |
| 200 | -0.0930 | -0.2013 | -0.6234 | -0.5022 |

Positive values show pairs of means that are significantly different.

**Power Details**

Test

Income

**Power**

| Alpha | Sigma | Delta | Number | Power | AdjPower | LowerCL | UpperCL |
|---|---|---|---|---|---|---|---|
| 0.0500 | 0.396524 | 0.130222 | 42 | 0.3662 | 0.1279 | 0.0500 | 0.9885 |

**Least Significant Number**

| Alpha | Sigma | Delta | Number(LSN) |
|---|---|---|---|
| 0.0500 | 0.396524 | 0.130222 | 75.98967 |

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