



COCIR **eHEALTH** TOOLKIT

INTEGRATED CARE:
BREAKING THE SILOS

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COCIR
SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



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HEALTHCARE NEED TO CHANGE IN ORDER TO BECOME MORE SUSTAINABLE!

COCIR continues to support the Juncker Commission's initiative to tear down regulatory walls and achieve further harmonisation with a view to creating a more innovative, safe and secure digital and industrial ecosystem across the EU.

While healthcare management has been mostly reactive in the past, it needs to become proactive, to avoid health issues and minimise their impact.

Modern healthcare goes beyond curing the ill. Preventing diseases and their complications, caring for the chronically ill and promoting wellbeing is also important and more cost-effective. In this setting, citizens, healthcare providers and social care workers communicate and collaborate to help the population remain in good shape. A healthy population, which remains physically and economically active, therefore relying less on expensive acute care, renders healthcare more sustainable.

Thus there is a sense for urgency to:

- Establish priorities for Integrated Care and patient-centred health services,
- Articulate more visibly the crucial role of partnerships and collaboration with private sector to improve eHealth services,
- Leverage Innovation.

Better integration of care will help deliver the "Triple aim": Higher quality care, decreased costs and improved population health. This urgent transformation will require new ways of working.

Integrated care requires increased communication and data sharing among healthcare providers and citizens. Citizens are trained to manage their health, prevent diseases and co-organise their care.

In this 2015 toolkit, we focus on Integrated Care and on how ICT technologies and procurement possibilities can facilitate it and break silos.

The toolkit outlines the concept of Integrated Care itself, what its value is and what the challenges are. The toolkit also outlines the supporting IT concepts which help make Integrated Care a reality, including technical ones like Cloud Computing, or procurement ones related like "Managed Services". Data sharing and fluid communication is crucial for Integrated Care to work. This is why interoperability is re-emphasized once again this year as a key enabler.

COCIR will continue to follow actions needed as a result of the newly published flagship Digital Single Market strategy, as the European Commission has recognised this potential, deeming eHealth and mHealth technologies critical to the Digital Single Market and a priority area for standardisation and interoperability.

Nicole DENJOY

COCIR Secretary General



INTEGRATED CARE

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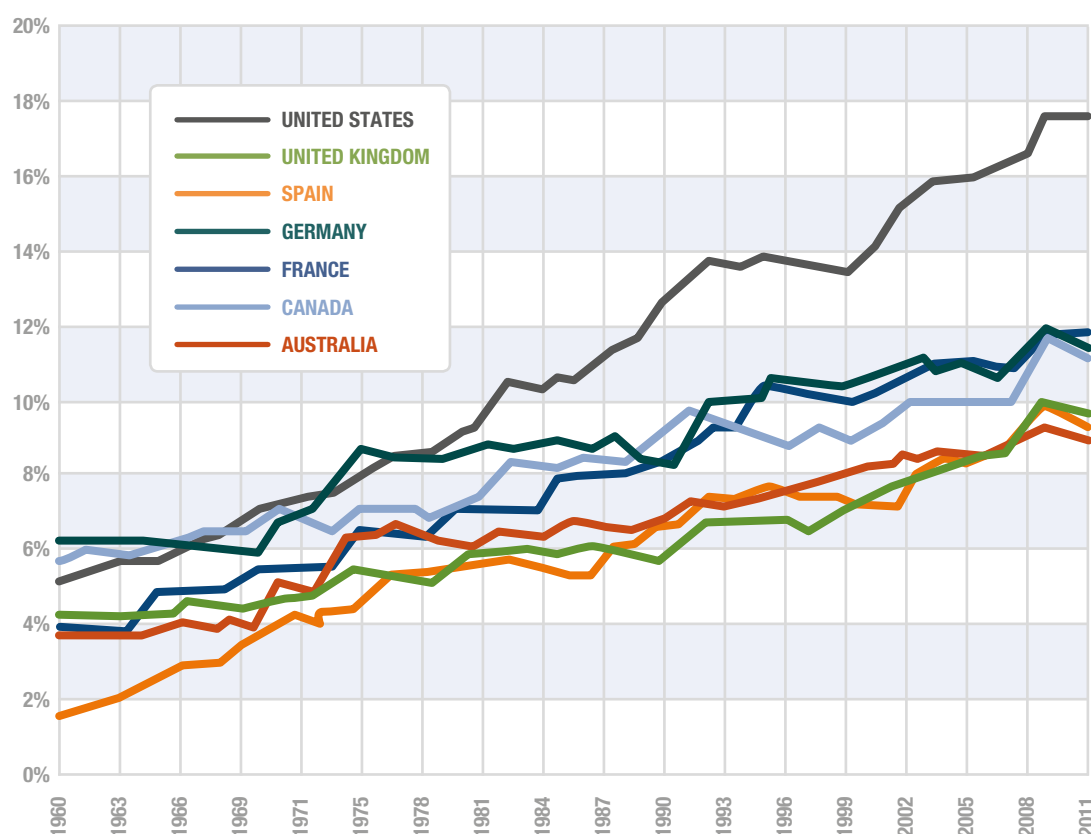
PART 1 INTEGRATED CARE

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European health and social care systems are set to undergo drastic changes. In recent years, the cost of providing care services has risen consistently and sharply in all OECD countries (Fig 1 - 5% of GDP in 1970, 7% in 1990 and 10% in 2010), outpacing the rate of inflation. This is partly fuelled by increasing demands from an ageing population. Not only do people live longer, but the older populations are living their extra years of life with more complex medical conditions and an increased level of co-morbidities. The complexity specifically arises from largely from these co-morbidities of which many are chronic, such as Type 2 diabetes, hypertension, cardiovascular disease and pulmonary disease.

Figure 1: Expenditure in health and social care systems in OECD countries



How society cares for the elderly has also changed in the last few decades. A generation or two ago, adult children cared for elderly relatives in their own homes. As more women entered the workforce, families increasingly turned to nursing home care for their elderly relatives.

Unfortunately, high costs do not necessarily mean higher quality. European Member States' health and social care systems are fragmented as they were designed to offer specialised support for individual medical problems – not dealing with the challenges of independent living. Information is not shared across service providers and the reality for many citizens is that they have to organise their own health services, having to communicate their care needs and medical histories. In many cases, individuals are unable to cope and soon become regular users of unscheduled care services, including emergency rooms and wards. This often results in poor medical outcomes and unjustified clinical variability in medical practices and decision-making across care providers.

Unnecessary medical escalations and adverse events, such as exacerbations of congestive heart failure or COPD, result in more cost, and in many cases they could be prevented with regular check-ups, medication reviews and improved disease management, hence Integrated Care. However, these expensive escalations also represent significant revenue for acute care providers. Porter and Teisberg, upon analyzing the failure of the healthcare industry to deliver higher quality and lower cost, came to the conclusion that a root cause was a misalignment of incentives with the current prevalent fees for service model.

When looked at holistically, healthcare systems are declared “unsustainable”. Better Integrated Care services, using Health IT (eHealth) to share information and collaborate across the care continuum, are increasingly viewed as a practical way to tackle this challenge. There are many definitions of Integrated Care and COCIR prefers:

Integrated Care consists of multi-agency and multi-disciplinary collaboration, focused on meeting the medical, social and practical needs of each individual in a coordinated way. It is enabled by eHealth services, including risk stratification, needs assessment, decision support, care planning, evidence based guidelines, information sharing and care team collaboration tools, as well as online services to help citizens participate fully in their care plan. The objectives of Integrated Care are to measurably improve the care experience and quality of care, whilst reducing the demand on costly and resource-intensive emergency and hospital services.

Put more concisely, integrated care could be summarized as: PREVENTION, PRODUCTION, PROMOTION and PARTICIPATION.

Chapter 1 outlines what is meant by Integrated Care and why it has become so topical. COCIR considers the evidence on the value of Integrated Care services and addresses the need to overcome challenges. COCIR's recommendations are presented at the end of this chapter.

COCIR RECOMMENDATIONS

Integrated Care is one of the most promising approaches for overcoming increasing demand on healthcare systems and the challenge of comorbidities. Care providers should pursue a more holistic approach to keeping citizens healthy, managing chronic diseases more efficiently and thereby minimising costs.

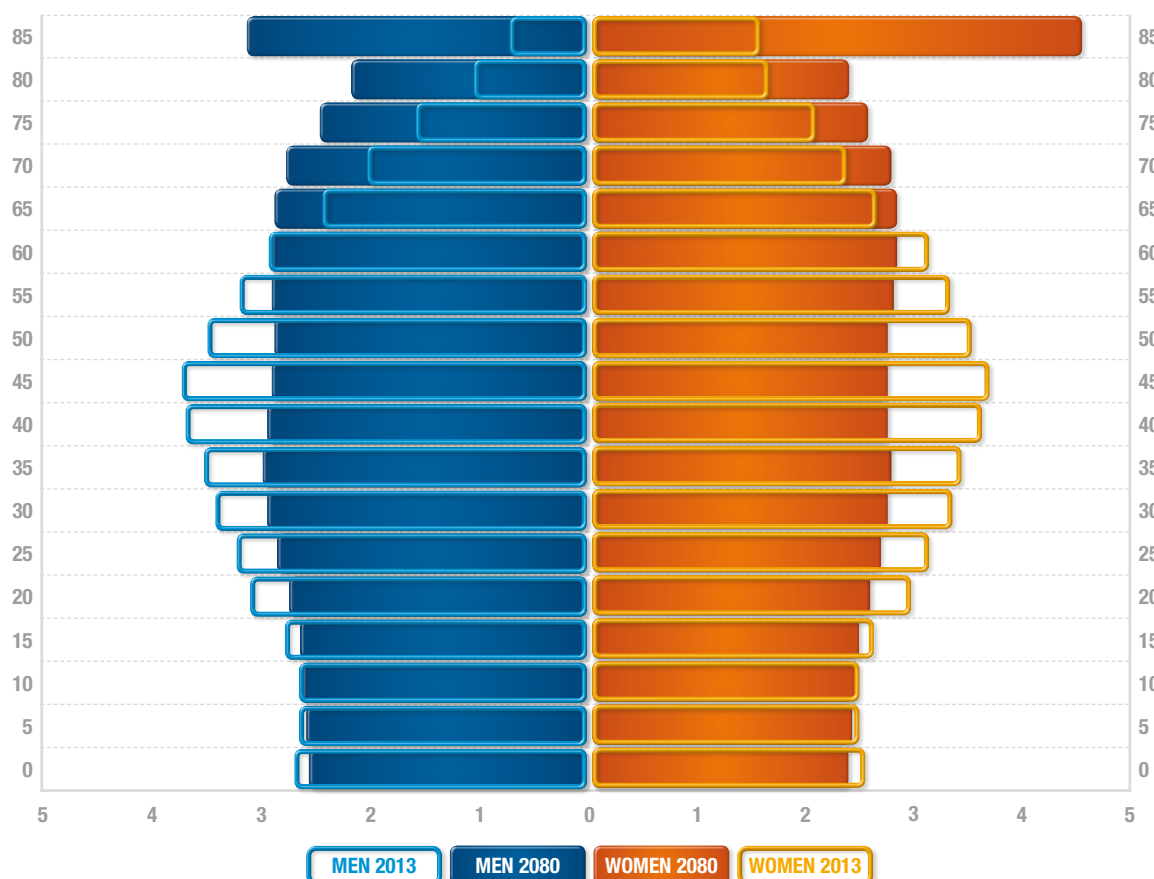
1. Every Member State's healthcare system needs a plan which addresses their population's healthcare needs and delivers integrated care to those who need it most.
2. The plan should include provisions for multi-year funding, stakeholder engagement, education and for overcoming governance, organisational, financial, operational, legal, technological and cultural barriers.
3. More focus is required on engaging citizens, providing information, care coordination services, online tools and platforms which empower them to manage their health and wellbeing.
4. Information sharing should build on existing eHealth solutions which are crucial in the context of Integrated Care e.g. citizen/patient identifiers, primary and acute electronic patient records, patient portals, longitudinal health records and shared care workflow Semantic and technical standards also need to be promoted. eHealth solutions are the mission critical enabler to successfully address the demands of Integrated Care
5. Incentives and appropriate business models should enable collaboration for better clinical outcomes by deploying shared care workflows, disease management and communications platforms which allow the entire care team – including the patient and their family – to work together on an agreed plan. This includes cross-organisational agreements, new organisational and financial models, and redefined roles where appropriate.
6. Patient organisations should be actively involved in designing better Integrated Care services, especially for complex, frail and elderly groups of patients which existing systems of care are failing to support.
7. The European Commission should continue to stimulate Integrated Care development, through Horizon 2020, the EIP AHA partnership, the EIT InnoLife KIC and other instruments, such as sharing and replicating good practice and scaling up successful deployments.

WHY IS THERE A NEED TO CHANGE CARE DELIVERY?

Integrated Care has been widely discussed in recent years, although the drivers have been recognised for some time. In 1988, the United Kingdom's Griffiths Report already noted that there was poor coordination between health and social services. As pressures on healthcare systems intensify, Integrated Care is increasingly seen as part of the response to quality and cost issues.

OECD data shows that the EU's population has increased 31% over the last 50 years, reaching 502 million in 2012¹. However, the population aged 65 and older has increased 157% in the same period, reaching 90 million. The proportion of the population aged 80 and over has grown from 1.2% to 5%. Average life expectancy at birth has increased by over two years in the last decade alone and by 2010, the EU average had reached 75.3 years for men and 81.7 years for women – although there is considerable variation between Member States². There is debate in the literature as to whether these additional years are being lived in better or worse health.

Figure 2: Demographic changes in recent years

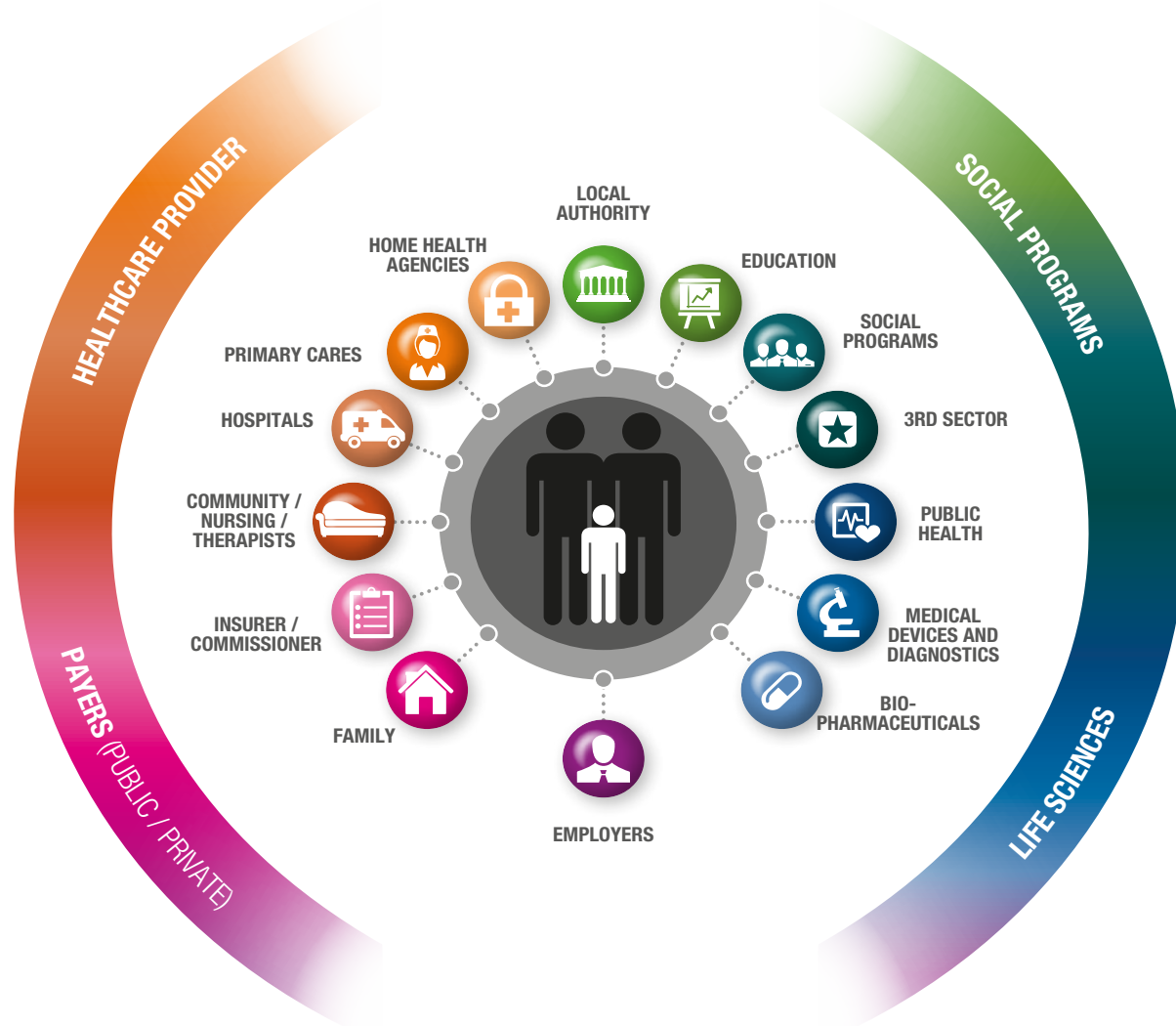


These demographic changes mean more people require care and more elderly people have greater healthcare needs. As the elderly population grows, so does the amount of multi-morbidity and complex chronic conditions, including patients with both physical and mental illnesses. Care is required from multiple specialists, brought together holistically, addressing the patient's needs and means. Specialists also encompass community carers, social carers, family carers, as well as the patient. However, the working age population – which is able to provide care services – is proportionally declining.

1. http://stats.oecd.org/Index.aspx?DatasetCode=POP_FIVE_HIST

2. http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Population_pyramids,_EU-28,_2013_and_2080_%281%29_%28%25_of_the_total_population%29_YB14.png

Figure 3: Circle of Care Diagram



Admissions to acute hospitals are increasing, yet the prevalence of hospital-acquired infections mean the hospital should not be a place for patients to stay too long. Hospitals are usually the most expensive environment in which to care for patients, especially when patients' medical needs have been addressed but are still waiting for social care services to be put in place. In many countries, health policy is attempting to move an increasing amount of care to a community setting.

Increasing (super-)specialization of hospitals and concentration of expertise and knowledge in fewer hospitals has proven to enhance the quality of difficult interventions but requires even more coordination between the different actors.

Unfortunately, even well-funded health and social care systems do not necessarily deliver high-quality care (as experienced by the citizen) or better outcomes (as measured by quality indicators) and this affects citizens' quality of life. In many cases, costs could be avoided with better care coordination, regular check-ups, medication reviews and improved management of chronic conditions. However, as no single provider is responsible — or reimbursed — for ensuring good care coordination or preventing health crises, it is difficult to drive change into care systems.

The burden of disease in the developed world is changing. We have long moved away from communicable disease as the major burden in the EU, that being replaced by chronic conditions. Lifestyle behaviours such as alcohol and drug use have been increasing, although tobacco use has generally been falling. Available food types and human behaviors have led to a considerable increase in obesity with attendant conditions such as diabetes. Advances in medical science mean that we can now treat many acute conditions, increasing life expectancy – although these extra years are not necessarily healthy, as there is an increased prevalence of diseases associated with ageing.

A majority of over 65s report suffering from two or more conditions and patients who experience multi-morbidity report problems with care coordination. For under 65s living with multiple conditions, there is evidence that better integrated care may allow them to remain in productive employment for longer, leading to economic gains for citizens and the wider economy.

It is clear that patients need holistic care from multiple sources. However, services are often fragmented, provided by different organisations with individual strategies, budgets and staff cultures. Handover between teams, even within the same organisation, is often uncoordinated and costly. In some domains, this is compounded by skill shortages. This also leads to geographical variations in care delivery.

Patient expectations have also changed. People are less deferential and more knowledgeable about the medical profession. Patients expect their needs to be dealt with comprehensively, rather than having to organise various parts of the care system themselves. Furthermore, family structures are changing, with members more geographically spread out, parents having fewer children and working lifetimes extending. This means care needs cannot be met within the family as easily.

After years of increasing investment, recent global financial hardships mean that governments have reduced healthcare funding and continue to do so. Social care has also seen a considerable decrease in investment. In some cases, voluntary organisations have had to step in to provide services, which is welcomed by patients, but may disorient coordination. Voluntary organisations are often better placed than traditional medical systems to address non-medical patient needs which contribute considerably to their wellbeing e.g. by providing companionship, walking groups or lunch clubs.

A range of demographic, financial, health and social issues mean changes are needed in healthcare delivery strategies. Better care integration will be part of that change and will help deliver the ‘triple aim’: higher quality care, decreased costs and improved population health³.

WHAT IS MEANT BY INTEGRATED CARE?

When looked at holistically, healthcare systems are declared “unsustainable”. When economic crises hit, all countries need to find ways to do more while containing health expenditures. The delivery of Integrated Care – which addresses hospital, primary, community, social care and includes patients – is recognised as one of the most promising concepts to assure healthcare systems’ sustainability in Europe and worldwide. Focus needs to shift from reacting to health crises, towards strategising, anticipating risks and needs, and promoting prevention as a way of managing demand. As stated by the European Commission’s European Innovation Partnership (EIP) on Active and Healthy Ageing, Integrated Care benefits all Europeans, especially fragile and elderly people and addresses resource efficiency and sustainability.

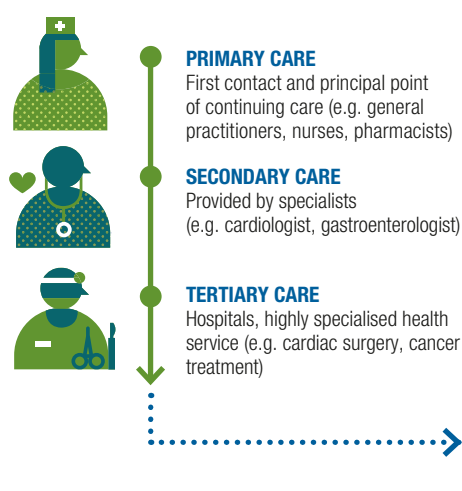
This means building health systems on Integrated Care models, including governance, financing, organisational, service delivery and clinical levels. Care continuum design must consider prevention, diagnosis, treatment, care, rehabilitation and health promotion, including monitoring and continuous patient care management, especially for chronic conditions.

3. Source: Berwick DM, Nolan TW, Whittington J. The triple aim: Care, Health, and cost. *Health Aff.* 2008;27(3):759–6

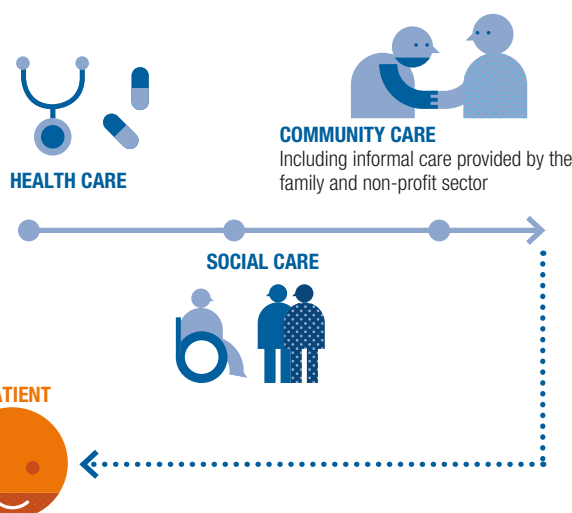
Integrated Care (IC) differs depending on care providers' ambition. Its scope can focus on primary and secondary care but can expand to social care. Different forms might co-exist, such as legal integration – where organisations merge together or virtual integration – where providers work together through virtual networks. Additionally, integration might be horizontal – between providers in the same care domain such as a group of hospitals, or vertical – between providers working at different levels in the patient life cycle, e.g. acute and primary care.

INTEGRATED CARE IS THE COORDINATION OF CARE:

VERTICALLY, ACROSS THE LEVELS OF HEALTH CARE:



HORIZONTALLY, ACROSS DIFFERENT TYPES OF CARE DELIVERY:



SOME RELEVANT FEATURES:

- ✓ Shift from reactive service delivery (after adverse health events, e.g. a cardiac arrest) to preventive and proactive care (prevent and manage chronic conditions, e.g. maintain healthy blood pressure / cholesterol level)
- ✓ Patient-centred approach and active involvement of the patients in understanding and managing their own diseases (patient empowerment)
- ✓ Move from institutional to community / home based care

As pointed out by UK think tank The King's Fund, IC may require integration between commissioners or payers and care providers. Whatever the scope of integration, providing access to better and safer care at a lower cost can only be addressed through transforming current care delivery mechanisms around the patient life cycle and its continuum of care. The upcoming IC era will therefore see care providers collaborate to share patient data, care plans, knowledge and insights from day-to-day operations, focusing on continuous care, disease prevention, disease management and population health insights. This will dramatically improve patients' clinical outcome. Coordination, alignment and connectivity are crucial for successful IC and the patient experience will be transformed, as IC enables a more personalised, timely and cost-effective care journey.

There are many examples of efforts to promote integrated care at different organisational levels. However, not enough attention is devoted to the patient's role, responsibilities and needs. The patient's care context and other behavioural, social and environmental aspects, need to be taken into consideration. Equally, the role of the Health ICT industry should receive more attention, technology is a necessary enabler and crucial for successful IC.

EXAMPLES OF INTEGRATED CARE ORGANISATIONAL MODELS

Many different organisational models of integrated care are being tested across the world.

These include:

- 1. Collaborative models:** organisations remain separate, but cooperate to share information and care plans. This requires regular communication, teamwork and a high level of trust.
- 2. Contractual models:** agreements are drawn up between different care providers, which set out responsibilities, service levels and escalation procedures. These models are more difficult to establish, but provide greater clarity and reduce the likelihood of gaps and inconsistencies. Examples include the contractual agreements between health regions and municipalities in Denmark to coordinate health and social care services.
- 3. Consolidation models:** organisations are combined under a single management structure and the leaders become accountable for integration. These models make it easier to deliver joined-up services and to redistribute funding. Examples include the Accountable Care Organisations (ACOs) in the USA, which usually follow the Patient-Centred Medical Home models of primary care.

EXAMPLES OF INTEGRATED CARE DELIVERY

There are many efforts to promote integrated care at different organisational levels.

- 1. In Scotland,** the parliament has passed a joint working bill which mandates the creation of new Health and Social Care Partnerships. It will provide governance for integrated health and social care.
- 2. In England,** over £5 billion of funding is being moved from the National Health Service and local authorities into the shared Better Care Fund to deliver integrated care. Other longstanding examples exist in areas such as Torbay, where services are co-located and care managers have been appointed to coordinate multiple organisations for the benefit of the elderly.
- 3. In France,** responsibility for healthcare delivery coordination is being devolved to Regional Health Authorities (Autorités Régionales de Santé). There is a strong emphasis on care coordination for the population across logical geographical regions around hospitals, called Territoires de Soins Numériques.
- 4. In the Netherlands,** there are now various networks of care developed around specific diseases, for example the challenge of functional decline caused by Parkinson's, with ParkinsonNet connecting 2,700 caregivers.
- 5. In Southern Denmark,** a Shared Care IT platform has been created to bring together information needed, from multiple sources, across the region.
- 6. In Catalonia,** the government is seeking to reduce hospital admissions and costs through the creation of the CCP (Complex Chronic Patient) programme and the associated i-SIS.cat technology platform. CCP will improve collaboration between clinicians and social workers through integrated information and a portal will be created for service providers.

WHAT IS THE VALUE OF PROVIDING MORE INTEGRATED CARE SERVICES?

Whilst integrated care is increasingly seen as one of the most promising approaches to tackle some of the challenges already outlined, we need realistic expectations about what benefits may accrue, and over what timescale. Some see more integration between services as a way of reducing, or at least containing, care costs. Others see the possibility of quality and safety improvements from IC, leading to better outcomes for patients and citizens. It is sometimes viewed as a short-term priority for more complex and costly cases, with the potential to increase the capacity of the system to 'do more'. What does the evidence show?

'Evidence on the Economic Impacts of Integrated Care'⁴, a study of 19 aggregated IC studies found that a measurable cost reduction was only seen in a small number of cases, mainly due to reducing utilization of hospital resources.

In many more of the cases, quality improvements were seen, resulting in better patient outcomes and experiences. The study suggests that Integrated Care should be viewed as a "strategy to innovate and implement long-lasting change in the way services in the health and social-care sectors are being delivered", rather than a cost-effective, short-term intervention.

It is difficult to imagine how IC can be delivered without supporting eHealth platforms and applications. The upcoming IC era will need care providers to use eHealth services for collaborating and sharing information, knowledge and insights from day-to-day operations. Information should focus on continuous care, disease prevention and disease management, and should cross organisational, professional and geographical boundaries. This requires accessing many information sources, aggregation of information into views of the citizen or patient and using effective tools to share information across the care team, providing a more seamless and dynamic service.

The basic concepts of population health management – clinical and social health data, risk stratification, disease management, evidence-based guidelines – require smooth information flow, care plans which can be agreed and also shared and acted on collectively and outcomes which can be tracked and measured.

IC goes beyond the normal capacity of medical and social record-keeping systems and requires investment in new platforms e.g. data aggregation sites, information portals, shared care systems and collaboration platforms. These, in turn, need to support new methods of working and care pathways to achieve the goals of Integrated Care. Countries and regions who have already invested in basic eHealth structures, such as unique citizen or patient identifiers, secure messaging networks, electronic patient records and standards to improve interoperability, are clearly in a better position to deliver integrated care to their citizens. These investments provide the ability to locate and manage the data, as well as the necessary trust that it will be well managed, and confidence in the accuracy and currency of the information.

THE NEED TO OVERCOME CHALLENGES AND INHIBITORS

The need to improve the integration of care has been seen as a challenge for many years. In 1997, the United Kingdom's Secretary of State for Health, Frank Dobson, called for the demolition of the «Berlin Wall» between health and social services, aptly describing the scale of the task.

The fact that there are different types of integration (horizontal, vertical, structural, virtual) is the first challenge. It must be clear what is trying to be achieved. Differing objectives and definitions of what IC is will present difficulties.

Structural reform has been attempted in a number of settings, with functions being moved between organisations. It is potentially easier to aim for virtual integration, with its aim to link functions across organisations. Large-scale structural change can misdirect staff focus away from caring for citizens, so maintaining organisational stability allows staff to overcome challenges

4. Nolte & Pitchforth, European Observatory on Health Systems & Policies 2014

of IC implementation in a more manageable way. However, virtual organisations need clear guidelines which ensure everyone works together efficiently. This applies to care and management processes – too many budgeting and approval processes can be inefficient. Physical separation can also be an inhibitor – bringing organisations together in a shared office can be very helpful.

Differing work cultures must also be taken into consideration – doctors, nurses and social workers have their own sets of standards and norms. Negotiating control and accepting solutions developed elsewhere is very difficult for any party. Different groups will also have their own views of what constitutes adequate evidence to justify change. Strong leadership, change management and communications skills are the greatest requirements for IC delivery and a shared vision must be actively developed and reinforced.

Finance will always be a central issue and economic pressures on healthcare systems are currently acute. Whether a specific care integration project will actually save money needs to be considered alongside the other benefits. Extra, transitional funding is often needed to allow old and new processes to run in parallel. With different organisations involved, costs may fall in different organisations compared to the benefits. Practitioner reimbursement may be a further issue, as many organisations are moving away from fee-for-service models to payments based on patient outcomes or population wellbeing. Funding for pilot projects may also prove to be too short lived to achieve a fully embedded solution.

Information sharing is key to successful care integration. A substantial challenge is to connect disparate IT systems. Difficulties can be technical or relate to privacy and legal aspects of data sharing. This issue affects efficient cross-border care in regions, countries and across Europe. Standards are necessary to secure three crucial aspects of eHealth: interoperability (addressing semantic, coding and data sharing issues), patient safety and privacy. Standards are prerequisites for companies to reach economies of scale for eHealth-related goods and services. They lead to lower costs for users and a more rapid take-up of eHealth solutions, as experience is transmitted faster between different areas. In any case, practitioners need a full picture of their patients, with information from multiple sources, presented in a timely and usable way.

Technology is the enabler and it should align with the usage to make this change successful, breaking down barriers between organisations and professions. Negotiation between who pays and who receives the benefits is essential. A lack of financial incentive to support eHealth adoption in daily clinical routine practice, is something which still needs to be overcome.

There is already pressure on care systems to move away from a 'fee for service' model, where reimbursement is based on the volume of medical procedures (inputs), towards a 'payment for outcome' model either for an episode of care such as knee replacement, or under a capitation model for certain patient population such as diabetes. Reimbursement based on quality measurements (outputs), improving individual health status and reducing dependency, will become more prevalent.

Appropriate investment in good change management, will ensure that these issues of culture, leadership and finance are addressed. Stakeholder expectations need to be carefully managed, especially notably on timeframe issues. Cross-sector support, bringing together the public sector, industry and academia, will also facilitate effective change.

Other barriers hindering eHealth market development include a lack of legal clarity and local market specificities, e.g. data privacy laws. Industry wants the creation of a single, competitive eHealth market in Europe. This can only be achieved by creating the same market conditions across Europe.

A final potential inhibitor is a lack of understanding of patient and clinician needs. In Integrated Care, the needs of the patient/citizen are central and it is necessary for eHealth to help them maintain good health, manage their conditions and live independently as long as possible.

To sum up, eHealth technologies could help transform healthcare as delivered today into an outcome-based healthcare tomorrow, if the challenges outline above are overcome.

COCIR RECOMMENDATIONS TO CAPTURE THE VALUE OF INTEGRATED CARE

Integrated Care is one of the most promising strategies available to overcome the challenge of increasing demand and more complex cases. Care providers need to pursue a more holistic approach to keep their population healthy, better manage chronic diseases and minimise healthcare costs.

1. Every healthcare system should have a plan which understands population needs and delivers integrated care to those who would need it the most.
2. The plan should include provisions for multi-year funding, stakeholder engagement, education and for overcoming governance, organisational, financial, operational, legal, technological and cultural barriers.
3. There needs to be a focus on citizen engagement, providing relevant information sources, care coordination services, online tools and platforms to connect with and empower citizens in the management of their health and wellness.
4. Information sharing should build on existing eHealth investments, such as citizen/patient identifiers, primary and acute electronic patient records, patient portals, longitudinal health records and shared care workflow, as well as promoting the use of semantic and technical standards.
5. Collaboration should be enabled by deploying shared care workflows, disease management and communications platforms which allow the entire care team – including the patient and their family – to work together on an agreed plan, including cross-organisational agreements, new organisational and financial models, and redefined roles, where appropriate.
6. Patient organisations should be actively involved in the design of better integrated care services, particularly frail and elderly groups, some of which have complex diseases, for whom existing care systems are failing to support.
7. The European Commission should continue to stimulate the development of Integrated Care through Horizon 2020, the EIP AHA partnership, the EIT InnoLife KIC and other instruments, such as sharing and replication of good practice and scaling up of successful deployments

MANAGED IT SERVICES

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PART 2 MANAGED IT SERVICES

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Managed IT Services outsource day-to-day management responsibilities to improve daily operations and cut costs. The organisation which owns or has direct oversight of the system being managed is referred to as the customer. The organisation which provides the Managed IT Services is regarded as the service provider or Managed Service Provider (MSP).

Also in healthcare, the decision to move to Managed IT Services is driven by economy of scale, but also allows the customer to outsource non-core skills. Demand for operational and financial sophistication in order to provide value based care will impose ever increasing IT needs and requirements, and managed IT services represent a real opportunity for care providers.

Under a Managed IT Services model, the care provider typically pays a fixed fee per month based on a specific and predefined metric such number of patients for a specific term (5, 7 or 10 years). However, a capital purchase model may also apply – the key difference in a Managed IT Service model is vendor ownership and management.

In the healthcare sector, technology infrastructure and systems have traditionally been managed in-house, due to concerns over privacy and security, as well as the inherent need to keep systems and their data near to the organisation. Healthcare is now learning from other sectors about how to get the benefits from Managed Services without compromising data security.

COCIR RECOMMENDATIONS FOR MANAGED SERVICES:

1. Adopt Cloud Computing to achieve a more connected and efficient healthcare system. Adopt a proven and accepted terminology, technical standards and a common framework of operational, financial and legal guidelines
2. Build trust and confidence in privacy and security
3. Healthcare stakeholders need to promote realistic adoption of Managed IT Services and help enable change by showing the potential in addressing the diverse needs of healthcare providers
4. Balance and manage security and privacy concerns, clarify data ownership
5. Stimulate adoption of industry standards

DEFINITION OF MANAGED IT SERVICES

In the general IT context, Managed Services can be defined as the practice of outsourcing investment, operation and life cycle management responsibility of IT infrastructure and software applications to IT service providers. The Managed Service provider (MSP) assumes an ongoing responsibility for 24-hour monitoring, managing and problem resolution for the IT systems within a business.

With a Managed Services model, the MSP or supplier takes care of issues an internal IT team would typically handle, such as keeping hardware up and running, ensuring software is up-to-date and handling patches. MSPs take over some key business and services usually done in-house, by the customer and under its ownership and responsibility. It can include: hardware, software, implementation services, infrastructure, professional services, maintenance and rental services.

Managed Services can be expanded beyond IT, covering human resources and related operations support, so-called Business Process Outsourcing (BPO). Therefore, Managed Services refers to innovative business, delivery and services models.

WHAT MAKES MANAGED IT SERVICES DIFFERENT?

DIFFERENT FROM TRADITIONAL DELIVERY MODEL

The key difference between a traditional and Managed Services model is the ownership. In a Managed IT Services model, the customer determines which IT services are needed but the MSP manages and assumes responsibility for providing the defined set of IT services to its customer.

In the traditional model, the customer invests and buys the needed infrastructure up-front, sized to the expected business needs and requirements. The customer runs and manages the service with its own dedicated resources and staff usually on its own premises.

As shown below, the customer is the owner in a traditional model, whereas in an Managed IT Services model, the supplier is the owner – with the exception of the data, whose ownership remains with the customer.

Table 1: Overview of differences between Managed IT Services model and a Traditional model

	MANAGING SERVICES MODEL	TRADITIONAL MODEL
FINANCING	OPEX	CAPEX
BUSINESS MODEL	PAY PER X	LICENSE BASED
OWNERSHIP (HW/SW)	SERVICE PROVIDER	CUSTOMER
INSTALLATION	HOSTED (CAN ALSO BE ON SITE)	ON-SITE
IT MONITORING	BY SERVICE PROVIDER	BY CUSTOMER
SERVICE MONITORING	BY SERVICE PROVIDER	BY CUSTOMER
RISK MANAGEMENT	BY SERVICE PROVIDER	BY CUSTOMER

Other characteristics such as installation (on-site, off-site), monitoring, performance measurement and risks management aspects differ between the two models.

NEED FOR A SERVICE LEVEL AGREEMENT (SLA):

When the decision is made to move forward with a Managed Services model, the customer and service provider conclude a Service Level Agreement (SLA).

A SLA is a written agreement between the customer and service provider which contains a description of the services to be delivered as well as the rights and the duties of both parties.

Typical components of a SLA include:

1. DESCRIPTION OF THE SERVICES TO BE DELIVERED

Scope/Functionalities of the delivered services:

- Scope/Functionalities to be delivered when and where;
- User help desk
- Training
- etc...

Performance of the delivered services:

- Availability (e.g. 99.7% of time)
- Response times
- Corrective and preventive maintenance
- Security level
- Disaster recovery
- etc...

Restrictions:

- Maximum simultaneous users
- Maximum transactions
- other

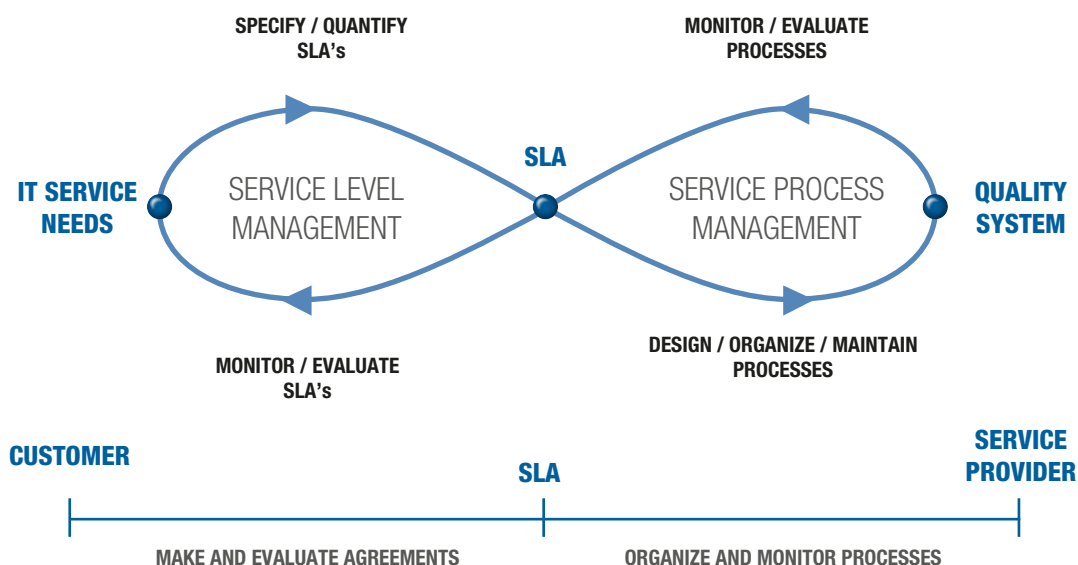
2. RELEVANT ADMINISTRATIVE ASPECTS

- Escrow arrangements
- Reporting type and frequency
- other

3. RELEVANT LEGAL ASPECTS

- Privacy and data security statements
- other

Figure 1: Service Level Agreement (SLA) process



SLAs need to be monitored continuously and evaluated/adapted regularly. KPIs need to be defined in the SLA (e.g. response-time, uptime) to measure performance. The service provider will monitor and report on performance of the delivered service on a regular basis. Issues will be discussed with the customer and addressed. The customer will verify if the requested service is meeting his business needs on a regular basis and whether he wants to adapt the SLA accordingly. (See Figure 1: SLA process)

DIFFERENT FROM TRADITIONAL FINANCING MODEL

CAPEX, OR CAPITAL EXPENDITURE

is a business expense incurred to create future benefit (i.e., acquisition of assets that will have a useful life beyond the tax year). For example, a business might buy new assets, like buildings, machinery, or equipment, or it might upgrade existing facilities so their value as an asset increases.

On the other hand, those expenditures required for the day-to-day functioning of the business, like wages, utilities, maintenance, and repairs, fall under the category of **OPEX**, or **OPERATIONAL EXPENDITURE**. Opex is the money the business spends in order to turn inventory into throughput. Operating expenses also include depreciation of plants and machinery which are used in the production process.

Financing Managed Services moves from the OPEX model to the CAPEX one. Its business model can be based on any metrics agreed by the customer and supplier. For example:

PAY PER

1. usage units
2. workstations (used or not)
3. use
4. exam
5. patient file
6. data volume
7. procedure
8. ...

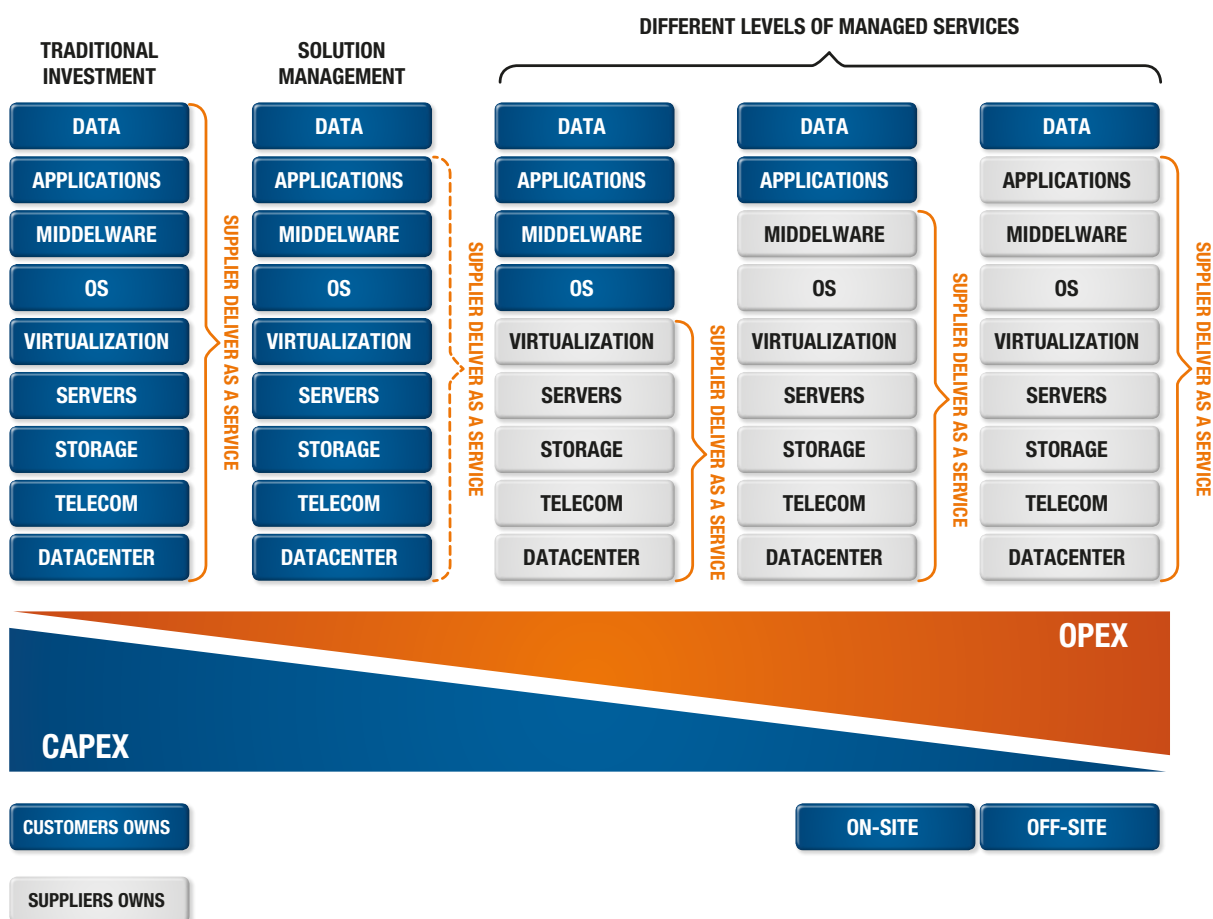
DIFFERENT FROM CLOUD COMPUTING

While Managed Services is the practice of outsourcing investment in IT solutions, Cloud is a technology which deploys the services. Cloud is based on innovative IT architecture and ways of configuring computing and technology resources (see chapter on Cloud Computing).

Therefore, the Cloud can support Managed Services (see figure below) but it is not a requirement. If a customer specifically wants Cloud services, they could buy the necessary infrastructure and have it implemented and maintained by their own staff, or it could be sourced from a vendor through Managed Services.

Both Cloud and Managed Services help organisations reach economies of scale through sharing or outsourcing.

Figure 5: Cloud Computing



DIFFERENT LEVELS OF MANAGED SERVICES

Since the IT resources of a healthcare provider consist of many different aspects involving hardware, software, infrastructure, implementation & support services, people and management skills as well as financing mechanisms, the Managed Service approach can address different levels of sophistication in the way specific elements are being outsourced. Also, and as indicated above, Managed Services can be broader and encompass more than IT resources.

DIFFERENT LEVELS OF OUTSOURCING VERSUS MANAGED IT SERVICES

The different levels of outsourcing can be defined as:

1. Basic solution management services: offering all the necessary services to guarantee system uptime and to keep the IT platform up to the latest state of industry standards in terms of software, data security.
2. A medium level addresses the inclusion of infrastructure, hardware, software and services
3. Total outsourcing includes processes and people e.g. human resources, facilities management

This leads to contracts with differing levels:

1. Low level - Long term service contract (e.g. 10 years) type break & fix offering remote maintenance
2. Mid-level – On-site or hosted services with on-site break & fix contact, helpdesk, problem and asset management, routine maintenance and others
3. High-level – Fully outsourced including staff (technical/IT people). It could mean total outsourcing of a department or even the hospital (building, equipment, staff)

The most important benefit of the Managed IT Services model is to let the customer focus on its core activities and to outsource part or all the IT activities.

Managed IT Services offer a vast array of options, such as data backup and recovery, system monitoring and management, hosting, DB maintenance and patch management, OS maintenance, security audits and updates and uptime guarantee. This allows small business owners to focus on their core business, avoid large, up-front IT-investments and hiring a dedicated IT staff. They can source IT services as needed. As the business evolves, owners can be assured that their IT is properly managed.

ON-SITE VERSUS OFF-SITE

In the Managed IT Services model, the customer does not require the location of the computing resources at its premises but merely the use of it. With the availability of affordable, high-capacity, and secure broadband networks, and the applications being built on a client-server architecture, the infrastructure, the solutions and the supporting services also do not necessarily have to physically reside at the customer premises. This saves the customer money on space, cooling, power backup facilities etc.

Two models which offer an economy of scale coexist:

1. Managed on-site at the customer location
2. Hosted off-site

Although to different levels, both hosted off-site and on-site offer economy of scale.

MARKET DRIVERS AND RESTRAINTS

Healthcare providers lag behind other vertical markets in adopting Managed Services. However, this model is an evolving paradigm, constantly increasing its offering to vendors and being adopted by users, and shows strong drivers to adopt it but also restraints.

Table 2: Overview of drivers and restraints for Managed Services

DRIVERS	RESTRAINTS
<p>1 IMPROVE SERVICE QUALITY:</p> <ul style="list-style-type: none"> • BUSINESS: customers can focus on its core business, not IT • DELIVERY: Simplified software delivery model, support models From Infrastructure as a Service (IaaS) (e.g. storage) to Software as a Service (SaaS) which reduce deployment and maintenance costs and limit upgrades/migration • KNOWLEDGE: Simplified access to shared content for decision support, Business Intelligence, secondary usage • CERTIFICATION: easier to comply with ISO 20000 	<p>1 LACK OF AWARENESS AT C-SUITE LEVEL</p>
<p>2 REDUCE COSTS:</p> <p>Managed Services often work on a flat-rate, monthly fee pricing structure which varies according to the services offered and the number of devices managed.</p> <ul style="list-style-type: none"> • COSTS: More predictable costs for the customers • TOTAL COST OF OWNERSHIP (TCO): Addressing the total cost of ownership for the customers 	<p>2 LACK OF EVIDENCE ON REDUCED COSTS/ INCREASED BENEFITS</p>
<p>3 REDUCE AND SHARE RISKS:</p> <ul style="list-style-type: none"> • SECURITY AND CONTINUITY: Better continuity guarantee (high uptime) and security • LOCALISATION: From customer premises towards more secure, off-site locations operated by experts 	<p>3 RESISTANCE TO CHANGE AND RELUCTANCE to be early adopters – need to be shown the potential of adopting Managed IT Services</p>
<p>4 REDUCE LIABILITIES:</p> <ul style="list-style-type: none"> • Less dependence on increasingly scarce and expensive IT skills 	<p>4 PROCUREMENT MECHANISMS</p>
<p>5 FOR MID TO LOW SIZE ORGANIZATIONS Managed Services is a way to access to best in class IT management at a fraction of the cost.</p>	<p>5 PRIVACY AND SECURITY: Big variance in regulation between EU Member States and regions, which limits cross-border data movement and therefore economies of scale.</p>

COCIR RECOMMENDATIONS TO CAPTURE THE VALUE OF MANAGED SERVICES

COCIR recommends public authorities, decision makers and users to remove the barriers preventing healthcare adopting Managed Services:

1. Adopt Cloud Computing as it delivers benefits and value for their use cases and contributes to a more connected and more efficient healthcare system. A necessary prerequisite would be to familiarize with a proven and accepted terminology, technical standards and a set of common framework of operational, financial and legal guidelines to guarantee success while executing a project. Further reference is given by NIST - <http://www.nist.gov/>
2. Building awareness at C-suite level on reduced costs and increased benefits, including the quality of services, risk management aspects
3. Build trust and confidence in privacy and security
4. Promote realistic adoption of Managed IT Services by healthcare stakeholders, and enable change by, showing the potential in addressing the diverse needs of healthcare providers
5. Balance and manage security and privacy concerns, and clarify data ownership
6. Promote adoption of industry standards

CLOUD COMPUTING

3



PART 3 CLOUD COMPUTING

3

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Cloud Computing is a model which enables ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, applications, and services). The Cloud can be rapidly provisioned and released with minimal management effort or service provider interaction. This chapter explains the main types of Cloud services available (Software as a Service or SaaS, Platform as a Service or PaaS, Infrastructure as a Service or IaaS) as well as the types of implementation (private, public, hybrid). As Cloud technologies are useful in Managed Services, market drivers and restraints are similar.

Cloud Computing is a new computer technology and architecture which allows for easy and flexible sourcing of computing power, storage and electronic services without needing to worry about a physical storage location. It can be sourced over the internet or implemented in-house. Upscaling and downscaling can be done rapidly, both technically and financially.

Healthcare is going through a transition towards more integrated care where all healthcare providers and also social care and the patient/citizen collaborate for his wellbeing. Cloud computing can address the needs of Integrated Care, providing flexible innovating solutions which can be easily scaled from pilots to widespread daily use. The technology can more easily enable self-provisioning by users and mobile applications.

Typically, Cloud models are Managed Services since all IT resources offered via this model are usually managed by the Cloud provider.

COCIR RECOMMENDATIONS FOR CLOUD COMPUTING

1. Adopt a standard Cloud terminology based on NIST definition
2. Build awareness at C-suite level of the reduced costs and increased benefits (better service quality, risk management)
3. Build trust and confidence in privacy and data security
4. Promote realistic adoption of cloud services by healthcare stakeholders, and manage resistance to change and adopt
5. Stimulate Cloud HIT solutions based on open standards

WHAT IS CLOUD COMPUTING?

In recent years, 'Cloud Computing' has emerged as an important trend in information technology and has become a commodity, available to anyone with an internet connection. Cloud storage services such as Dropbox, Skydrive and iCloud are used daily by millions of users. On Amazon virtual servers in the Cloud can also be easily and activated online by anyone. Google apps are also a good example of applications in the cloud. It's a very broad concept with many interpretations.

The US' NIST defines Cloud Computing as: "A model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction."

Two key points:

1. Cloud Computing is an on-demand model, an IT architecture – not a category of web-based services. Cloud is an approach that enables the IT service, not the IT service itself.
2. Cloud Computing is a model which allows resources to be rapidly and automatically provisioned to users. This allows for massive scaling possibilities and better economics. Most of these services are software applications.

Cloud Computing encompasses several trends in information technology:

1. Off-premises data centres offering computing services on an industrial scale
2. "Software as a service" (SaaS) delivered to customers via the internet on an as-needed basis
3. Broadband networks connecting a growing number of devices to these services, often wirelessly

Therefore, Cloud Computing is a transformational technology with a disruptive impact on business models, delivery mechanisms and the architecture of Health IT solutions.

In the traditional computing model, each business maintained its own data centre, with its own servers. As businesses added applications, servers were added to run the new applications separately, to ensure the stability of the overall system. However, the capacity of such servers was often highly underused. Also, although the servers themselves were not expensive, their proliferation increased electricity and cooling requirements and staff as data centres needed more qualified systems administrators.

The solution which arose was 'virtualisation' software, which enables servers to run multiple operating systems and applications at once, effectively transforming servers into many "virtual machines" which customers can access remotely. Users, particularly those with variable demand (such as seasonal businesses), can vary their consumption without needing to invest in enough servers to meet peak demand year round.

Companies which have built large 'server farms' to offer these services include Microsoft, Amazon, Google, IBM and Yahoo. Such facilities tend to be located where land, electricity, cooling and labour are less expensive, often abroad.

Other technical trends driving the adoption of Cloud Computing include the spread of affordable, high-capacity broadband networks (cable, fibre-optic, satellite, and wireless) and the development of more powerful, low-cost computer processing chips. The combination of these two factors allows a growing number of devices – such as laptops, netbooks, mobile phones, specialised handhelds, smart meters and appliances – to be embedded with more intelligent, portable, and 'connected' capabilities.

Along with physical infrastructure, software is increasingly being designed as service-oriented architecture (SOA) – services which users can mix and match as needed and are distributed online, often on a pay-as-you-go model. Software often resides on the provider's servers, with the user accessing it via their Internet browser.

COCIR WOULD RECOMMEND THE ADOPTION OF THE NIST DEFINITION OF CLOUD COMPUTING:

Cloud Computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, applications, and services) that can be rapidly provisioned and released (elasticity) with minimal management effort or service provider interaction. This Cloud model is composed of service models and deployment models.

Key characteristics of Cloud Computing are:

1. On-demand self-service
2. Accessible from everywhere
3. Broad network access
4. Resource pooling
5. Rapid elasticity
6. Measured service

HOW DOES CLOUD COMPUTING RELATE TO MANAGED SERVICES?

CLOUD is a technology and architecture, delivering IT resources in an innovative way.

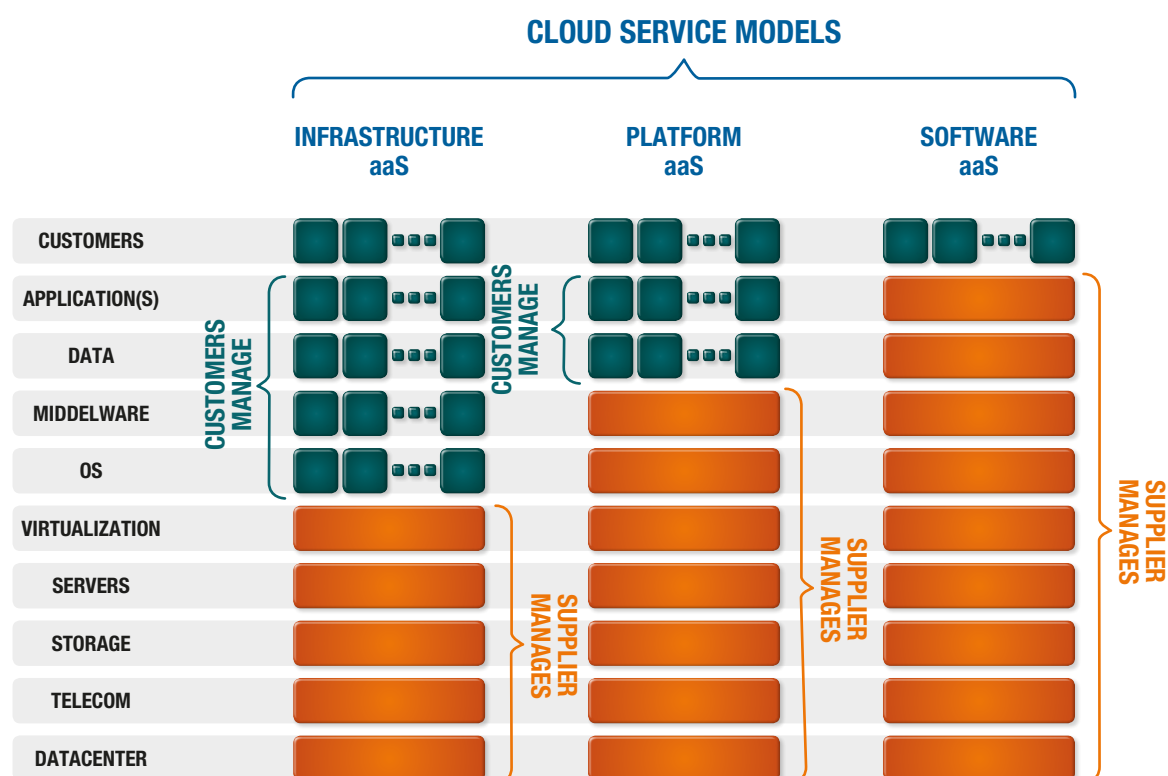
MANAGED SERVICES is the practice of outsourcing investment, operation and life cycle management of IT infrastructure and software applications to service providers. Key business and services functions originally done in-house are now outsourced by the customer, but remain under its ownership and responsibility. It can include: hardware, software, implementation services, infrastructure, professional services, maintenance and rental fees. Managed Services is therefore referring to innovative business, delivery and services models. Ownership is a key difference between the two approaches.

Cloud can support Managed Services, but it is not a necessary requirement. Both can help organisations reach economies of scale by sharing. Cloud models are typically Managed Services since all IT resources offered via the Cloud are typically managed by the Cloud provider. If a customer needs or wants Cloud technology they can source it from a vendor through Managed Services.

DIFFERENT CLOUD SERVICES

Cloud Computing is a broad concept, usually referenced into 3 different major services as illustrated below:

Figure 6: The three different services models of Cloud Computing.



1. IaaS: INFRASTRUCTURE AS A SERVICE:

Providing fundamental computing resources, e.g. processing, storage and networks. The customer deploys and runs arbitrary software, which can include operating systems and applications. The customer only has control over operating systems, storage, deployed applications and control of select networking components.

2. PaaS: PLATFORM AS A SERVICE:

Providing a Cloud platform which can deploy applications. The customer controls deployed applications and configuration settings for the application-hosting environment.

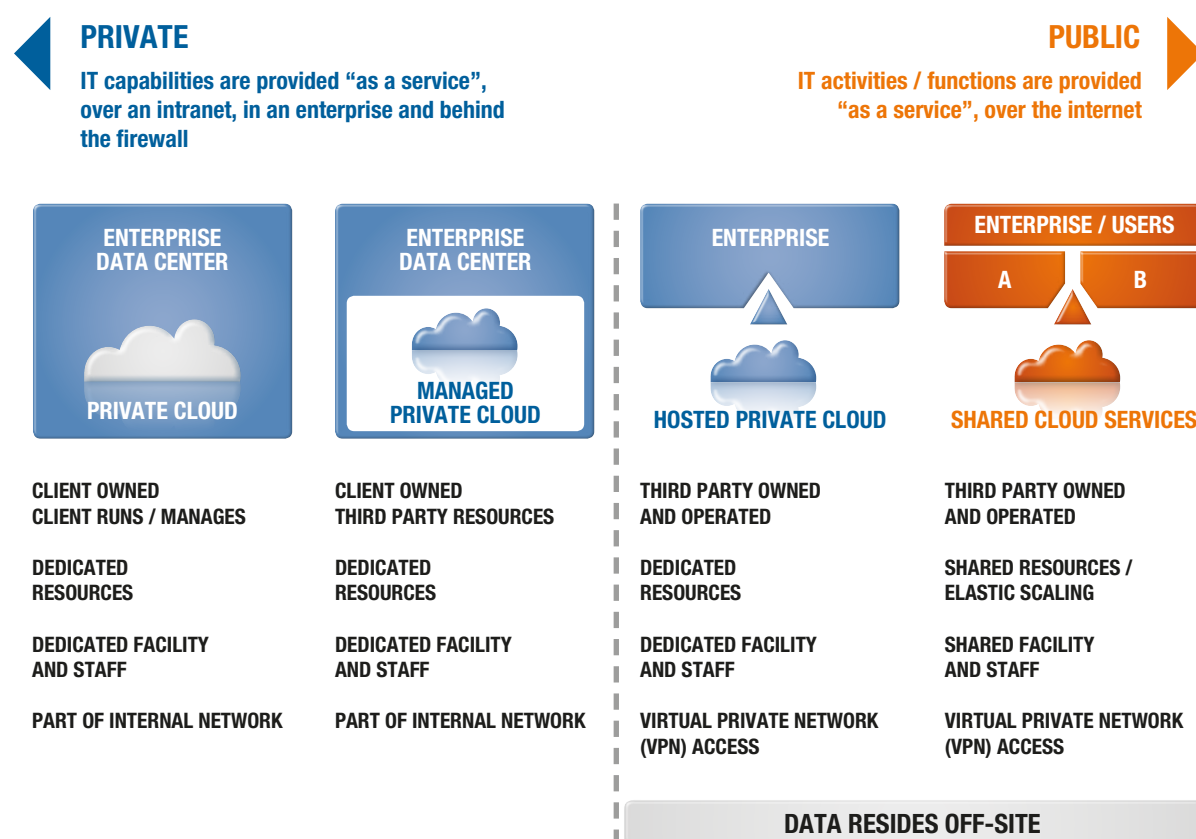
3. SaaS: SOFTWARE AS A SERVICE:

Providing Cloud applications. Applications are accessible from various client devices through a thin client or a program interface. The customer can choose to control limited user-specific application configuration settings.

Furthermore, there are three deployment models for Cloud Computing:

1. **PUBLIC CLOUD:** services which are widely accessible over the internet, available to everyone. Usually requires a low-level commitment from the end-user and is used on a temporary or as-needed basis. Due to public availability, these services need to be scalable for peak usage.
2. **PRIVATE CLOUD:** a computing environment which is shared within the customer's organisation, located within the firewall of a company and only accessible to its own user groups. It is a more secure environment and more commonly used for mission-critical business applications. Typically, this deployment model is much more tailored to the company's specific needs and an enterprise-wide approach to IT.
3. **HYBRID CLOUD:** a combination of the first two deployment models and the most common implementation of Cloud Computing today. This environment combines Public Cloud services in some areas with Private Cloud services in others. Each pool of resources is configured for a specific set of company requirements.

Figure 7: The 3 deployment models for Cloud Computing



While SaaS is increasingly popular, the traditional model of companies installing software on-site is still the most common approach and the two models (SaaS and traditional) are set to co-exist for some time. Today, the SaaS model is more common when the software application is not mission-critical and the business is able to continue even when the software access is interrupted. It is also more commonly used when there is little need to customise the software for the company. The on-site model is more common when there is a need for tighter security and when there is a high degree of company customisation or a high degree of integration with other software systems required.

MARKET DRIVERS AND RESTRAINTS

Cloud Computing is an evolving paradigm. Cloud has a strong potential to be adapted within Integrated Care, but it also suffers from restraints.

Table 3: Drivers and restraints for Cloud Computing

DRIVERS	RESTRAINTS
<ul style="list-style-type: none"> Healthcare is in transition, and calls for a paradigm shift: <ul style="list-style-type: none"> Seeking lower costs for developing and deploying Health IT solutions Evolving towards OPEX-based business models Continuously looking for innovation Increasing amount of consumers using health apps 	<ul style="list-style-type: none"> Lack of standards in Cloud interoperability, APIs and migration
<ul style="list-style-type: none"> The Cloud enjoys early adoption in primary healthcare, homecare and self-care: <ul style="list-style-type: none"> End-users of health IT solutions can use them alone Enabled by mobile, Internet of Things Elasticity of resources for Health IT solutions 	<ul style="list-style-type: none"> Privacy and security concerns for Personal Health Information storage and cross-border data transfer.
<ul style="list-style-type: none"> Increasing IT dependence on healthcare providers puts pressure on internal IT (skills, 24/7 access, cost). The Cloud allows them to concentrate on their core business 	<ul style="list-style-type: none"> Availability of high performing, reliable network infrastructure (especially mobile) Legal concerns due to immature regulatory framework and national differences.
	<ul style="list-style-type: none"> Health IT has a lack of funding, which may lead to substandard quality levels. Moving to high-quality Managed Services such as the Cloud may be harder. The cost of moving may offset the cost benefit of the economies of scale.

It is imperative to build trust and confidence in Cloud Computing, for both consumer and care providers. The restraints mentioned above have specific challenges.

FOR USERS, KEY CHALLENGES ARE:

- **GUIDANCE:** On which deployment model better suits their needs and requirements and how to take advantage of Cloud Computing.
- **ECONOMIC:** healthcare providers are still unclear about the cost and benefits of moving from a traditional CAPEX to an OPEX model
- **PROCUREMENT:** healthcare providers still lack good procurement practices to support OPEX-based model and Cloud-based ones.
- **MANAGE CHANGE:** acquire relevant knowledge for managing Cloud, build trust and confidence in the IT manager and user and manage resistance to any IT change
- **SECURITY AND PRIVACY STANDARDS:** users need assurance that data security and privacy risks are understood and appropriately managed. Gaps must be closed in compliance with Article 29 Working Party. This covers the Protected Health Information (PHI) storage in the public Cloud, the cross-border data transfer (community-state-region), adoption of Cloud-specific rules and the terms and conditions of Cloud providers
- **FRAUD PROTECTION:** illicit activities in Cloud Computing, such as digital theft, fraud and malicious hacking are a threat to both users of the Cloud and service providers

- **INTEROPERABILITY:** data portability and seamless use of interoperable applications on message and PI levels are crucial for all Cloud users. Additionally, users face the arrival of de facto standards (Amazon AWS/S3). Finally, the lack of possibilities to migrate data between Cloud solutions is perceived as an issue.

FOR SUPPLIERS, ISSUES UNDERPIN THE BUSINESS INCENTIVES TO INNOVATE IN THE CLOUD:

- **READINESS:** many healthcare applications are not ready yet for the Cloud
- **IP PROTECTION:** Intellectual property laws should provide clear protection and vigorously fight against infringement
- **INTERNATIONAL HARMONISATION OF RULES AFFECTING GLOBAL DEPLOYMENT:** governments sometimes implement or develop conflicting legal obligations with respect to user data and content held by Cloud Computing service providers. Governments, together with industry, should collaborate to harmonise rules in areas that affect Cloud Computing, such as data protection.
- **FREE TRADE POLICY WHICH ASSURES COMPETITIVE GLOBAL INDUSTRY:** Cloud technologies operate across national boundaries and their success depends on access to global markets. Countries should commit to a moratorium on implementing policies which create trade barriers to the evolution of Cloud Computing. They should also monitor existing international trade rules and revise them where needed.

THE ADOPTION OF CLOUD COMPUTING AND THE MARKET

COCIR notes that Cloud solutions are usually adopted when economically justifiable, therefore mostly in low to mid-end markets. The adoption rate has been slower for business-critical applications. Customers tend to wait until Cloud solutions are mature and legacy applications obsolete. Gartner predicts that Cloud maturity is expected in 2018 for the IT industry and after 2020 for Health IT.

In healthcare, COCIR anticipates that initial customers will be small-to-medium size care providers and legacy applications. These are two or more versions behind the current version and require limited integration needs with other applications and limited internal IT staff (for backups, support).

However, COCIR also expects the adoption rate will grow quickly after the market has reached maturity (hockey stick effect) and predicts that soon, 70% or more of the healthcare applications will be deployed in Cloud.

COCIR RECOMMENDATIONS TO CAPTURE THE VALUE OF CLOUD COMPUTING

1. Adopt a standard Cloud terminology – based on NIST (National Institute of Standard and Terminology) definitions
 - Deployment Model: private – public – hybrid
 - Service Model: SaaS – PaaS – IaaS
2. Build awareness at C-suite level on reduced costs and increased benefits (service quality risk management)
3. Build trust and confidence in privacy and security
4. Promote realistic adoption of Cloud services by healthcare stakeholders, and manage resistance to change and adopt
 - Introduce reference architecture for Cloud-based solutions which define the different common cloud components/services
 - Introduce a Cloud adoption roadmap for healthcare solutions
 - Introduce a Cloud adoption maturity model for healthcare providers
 - Provide a template of Cloud-related terms and conditions for healthcare and Cloud providers to minimize risks and liabilities
 - Provide examples of TCO-based cost models and OPEX-based services
5. Improve Cloud Health IT solutions based on open standards
 - Standardise cloud services e.g. for billing
6. Create or improve existing Cloud standards

NOTES

PROCUREMENT INNOVATIONS

4



PART 4 PROCUREMENT INNOVATIONS

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Procurement innovation is necessary and helpful to adapt the economic, social and political developments as well as increasing budget constraints of the Member States and on the other hand to balance the underlying efforts (less volume – more easier and transparent processes) for Public Authorities and vendors offering products and services as well as decrease decision timelines even for big and complex projects. With the initiation of the Public Procurement Reform by the European Commission in December 2011, primarily tasked to reform Directive 2004/17/EC and 2004/18/EC (public works, supply and service contracts) – the exclusive focus of this section – the goals outlined above were addressed. The new Directives were voted by the European Parliament on 15 January 2014 and adopted by the Council on 11 February 2014. The Member States have until April 2016 to transpose the new rules into their national law (except in regards to E-procurement, where the deadline is September 2018).

COCIR RECOMMENDATIONS FOR PROCUREMENT INNOVATIONS

1. Apply and leverage the European Commission's new Procurement Reform for public Health IT procedures
2. Use the Reform's Innovation Partnerships only when ICT vendors are able to customise their solution to fit the specific needs of a public authority

INTRODUCTION

This chapter will focus on procurement related to eHealth products, goods and services, when engaging with public state, regional or local authorities within the Member States. It will discuss how public authorities, to a large extent, still procure the 'traditional way' and the strengths and weaknesses of this approach. Differences between the Public Procurement Reform and the EU Directive 2004/18/EC will be outlined. Finally, this section will discuss different Procurement Partnerships and IT-supported applications for tendering, also known as E-procurement. COCIR's recommendations on public procurement is also outlined.

'TRADITIONAL' PUBLIC PROCUREMENT

The term "Traditional" would refer to the "normal cause of a public tendering procedure – as set forth in the EU Directive 2004/18/EC - Public Works, Supply and Service contracts" - for purchasing any goods and services. While "any" goods or products would refer to any Hardware, Software or Service it is first very important to understand the major differences of an IT purchase vs. a more Equipment, such as e.g. a Medical Device oriented one. The table below outlines the most decisive differences between procuring a Medical Device such as a CT or MR or any other Medical Equipment vs. procuring an IT systems such as EMR/HIS/CIS.

Table 3: How procuring hardware differs from procuring software.

MEDICAL EQUIPMENT	IT PROJECT
Medical equipment is used by small teams	IT systems are used by the entire hospital staff
If a modality is not working, it causes delays and minor problems	If the Hospital Information System is not working, the whole hospital is running out of cash
Low impact on customer's business processes	A new IT system may change the customer's organisational processes and how they work together
The medical equipment is a piece of hardware which can be seen and touched	Software operating properly you will hardly notice
The medical equipment itself is the product	The product is generated via customisation and implementation.
Easy delivery	Handing over IT is complex
Only installation is required, according to vendor's guidelines	Implementation is required following vendor's methodology. How and what is defined in a Statement of Work
Installed in a few days	Implementation takes at least 6 to 18 months – or even more
No patient data to be migrated	Common to migrate electronic patient data generated within the last 15 years
No need for localisation	High need for localisation (e.g. billing rules)
Clear and easy description what is purchased and what will be installed	Complex , functional implementation with third-party integration leading almost to change requests
No IP rights are generated or touched	Most customers expect to generate own IP due to high customer-specific customization
Risks are clear, low, transparent and easy to evaluate	Risks are high, diverse and complex .
Clear Limits of Authority	Risks are closely linked with customer's skills, resources and activities. Can also impose high non-conformity costs
Limited customer interaction	Customer input needed to define how the IT system should function
Limited dependency on customer's ability/resources for system delivery	Successful projects can only be generated jointly
Easy integration into customer's software or network environment, often via single DICOM/HL7 interfaces	Complex: HIS/CIS exchange data with up to 100 customer-specific SW/proprietary/sub-systems via interface engine.
Performance is easily checked and mostly the vendor's responsibility	Performance largely depends on the customer's network and bandwidth .
Limited project management required from both sides	Project management from both sides is crucial
No change management needed	Change management and communication skills from customer's C level are highly critical
Changing equipment happens quite often . Resources, skills, and processes needed are usually well known on both sides	An HIS/CIS system is changed once 10-15 years , and for some customers, this will be the first time
Installing medical equipment usually requires no organisational change	Implementing IT projects usually requires some organisational changes

As seen in Table 3, purchasing software is completely different to purchasing hardware and requires a different skill-set from the Public Procurement Authority. However all have to be performed still under the existing and same EU directive. When assessing Member States' ability to address the differences laid out in Table 3, differences are clearly seen. Northern European countries such as Norway, Sweden, Finland, Denmark are used to performing Purchasing Processes for Health IT solutions, including related legal contract templates and terms and conditions applicable under local Public Procurement Law. Other Member States are struggling to gain the expertise which would allow them to build a compelling and highly competitive tender process, under the appropriate EU Directive.

For simplicity's sake, COCIR outlined the purchase of a Health IT solution within one public facility or customer. Due to the planned introduction of Integrated Care – multiple stakeholders organised in operationally and legally different entities orchestrating care, accountable for a certain population – another level of complexity is added when purchasing. No longer a single eHealth solution, purchasing requires an integrated IT network with applications for the many different care providers.

COCIR members represent a large group of companies experienced in designing, developing and delivering eHealth solutions within Member States' markets. The following 'Strength and Weaknesses' review of Europe-wide tender proceedings is based on the experience of these vendors and outcomes of executing these eHealth projects.

STRENGTH AND WEAKNESSES OF EXISTING PUBLIC PROCUREMENT PROCESSES RELATED TO HEALTH IT SOLUTIONS

MAJOR STRENGTHS

1. The procurement process under the EU Directive and Public Procurement law is well known by public authorities and Health ICT vendors.
2. Rules and guidelines/Do's and Don'ts/terms and conditions and their related impacts are also well known. However, some terms and conditions from the EU directive are not always clear from a legal standpoint –what is and is not allowed within the tendering procedure is not always clear. Despite applying EU Public Procurement law, there are also local procurement laws in place and in force which also need consideration.
3. Several countries have 'adapted' EU Directives and are executing tenders under Public Procurement Law, with specific standardised and IT-only contract templates also being adapted by the IT industry
4. Where their expertise is lacking, public authorities typically engage with consultants from large Health IT companies who help govern and support the public procurement process.
5. If prepared in great detail, with clear transparency, by skilled personnel from the public authority and external IT consultants, vendors will have a good understanding of their product scope-fit, costs, operational and legal risks when bidding.

MAJOR WEAKNESSES

1. As eHealth solutions need to:
 - have multidimensional tasks executed, related to specific staff roles within the provider's organisation, over diverse departments or a network of providers who offer pre-, acute-, post-care and long-term care
 - be executed within a given network infrastructure, with a given bandwidth and performance
 - be implemented according to a specific methodology and within a certain time frame
 - have a high staff engagement

It is almost impossible to define – even when trying to consider all details and even with the help of experienced Health ICT consultants – a complete tendering document which covers all eventualities.

The existing public procurement process is closed and inflexible. Interacting with the Procurement Authority to clarify specific language within the tender is often impossible for vendors because any modification/amendment/comment would lead to exclusion from the procurement process. The same applies for the public authority: post-offer 'negotiating' with a vendor is almost impossible and is intended to be an exceptional procedure and difficult to justify under EU Directives.

The result: wrong assumptions are explored, while the tender documents are handed in and first evaluations are made. One obvious example is how eHealth solutions are implemented. Some public authorities develop their own implementation methodology or even demand vendors to follow their way. However, Health IT vendors have clear methodologies developed, which the authorities need to follow. This mismatch leads to different cost estimations on both sides and is only discovered when tendering documents have been submitted, without both parties having the chance to confer in advance.

2. Public authorities are increasingly writing long Health IT tenders because they believe that the more pages, the better! Public authorities tend to over-describe the smallest details. There are three main reasons for this:

- A lack of competence and inexperience. A Health IT procurement process may happen only once or twice in 30 to 40 years
- To avoid being held accountable or taking any risks associated with the tender
- To address every need of every user.

However, volume does not improve the quality and is more likely to lead to an unsuccessful tender.

3. Public authorities are often under the assumption that vendors will fulfil the tender deliverables, neglecting the necessary involvement of their skilled and available staff for the overall project-success. Additionally, they rarely address the fact that any new software procured will need capacity for organisational and change management.

HOW TO ADDRESS THE WEAKNESSES RELATED TO PUBLIC PROCUREMENT PROCESS FOR eHEALTH SOLUTIONS

With many weaknesses in existing procurement processes, there needs to be more flexibility for public authorities under the EU Directive 2004/18/EC, specifically for large and complex infrastructure projects (in some cases, eHealth falls into this category). One approach to improve flexibility, but remain competitive, is the Competitive Dialogue, which was introduced in 2004. These projects began in 2006, when Public Procurement Directives transposed into national law. The Competitive Dialogue outlines a framework to 'dialogue' in confidence, with a certain set of shortlisted vendors, to further clarify important topics before calling for a final bid. Sometimes, the process begins with a bigger sample of vendors, but they are removed as the tender goes on, to create more transparency and map what public authorities want from vendors. Often, the Competitive Dialogue is linked with the implementation of a Public Private Partnership (PPP) model. Before initiating a Competitive Dialogue, the public authority needs to check, whether the 'traditional' Public Procurement process (open or restricted procedure) will be the best value for money. Additionally, the public authority is tasked to evaluate, whether the planned purchase is complex in nature.

MAJOR STRENGTHS

1. Thanks to the Competitive Dialogue, public authorities and IT vendors can discuss all aspects of an IT project, in a competitive fashion. This includes the scope, implementation methodology, project management, staff engagement of the public authority, risks, benefits, rough financial estimates and legal terms and conditions.

MAJOR WEAKNESSES

1. To access the Competitive Dialogue, the public authority must show that traditional procurement processes are not the best value for money and that the project is complex.
2. This will take vast resources and time from the public authority and IT vendor, as several topics will need to be explored in far greater detail. All documents need to be completed before handing over to the public authority during the dialogue, as they can form a binding document. Depending on how many vendors have been shortlisted, more effort may be required from public authorities.
3. Meetings need to be prepared well in advance, so an efficient outcome is guaranteed. The same applies to any documents to be handed in following a single session.
4. During the Dialogue, the public authority and vendor focus on a single important item, although topics are interdependent. They may reopen conversations on a previously discussed topic which is relevant again due to updates. The same applies to legal terms and conditions.

Although it requires more effort from both sides, a well-prepared and executed Competitive Dialogue can limit risk exposure and is an important aspect for a successful eHealth project.

PUBLIC PROCUREMENT REFORM AND HOW IT APPLIES TO HEALTH IT PROJECTS

While existing EU Directive 2004/18/EC is from 2004, economic, social and political developments – as well as increasing budget constraints – has made it necessary to reform the rules which make the overall process of purchasing more efficient for public purchasers and vendors. COCIR has listed the rules which have changed and how this will impact eHealth solution procurement:

MAJOR CHANGES OF RULES

- Flexibility to adapt the most appropriate procurement process to fit the specific needs of a procurement case
- A more clearly structured competitive procedure, with negotiation replacing the current negotiated procedure
- Competitive Dialogue – same basic conditions and principles as the competitive procedure, but simplified, improving flexibility of the public authority to choose the appropriate procurement process
- Bureaucracy reduction, resulting in greater efficiency
- Enhanced access to public procurement for SMEs improves competitiveness and cost-efficiency
- E-procurement will progressively become mandatory, improving efficiency for both authorities and vendors
- Threshold for procurement rules increases from €207,000 to €750,000 and a 'Light Regime', specifically applicable to Healthcare Services, balances efforts per purchasing case
- The focus on innovation and 'Innovative Partnerships' addresses very specific purchasing needs which have not yet been offered in the market place
- More transparent regulations for the pre-consultation phase so that a large number of vendors can satisfy the needs of the public authority, where vendors must make sure the needs are satisfied.

The changes of the rules for the purchase of Goods and Services are greatly appreciated by COCIR members as most of them will help to drive efficiency and outcome for the vendors of Health ICT solutions. As most of the topics outlined above will be more or less self-understanding, two aspects in the context of eHealth procurement processes with public authorities should be mentioned in here.

1. As outlined earlier, purchasing Health IT solutions can be complex and changing purchasing rules for goods and services does not automatically simplify things. To deliver a high quality bid which considers all technical and legal aspects requires tremendous effort, resources and time. Vendors experience high costs before even delivering all related information. Decreasing the time it takes to apply for complex Health IT bids will lead to lower quality bids and associated risks for both parties involved – even when considering that several vendor processes have now been standardised. Consequently, the public authority should negotiate with the vendors on delivery within a reasonable timeframe.
2. COCIR is valuing the possibility to address the topic of Innovation Partnership within a public procurement procedure. However and although Health ICT Solutions could be highly customized to fit the local, regional or national needs, it is rarely to be expected, that Health ICT vendors will – as outlined in the new rule – start developing jointly with the authority a dedicated eHealth Solution fitting just the needs of this specific public authority. 1) Public Procurement Reform, Fact Sheet No 1-13, EU Commission

PROCUREMENT PARTNERSHIPS

One type of Procurement Partnership is the Public Private Partnership (PPP). PPP is a contractual partnership between the public sector and a private company where the private partner exclusively builds, operates and develops the project or service, while the public authority takes care of the specific project deliverables for the community. The public authority – while engaging a private company – can execute necessary projects for the sake of the public even if it means increasing a tight budget.

PPP projects have rarely been considered in healthcare and are even less common in Health ICT. This could be due to public authorities' conservative stance when it comes to healthcare service delivery. The sensitive nature of dealing with patient data and associated security and privacy constraints, including data management by a private company, is also a concern.

COMPUTERISATION OR E-PROCUREMENT

As discussed, the EU will progressively demand that Member States execute Public Procurement Processes electronically, which will become mandatory in 2018. E-procurement will simplify the process between the contracting parties, save paper and also stimulate greater competition due to “unlimited” access to the process. Evaluating and comparing content will become easier for public authorities, as the information is submitted in a structured way. All COCIR members dealing with electronic communication in healthcare greatly appreciate the EU's efforts in E-procurement.

COCIR RECOMMENDATIONS FOR PROCUREMENT INNOVATIONS

1. COCIR is glad that the Public Procurement Reform will finally be in place in all Member States by September 2018. The timing of the purchasing process –answering complex tenders within Healthcare IT projects – needs to be carefully negotiated to achieve valuable and high quality bids from the vendors.
2. The introduction of Innovations in health-related Public Procurement processes is a great achievement. It offers a flexible way to address the high dynamic in healthcare related to knowledge and ICT used in Healthcare. However, ICT vendors and SMEs, although capable of delivering highly customised goods and services, would not be in able to develop a 'one off' service for any public authority. It is essential to clarify what can be customised versus what needs to be developed and clarify who owns the intellectual property rights.

WORTH NOTING: The Council of the European Union adopted the legislative package for the modernisation of public procurement in the EU on February 11th, 2014.

INTEROPERABILITY

5



PART 5 INTEROPERABILITY

5

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eHealth has the potential to revolutionise healthcare, but a lack of interoperability hinders market development and delivery of eHealth's promised benefits. The European Commission and most Member States are aware of this challenge. Although progress is slow, COCIR recommendations issued in 2010 continue to be taken into consideration. These recommendations have been reviewed and enhanced by the European eHealth Stakeholder Group. This up-to-date list is expected to impact eHealth beyond isolated projects.

Progress is being made to reach the first level of eHealth interoperability by the end of 2020 .

COCIR RECOMMENDATIONS FOR INTEROPERABILITY

1. Focus on priority use cases: patient summary, E-prescription, laboratory results sharing, medical imaging sharing and telemonitoring
2. Clarify privacy and data protection requirements
3. Foster use of international standards and market-focused profiles recognised in a health European technical and semantic interoperability framework.
4. Educate national, regional and local eHealth project leaders on interoperability
5. Address semantic interoperability step-by-step
6. Investigate the particular interoperability requirements of mobile health, big data and online social networks

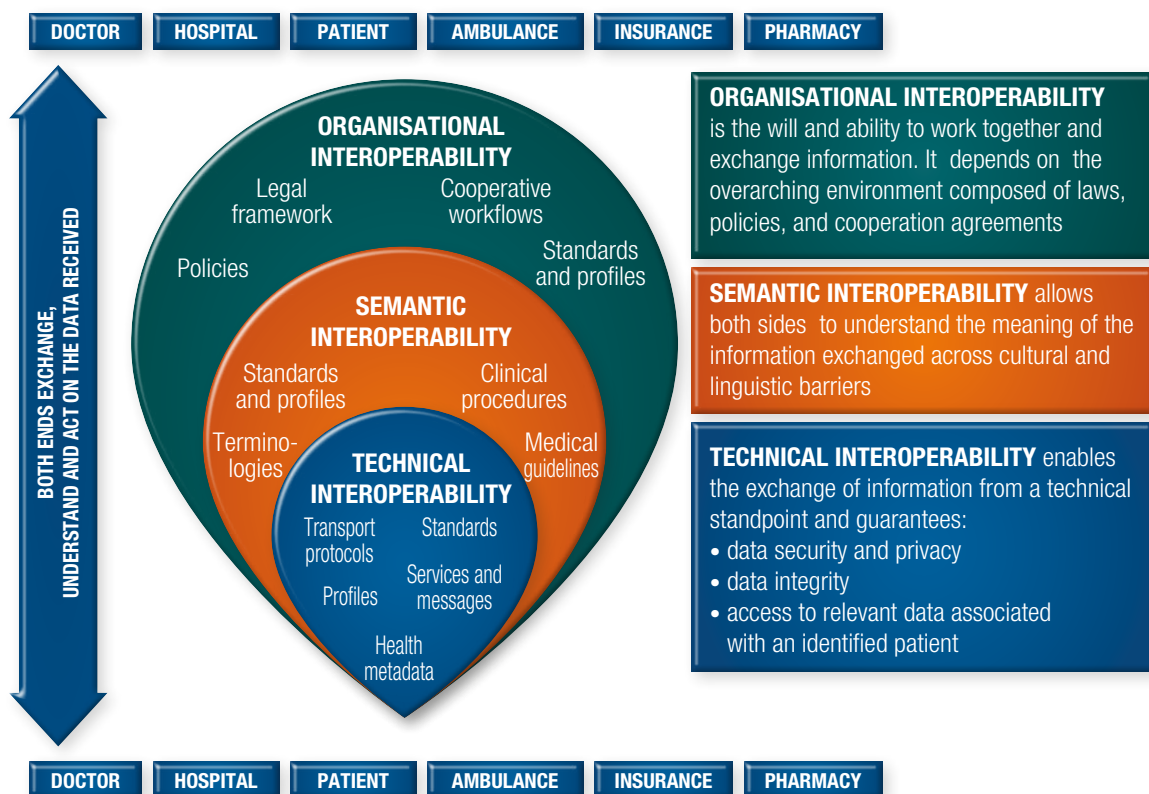
DEFINITION: WHAT IS 'INTEROPERABILITY'

eHealth interoperability is the ability for two or more eHealth systems to use and exchange both computer-interpretable data, human understandable information and knowledge.

THERE ARE THREE LEVELS OF INTEROPERABILITY:

1. **ORGANISATIONAL INTEROPERABILITY** also referred to as legal, process or co-operability interoperability - refers to the broader environment of laws, policies, procedures and bilateral cooperation needed to allow the seamless exchange of information between different organizations, regions and countries.
2. **SEMANTIC INTEROPERABILITY** refers to the ability to ensure that the precise meaning of exchanged information is interpretable by any other system or application not initially developed for this purpose.
3. **TECHNICAL INTEROPERABILITY** means the ability of two or more ICT applications, to accept data from each other and perform a given task in an appropriate and satisfactory manner without the need for extra operator intervention.

Figure 8: 3 levels of interoperability



BENEFITS OF INTEROPERABILITY

EASIER AND FASTER ACCESS TO PATIENTS' INFORMATION

With interoperable systems, data can be exchanged and stored automatically rather than re-typed into the system each time. This applies to all kinds of data used in healthcare – laboratory results, therapeutic procedures, medication administration, clinical notes, billing etc.

This leads to:

- Faster communication
- Reduction in data (re-)capture errors
- Less duplication
- Workload reduction

BETTER DIAGNOSIS, BETTER QUALITY OF TREATMENT, BETTER PATIENT SAFETY

Giving medical professionals faster access to patients' data allows for better diagnosis, better quality treatment, and better patient safety through:

- Avoidance of medication interactions
- Improved knowledge of patient's health status, family history and personal history
- Better care coordination between the different healthcare professionals

IMPROVED COST EFFICIENCY

As outlined above, interoperability reduces administrative costs and leads to higher efficiency.

Systems built on the same data exchange standards, using open access technologies are easier to integrate and reduce implementation costs of new IT solutions in hospitals. Interoperability reduces adaptation time to the hospital's existing IT infrastructure and requires less technical support from the vendor.

INCREASED CONSUMER CHOICE AND ENHANCED COMPETITION

Interoperability between vendors and systems enhances consumer choice. If solutions are interoperable, customers have more choice when buying. At the same time, providers and vendors can introduce their products to more markets. Interoperability also opens the market for new entrants, increasing competition and innovation.

SECURITY AND TRUST FOR DATA TRANSFERS

The privacy risks associated with the exchange of electronic patient data (identity theft, intrusion, alteration of data and unauthorised access) need to – and can be – addressed. A robust, end-to-end, trust and privacy model between interoperable IT systems is best achieved through compatible security models, identification and authentication processes, data encryption etc.

OBSTACLES TO eHEALTH INTEROPERABILITY AND SOLUTIONS

While plug and play is a reality in other innovative domains (e.g. GSM, USB, mobile apps), interoperability is widely seen as a headache in healthcare. Healthcare is a large ecosystem, consisting of complex, human organisations. Linking different actors, IT systems and institutions across different medical disciplines, cultures, languages, jurisdictions and administrative entities is a challenge. The personal nature of the information and the need to provide choice requires an adoption of open approaches to interoperability. COCIR outlines the main obstacles to interoperability in healthcare below.

INCONSISTENT USE OF EXISTING ICT STANDARDS

The interoperability of IT systems depends on the use of recognised standards which describe how to build technical specifications, methods and processes into the system, with a view to securing compatibility, reproducibility, safety, interoperability and other qualities.

However, finding the best standard can be difficult. The 'not invented here' syndrome and the desire to keep control over an organisation's IT system motivate many customers to develop proprietary custom solutions a similar isolated approach (e.g. a hospital electronic medical record developed in-house) rather than using existing standards. This approach creates further challenges and is a significant hurdle to eHealth interoperability.

Being able to refer to a common set of market-leading standards will enable the eHealth sector to achieve interoperability and develop synergies which deliver higher quality services while reducing costs.

Progress has been analysed and identified by the ANTILOPE project (<http://www.antilope-project.eu/>) who recommends adopting the first version of a European eHealth Technical and Semantic Interoperability Framework.

An eHealth European Interoperability Framework should be considered a priority for efficient deployment of the eHealth solutions in Europe. The Framework should:

1. Provide a good level of certainty in eHealth interoperability (including terminologies) to which industry is well underway to comply.
2. Include a set of supporting IHE and Continua profiles (referencing widely accepted standards) for each case. This is a building block which can be used in a project-specific interoperability specification.
3. These profiles should cover: information transport, data access services, data structures, terminology (value sets), security/privacy, workflow and collaboration, decision support and analytic services.
4. Some of these profiles could be reused across use cases.

Some important groundwork for the eHealth European Technical and Semantic Interoperability Framework is already available. 27 profiles have been officially proposed by the EU Commission for recognition in European Tenders and the EU Multi Stakeholder Platform also gave a positive recommendation in November 2014. Once recognised, these profiles should become the first version of the eHealth European Technical and Semantic Interoperability Framework.

The eHealth Stakeholder Group, hosted by the European Commission, has published 'Perspectives and Recommendations on Interoperability' where alternative standards and profiles converge.

(http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=5168). On Page 10, Standards choices in Europe where adoption of IHE profiles such as XDS and XCA as well as use of HL7 CDA for content is quite extensive, as shown in the table below.

Table 4: Current status on standards adoption

CONTENT AND EXCHANGE ON STANDARDS ADOPTION NATIONAL/REGIONAL eHEALTH PROJECTS				
COUNTRY	Leverages HL7 CDA R2 for content	Leverages HL7 V3 Messages for content	Leverages OpenEHR/ISO13606	Transport or Sharing
AUSTRIA	Yes	No	No	IHE XDS/XCA
DENMARK	No, but planned	No	No - Local Std	Local WS- IHE-XDS
ENGLAND	Yes	Yes	No	HL7 V3
FINLAND	Yes	No (transport only)	No	HL7 V3
FRANCE	Yes	No (Pt ID only)	No	IHE-XDS
GERMANY	Some Regions	No	No	Some IHE-XDS
ITALY	Yes	No	No	IHE-XDS and other
LUXEMBURG	Yes	No	No	IHE-XDS
THE NETHERLANDS	Yes	Yes	No	HL7 V3 & IHE-XDS
POLAND	Yes	No	No	--
SLOVENIA	No	No	CDR Internal design	--
SPAIN	Some	No	Some	--
SWEDEN	No (Analyzed)	No	Yes	--
SWITZERLAND	Yes	No	No	IHE-XDS/XCA
AUSTRALIA	Yes	No	Some (only Models)	IHE-XDS-Pt-Pt
BRAZIL	Some Pilots	Pt ID only	Some Pilots	--
CANADA	Some	Yes	No	HL7V3/XDS
CHINA	Yes	No	No	--
JAPAN	Yes	No	No	Some IHE-XDS
KOREA	Yes	No	No	XDS Pilot
NEW ZEALAND	Yes	No	Some (only Models)	Various
RUSSIA	Yes (Nation-wide)	No	Only a part of Moscow	IHE-XDS
TAIWAN	Yes	No	No	--
USA	Yes	Limited to Pt ID	No	E-Mail/IHE-XDS-XCA

EXTRA WORK FOR MEDICAL PROFESSIONALS

- **ENTERING STRUCTURED DATA IN THE SYSTEM:** Data interoperability requires medical professionals to enter 'structured data' into the system. This requires additional time and the complexity may be a challenge, as medical professionals may not see the immediate benefit and may not be rewarded for the extra effort.
- **CHOOSING THE RIGHT TERMINOLOGY FROM A PROPOSED LIST:** Medical disciplines have different jargon which is reflected in the use of electronic clinical information. For interoperability to work, there must be an extensive mapping of existing vocabulary. Otherwise, professionals face long vocabulary lists in scroll-down menus before they find the term which best reflects the information to be communicated. Both aspects result in little or no structured data being collected at the clinical level. When the initial contributor of information in the communication chain cannot provide data in a structured form, or cannot use the right terminology, the whole communication chain will not work as well as it could and should.

FRAGMENTATION OF HEALTHCARE SYSTEMS ACROSS EUROPE

Europe is fragmented when it comes to healthcare: each country and some regions have their own healthcare systems. Different national and regional health systems will use different laws, procedures, policies and terminologies, leading to difficulties in communicating effectively and efficiently.

Regrouping this fragmented reality is an opportunity for a joint approach to progress on interoperability. Specifically, the organisational dimension of interoperability is likely to remain largely country-specific, but the possibility of a European convergence at the semantic and technical levels of interoperability is now being seen as an achievable objective. This is why COCIR recommends that:

- The European Interoperability Framework only focuses on the semantic and technical levels and covers cross-border and intra-country use cases. COCIR also thinks it should be renamed 'eHealth European Technical and Semantic Interoperability Framework'.
- An eHealth European Interoperability Organisational Framework should be developed as a distinct agreement between Member States and focus solely on cross-border health information exchange.

DIFFICULTY TO CAPTURE THE COMPLEXITY OF HEALTHCARE IN IT SYSTEMS

While a medical professional can easily put their thoughts on paper, it is more difficult to report them electronically – what should be communicated? Should the medical professional report the basic clinical facts (e.g. skin colour, blood glucose level, blood pressure etc), symptoms, causes and the holistic view or different levels of aggregated, consolidated health data? Should the medical professional also include their reasoning to justify the diagnosis and clinical order?

Knowing which information is required at the end of the chain, sharing a personal opinion or reasoning in an IT tool is a difficult exercise which requires time, training and experience.

This is why COCIR recommends a step-by-step approach to semantic interoperability, focusing firstly on frequently used fragments of health information which can easily be standardised e.g. medication (prescribed or dispensed with product identification, ingredients, dose, form, strength, etc), allergies (allergen, severity, frequency, etc), problems and procedures. This concept is now well recognised, although confusion remains over the correct terminology for fragments, as they are sometimes called module, archetype or template. A number of European projects have analysed this concept⁵, but only epSOS⁶ has shown that it is feasible in some countries.

5. Semantic Health Net (<http://www.semantichalthnet.eu/>), EHR4CR (<http://www.ehr4cr.eu/>), PARENT (<http://patientregistries.eu/>), etc.

6. epSOS (<http://www.epsos.eu/home/about-epsos.html>)

This is not a standardisation challenge – the standards to represent this concept exist – but harmonisation is required. This needs to be understood as a mutually beneficial objective and supported politically by Member States, with the backing of their health constituencies. The eHealth Network has initiated this process by creating a list of such fragments in a cross-border patient summary and a cross-border E-prescription in a policy agreement. It is hoped that the next step, to refine this concept in a voluntary policy agreement, focusing on the structure and coded terminology value sets.

ENSURE PATIENTS' PRIVACY AND PROTECTION OF PATIENTS' DATA

The current legal framework around EU data protection is fragmented and lacks clarity. This has two main consequences:

- Healthcare providers may be reluctant to share patients' data due to the increased risk of a privacy breach and because of the complex rules around the processing, sharing and storage of health data.
- Additional measures and procedures must be embedded in the organisational and IT systems levels to ensure patients' privacy and the protection of their data. This translates into additional costs and increased complexity of systems.

The challenges resulting from this situation are quite visible when cross-border exchange of health information is attempted. This was very well analysed by the epSOS project, which used its large-scale pilot project status to negotiate a joint, one-year privacy and security agreement. Thanks to the eHealth Network's Joint Action (2015-2018) to converge towards a more coherent European-wide framework, efforts should continue. However, convergence may occur slowly due to some countries lacking eHealth deployment experience. Such experience has often resulted in practical adjustments accepted by the citizens and law makers when faced with having to effectively balance their privacy and security protection with the necessity to be medically treated in an effective way.

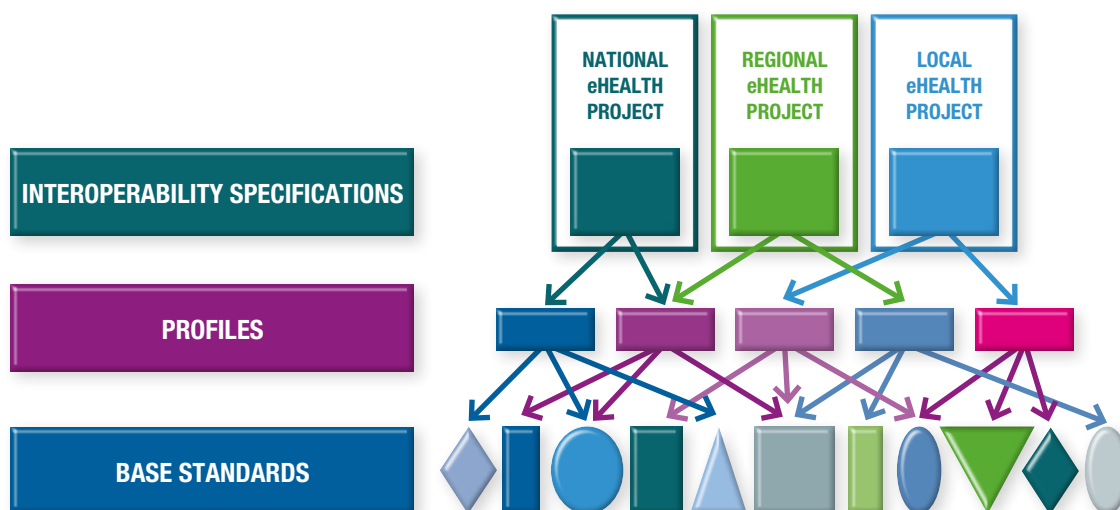
THE ADOPTION OF INTEROPERABILITY AND THE MARKET

FROM INTERNATIONAL STANDARDS TO INTEROPERABILITY SPECIFICATIONS OF LOCAL eHEALTH PROJECTS

One size does not fit all – national or local extensions to international standards are needed to fit the exact needs of the local eHealth program. Local or regional interoperability specifications – also called implementation guides – are needed to describe what messages and vocabulary should be used in each use case (e.g. E-prescription). The development process of such implementation guides should be transparent to ensure engagement from all stakeholders.

Authors of interoperability specifications should be aware of local needs, local medical settings and should consult standardisation experts to identify relevant standards. Interoperability specification guides are based on Integration Profiles, which are themselves based on standards, as shown below.

Figure 9: From international standards to interoperability specifications



Profiles developed by Integrated Health Enterprise (IHE) and the Continua Health Alliance meet the quality criteria and are considered best in the field:

- **IHE** is a user-vendor initiative which engages numerous stakeholders to advance interoperability in eHealth, including care providers, medical and IT professionals, professional associations and vendors. IHE develops integration profiles based on existing standards in a three step process:
 1. It develops integration profiles for implementing established data standards to assure IT systems can 'talk' to each other.
 2. It tests these systems to verify that complex computer coding delivers the data.
 3. It promotes wider awareness of these methods for establishing local and regional interoperability specifications.

In addition, IHE organises annual 'Connectathons', industry meetings for interoperability testing and exchange of tools.

- **CONTINUA HEALTH ALLIANCE** is an organisation which brings patients, caregivers and healthcare providers together to establish a system of interoperable, personal telehealth solutions. Continua develops interoperability guidelines and a product certification program with a recognised consumer logo. Continua also engages with regulatory authorities and governments to address cost, safety and security issues in personal health systems.

GUIDANCE FOR eHEALTH PROJECTS TO REALISE eHEALTH INTEROPERABILITY IN SIX STEPS

A number of eHealth projects in Europe and beyond have demonstrated the effectiveness of the interoperability approach described by COCIR. Analysing such experience is critical for reducing risks in eHealth projects. The guide to eHealth interoperability in six steps, which was published on the basis of such experience, remains current, as demonstrated in part 4 of the 2012 COCIR eHealth Toolkit.

(http://cocir.org/fileadmin/Publications_2012/MAY_2012__COCIR_eHealth_Toolkit_2012.pdf).

The 6 steps are as follows:

1. IDENTIFY USE CASES

Describe the proposed eHealth functionality in medical terms (e.g. E-prescription), avoiding any technical language.

2. SELECT PROFILES AND STANDARDS

Identify existing profiles and standards which support the eHealth use case.

3. REFINE DATA CONTENT

Design messages and data structure required in the eHealth use case.

4. WRITE THE INTEROPERABILITY SPECIFICATIONS

Assemble project-specific requirements by building on existing international profiles and standards recognized in Europe.

5. ORGANISE TESTING

Prepare test cases and a test environment for implementers to demonstrate component interoperability in a multi-implementer interaction scenario.

6. EDUCATE END-USERS ON INTEROPERABILITY

Develop communications materials to familiarise end-users on the benefits and impact of interoperability.

In the section below, we expand on testing and certification in step 5, which has seen significant progress based on experience.

INTEROPERABILITY CONFORMITY ASSESSMENT IN eHEALTH

Interoperability testing and certification is a complex topic which has been under discussion for many years. There is a broad agreement that some form of testing is necessary before systems are interconnected, to increase certainty about the interoperability possibilities and ensure parties only have to put in a minimal effort.

Certification refers to a third-party attestation confirming certain characteristics of a product while testing is a demonstration where specified requirements related to a product are fulfilled (measurement, evaluation or conformity assessment). As certification builds on testing, we will first consider the testing of interoperability.

As derived from the newly published ISO 28380 Technical Report (Health Informatics – IHE Global Standards Adoption – Part 3 Deployment) in the development and deployment of interconnected eHealth products in projects, several stages of testing need to be distinguished:

1. Testing performed by the vendor in its own lab must go beyond interoperability to test performance, security, usability, etc.
2. Testing which demonstrates a product's profile conformity to its potential customers.
3. Testing which shows that a product conforming to profiles must interoperate with a number of other vendor products claiming conformance to the same profiles.
4. Testing which shows product conformity to the interoperability specifications set by a specific eHealth project (as the specifications would be built upon profiles). Such testing may also include other aspects such as security and privacy.
5. Testing which demonstrates that a product installed and configured at a customer site adheres to the interoperability specifications set by a specific eHealth project. Such testing must also include other aspects such as security, privacy and performance.

In intra-enterprise eHealth projects, the stages 2, 3 and 4 have been minimally considered, and often simply skipped. When eHealth projects scale up to regional or national projects and the number of products deployed over the project life-time becomes large and vendors product are used across several such projects, each one of these intermediate testing stages become critical. As these stages become an absolute necessity to sustain projects where deployment responsibilities are distributed, a strategy needs to be established.

With the experience gained from regional and national projects using IHE profiles in Europe and the USA. which leveraged Stages 2 and 3 at the Connectathon, vendors and project leaders unanimously recognised the importance of these intermediate stages. They have asked for some additional rigour to be applied by IHE in its stage 2. This is addressed by the new IHE International Conformity Assessment (http://www.ihe.net/Conformity_Assessment.aspx) launched in 2015. A new Conformity Assessment Report by ISO 17025 accredited laboratories and the related testing report will bring a new level of rigour, quality management and benefits as they will:

- Avoid vendors and buyers duplicating testing for the same profile across different projects.
- Put in place a robust quality management process around interoperability in Health ICT systems, as studied and recommended by the Antelope project.

After testing, there is 'attestation'. Depending on the body which issues it, attestation may be:

- A certificate, when the attestation is issued by an accredited certification body (its competence is formally demonstrated according to a standard, e.g. ISO 17065)
- A label, which is issued by a body not under a formal third-party accreditation process).

These concepts are further described in the Antilope D4.1 deliverable (http://www.antilope-project.eu/wp-content/uploads/2013/05/D4.1_V08_Certification_Processes.pdf). It is important to understand that no label or certificate may be issued unless testing or conformity assessment has been performed. This is why COCIR believes testing or conformity assessment is a primary concern.

COCIR places significant value on testing, especially the rigour associated with testing at stages 1, 2 and 3 such as the IHE Conformity Assessment and Connectathon testing. COCIR encourages the recognition of European non-governmental third-party conformity assessment schemes, which rely on ISO 17025 accredited testing laboratories such as those offered by IHE and Continua for their respective profiles, as they are recognised in the eHealth European Interoperability Framework.

However, the benefits of certification or issuing labels for products at the profile level (added to Stage 2 testing) for eHealth interoperability are not clear. In contrast, the value appears much more credible for regional and national eHealth projects, as a number of them already issue some form of labels for the stage 4 testing, and include some process of on-boarding for stage 5. COCIR recommends that these regional and national eHealth projects adjust their process to stop the duplication of stage 2 and 3 testing by recognising conformity assessment test reports issued for IHE or Continua profiles in interoperability specifications.

COCIR RECOMMENDATIONS TO CAPTURE THE VALUE OF INTEROPERABILITY

1. FOCUS ON PRIORITY USE CASES

Efforts towards interoperability in healthcare should focus on a set of priority use cases to achieve maximum benefits.

SEVEN STEPS FOR FOCUSING ON USE CASES:

1. Patient summary (at national and cross-border level)
2. E-prescription (at national and cross-border level)
3. Medical imaging information sharing (cross-regional)
4. Hospital diagnosis imaging workflow (intra-hospital)
5. Laboratory information sharing (cross-regional)
6. Hospital laboratory workflow (intra-hospital)
7. Telemonitoring

Our observations of eHealth projects around the world found that these are the most frequently prioritised use cases and are a subset of those identified by the EU Antilope Project. These seven use cases have also been successfully implemented and profiles associated with these use cases are mature. They should be the foundation to develop eHealth interoperability in Europe.

2. CLARIFY PRIVACY AND DATA PROTECTION REQUIREMENTS AND ESTABLISH CLEAR GOVERNANCE

The first step to achieve eHealth interoperability is developing a legal environment which allows information exchange across care settings and across borders. Deploying cross-border patient summaries and prescriptions, in the context of the Connecting Europe Facility (CEF), is a timely opportunity to converge towards a more coherent European-wide security and privacy framework for cross-border exchanges.

The healthcare sector would also benefit from a harmonised data protection legal framework in the EU, where a single, uniform set of rules would apply to all 28 Member States. COCIR welcomes the European Commission's proposal for a related Regulation and calls for caution on the use of delegated acts to specify conditions and requirements for data sharing, as they may result in legal uncertainty.

3. FOSTER USE OF INTERNATIONAL STANDARDS AND MARKET-FOCUSED PROFILES

COCIR welcomes the Digital Agenda's aim to foster EU-wide standards and encourages the European Commission to create international standards and profiles.

- Standards must be user-driven and market-focused to be effective. Often, the standard development process is slow and many published standards do not fulfil the requirements of the market players and users, as their needs changed as the standard was being developed. The effective adoption of standards needs to rely on a user-driven and market-focused profiling and implementation processes to deliver ready-to-implement specifications which result in successful interoperability (e.g. IHE profiling process).
- The European Commission should act rapidly on the positive Antelope recommendation of 27 IHE Profiles by the EU Multi Stakeholder Platform in November 2014. Once recognised, these profiles should quickly become the first version of the eHealth European Technical and Semantic Interoperability Framework. These recognised interoperability profiles should be included as a requirement for EU-funded eHealth projects (e.g. Horizon 2020, Structural Funds, Connecting Europe Facility).

4. EDUCATE LOCAL LEVEL ON eHEALTH INTEROPERABILITY

COCIR welcomes progress made by certain platforms in improving interoperability, such as Continua and IHE Europe. COCIR also welcomes the EU-driven initiatives in the field, such as the Antelope Project and its 10 interoperability summits in 2014, which promoted the need for a European eHealth Interoperability Framework, the eHealth Governance Initiative and the first set of recommendations by the eHealth Network. Unfortunately, local eHealth actors remain uninformed on these initiatives and tend to build local eHealth programs in isolation.

The European Commission should fund awareness-raising and educational campaigns to transfer European knowledge to the local levels, so interoperable solutions are used properly. COCIR has developed an Industry Guide to eHealth Interoperability in Six Steps (see section 5), aimed at national, regional and local eHealth project leaders, to support this goal.

5. ADDRESS SEMANTIC INTEROPERABILITY STEP BY STEP

Semantic interoperability is a complex field which requires the 'marriage' of health informatics with clinical practice. The issue of semantic interoperability cannot be easily resolved, but requires a step-by-step approach.

COCIR is aware of a disconnect between research projects looking at semantic interoperability as the end goal and the few pragmatic efforts to reach basic levels of achievable semantic interoperability - although projects like epSOS have demonstrated this is feasible.

This is not a standardisation challenge, rather a policy-driven harmonisation of requirements. This needs to be understood and accepted as a mutually beneficial objective and supported politically by the Member States with the backing of their professional health constituencies. The eHealth Governance Initiative (eHGI) has initiated this process, defining a policy agreement based on a list of such fragments in a cross-border patient summary and E-prescription.

A cross-stakeholder effort on frequently used fragments of health information such as medication (prescribed or dispensed with product identification, ingredients, dose, form, strength, etc), allergies (allergen, severity, frequency, etc), problems and procedures is required. This effort needs support from the eHealth Network Support Joint Action (2015-2018) and should result in an established, sustainable process.

6. INVESTIGATE INTEROPERABILITY REQUIREMENTS FOR MOBILE HEALTH, BIG DATA AND ONLINE SOCIAL NETWORKS

From the EU Green Paper on Mobile Health consultation, (http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=5147), two recommendations on interoperability emerged. COCIR agrees with both of them:

- mHealth is not only about apps, but also open interoperability: The actions of the eHealth Action Plan as regards interoperability are still valid (e.g. by setting up an EU eHealth interoperability framework). A series of additional actions were put forward, e.g. promoting open standards for interoperability.
- Interoperability in mHealth and eHealth requires consistency: "EU and national actions should seek to ensure interoperability of mHealth solutions with Electronic Health Records (EHRs) as this would be beneficial for enhancing care continuity, patient empowerment and research". The first set of IHE Profiles optimised for mobile platforms are now ready for implementation. Their design is consistent with existing profiles, which helps maintain interoperability between mobility on the "edge" and robustness of existing eHealth infrastructures (e.g. Mobile Health Documents and Cross-Enterprise Document Sharing).

Big Data is a high-volume, high-velocity and high-variety asset which demands cost-effective and innovative forms of information processing. Applied to healthcare, the collection of high-volume data is much more effective when this data is structured, either natively or from text processing. As health data becomes interoperable, it can already be transformed in a structured and even standardised form which is semantically expressive and consistent. Therefore, big data is effective for integrated care as well as secondary uses such as public health, research and quality management. The synergy between interoperability and big data needs to be explicitly addressed.

COCIR GLOSSARY OF TERMS

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PART 6 COCIR GLOSSARY OF TERMS

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PART 1: eHEALTH DEFINITIONS

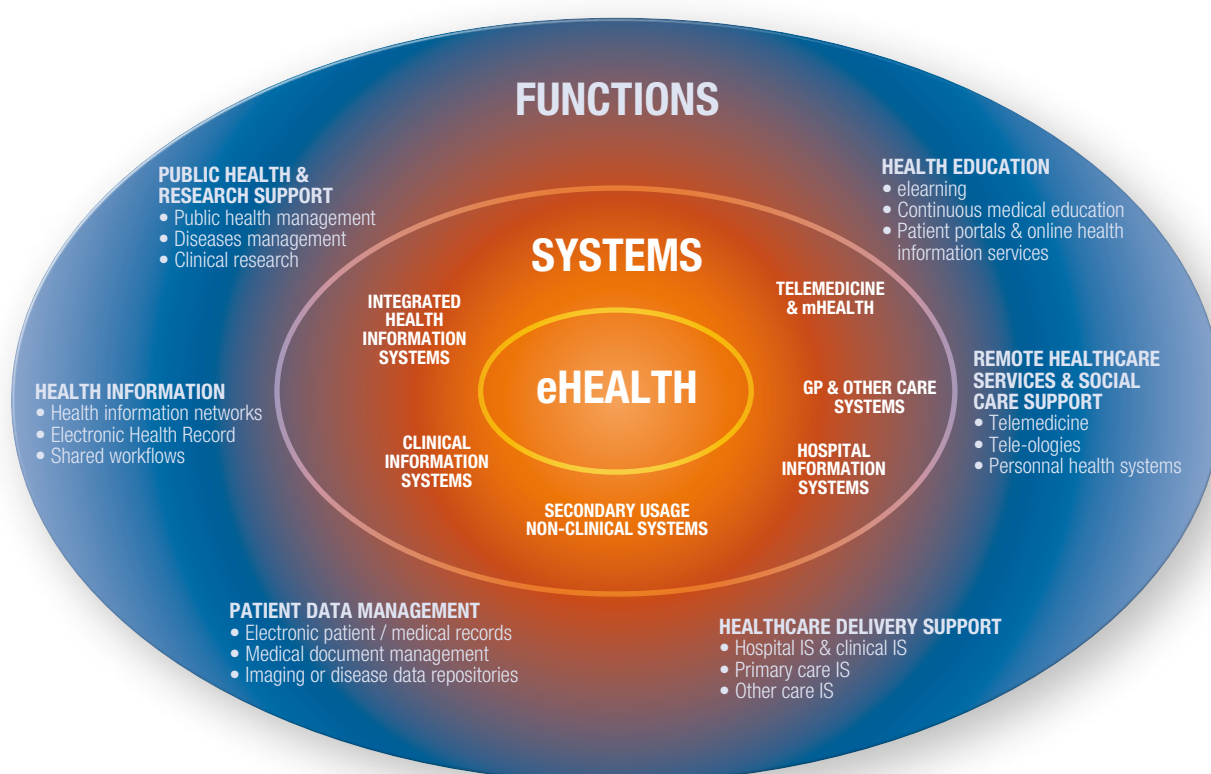
eHealth describes the application of information and communications technologies (ICTs) across the whole range of functions that affect the health sector. “eHealth”, “healthcare IT”, “health ICTs” and “health informatics” are synonymous. eHealth includes tools for health authorities and professionals as well as personalised health systems for patients and citizens. eHealth can therefore be said to cover the interaction between patients and health-service providers, provider-to-provider transmission of data, or peer-to-peer communications between patients and/or health professionals. It can also include health information networks, Electronic Patient Records, telemedicine services, and personal wearable and portable communicable systems for assisting prevention, diagnosis, treatment, health monitoring and lifestyle management.

eHEALTH COMPRISES SIX TYPES OF SYSTEMS:

1. Hospital information system (HIS)
2. Clinical information system (CIS)
3. Other GP or speciality systems
4. Integrated health information exchange networks (HIE/EHR)
5. Telemedicine
6. Secondary-usage non-clinical systems (care analytics, public health and research)

eHEALTH COVERS THE FOLLOWING SIX FUNCTIONS:

1. Healthcare delivery support systems
2. Patient Data management
3. Health information exchange
4. Remote healthcare services & social care support
5. Care analytics, public health & research support
6. Health education



PART 2: GENERAL eHEALTH RELATED DEFINITIONS

ACTIVE AND HEALTHY AGEING

Active and healthy ageing is the process of optimising opportunities for health, participation and security in order to enhance quality of life as people age. It applies to both individuals and population groups. 'Health' refers to physical, mental and social wellbeing. 'Active' refers to continuing participation in social, economic, cultural, spiritual and civic affairs, not just the simple ability to be physically active or to participate in the labour force.

ACUTE CARE HOSPITAL

Acute care hospitals provide a wide range of diagnoses as well as inpatient care and treatment for seriously ill or injured patients. Typically, services include consultation with specialist clinicians; emergency treatment; routine, complex and life-saving surgery; specialist diagnosis procedures; close observation and short-term care of patients with worrying symptoms. Some acute care hospitals are specialised (e.g. maternity hospitals or cancer hospitals), while others are general, covering different clinical specialities.

AMBIENT ASSISTED LIVING

Independent living supported by unobtrusive devices and systems within the home⁷.

ANONYMISATION

The process used to strip personal data from all elements likely to help identify directly or indirectly the data subject (e.g. name, age, address, social security number, etc.). These elements are deleted to ensure re-identification is not possible.

AUTHENTICATION

Authentication, in the context of eHealth information security, refers to the confirmation of the identity of a user requesting access to eHealth services and/or patient data. Its purpose is to verify whether or not the user really is who they claim to be. Authentication is not to be confused with Authorisation, which deals with rights particular users or user groups may or may not have. While Authentication deals with questions like: "Is this person really Dr. X?", Authorisation might ask "Does Dr. X have the right to access this specific kind of data?".

BIG DATA

Big Data refers to datasets whose size is beyond the ability of typical database software tools to capture, store, manage, and analyse. Big Data also refers to the management of these ultra-large amounts of information (e.g. storage, aggregation, search, analysis, visualisation, and combination) and the use of the results to extract knowledge.

BIOBANKS

Repositories that store biological samples for use in research. Biobanks give researchers access to data representing larger numbers of individual people than could be analyzed in previously used systems. Furthermore, samples in biobanks and the data derived from those samples can often be used by multiple researchers for multiple purposes. Biobanks have become a key resource, supporting many types of contemporary research like genomics and personalized medicine.

BIOMARKERS

Biological parameters that can be used to identify a physiologic condition. They are traceable substances that are introduced into an organism as a means to examine organ function, or indicate a particular disease state or other aspects of health. Used in medical imaging, biomarkers are an essential element of predictive, preventive and Personalised Medicine.

CAPEX/OPEX

Capex, or capital expenditure, is a business expense incurred to create future benefit (i.e., acquisition of assets that will have a useful life beyond the tax year). For example, a business might buy new assets, like buildings, machinery, or equipment, or it might upgrade existing facilities so their value as an asset increases.

On the other hand, those expenditures required for the day-to-day functioning of the business, like wages, utilities, maintenance, and repairs, fall under the category of Opex, or operational expenditure. Opex is the money the business spends in order to turn inventory into throughput. Operating expenses also include depreciation of plants and machinery which are used in the production process.

CARE COORDINATION⁸

The deliberate organisation of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of healthcare services. Organising care involves the marshalling of personnel and other

7. Telescope project: http://www.telehealthcode.eu/images/stories/telehea/pdf/tp1_glossary_of_terms_v3_final.pdf

8. US national Institute of health <http://www.ncbi.nlm.nih.gov/books/NBK44012/>

resources needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care.

CLINICAL PATHWAYS

Clinical pathways, also known as care pathways, critical pathways, integrated care pathways, or care maps, are one of the main tools used to manage the quality in healthcare concerning the standardisation of care processes. It has been proven that their implementation reduces the variability in clinical practice and improves outcomes. Clinical pathways promote organised and efficient patient care based on the evidence-based practice. Clinical pathways optimise outcomes in the acute care and homecare settings. Generally clinical pathways refer to medical guidelines. However a single pathway may refer to guidelines on several topics in a well specified context.

CLOUD COMPUTING

Cloud computing is internet-based computing, where shared servers provide computing power, storage, development platforms or software to computers and other devices on demand. This frequently takes the form of cloud services, such as 'Infrastructure as a Service' (IaaS), 'Platform as a Service' (PaaS) or 'Software as a Service' (SaaS). Users can access web-based tools or applications through a web browser or via a cloud-based resource like storage or computer power as if they were installed locally, eliminating the need to install and run the application on the customer's own computers and simplifying maintenance and support.⁹

There are several possible deployment models for clouds, the most important being public, private and hybrid.

- **A PUBLIC CLOUD** is one in which a service provider makes resources, such as applications and storage, available to the general public over the internet, for maximum cost-efficiency, resilience and elasticity.
- **PRIVATE CLOUD** is infrastructure operated solely for a single organisation. The resources have all the key characteristics of the public cloud (see above) but are dedicated to one single organisation, giving it more control over security and access, and the ability to tailor/customise characteristics offered by public cloud.
- **HYBRID CLOUD INFRASTRUCTURE COMBINES** the first two approaches, with sensitive applications and data in a private cloud and more generic systems and processes in a public cloud.

COMPOUND ANNUAL GROWTH RATE

Compound annual growth rate (CAGR) is an average growth rate over a period of several years.

CONFORMANCE

Refers to the ability of a product or system to perform a set of functions according to specifications that are defined within a standard. Testing whether a system conforms to a set of standards is called conformance testing.

CONSENT

Data subject consent means any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed.

DATA ANALYTICS

The discovery and communication of meaningful patterns in data, in order to make sense of the 'Big Data'. Data analytics techniques analyse datasets to describe, predict, and improve performance. Commonly applied in business, data analytics are increasingly used in healthcare.

DATA CONTROLLER¹⁰

The natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of processing are determined by national or Community laws or regulations, the controller or the specific criteria for his nomination may be designated by national or Community law.

DATA PROCESSOR¹¹

A natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller.

DATA SECURITY

The protection of personal data from unauthorised or unintentional loss, theft, access, use, modification, or disclosure.

9. COCIR definition, eHealth Toolkit, May 2011

10. http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

11. http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

eDISPENSATION (ELECTRONIC DISPENSATION)

eDispensation – or eDispensing – is defined as the act of electronically retrieving a prescription and dispensing medicine to the patient as indicated in the corresponding ePrescription. Once the medicine has been dispensed, the dispenser sends an electronic report on the medicine(s) dispensed.

ELECTRONIC PATIENT RECORD (EPR)

An Electronic Patient Record (EPR) is a record in digital format containing medical information about a patient. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.

There are different types of Electronic Patient Records:

- Electronic medical record / Electronic Patient Record
- Patient summary
- Personal health record

ELECTRONIC MEDICAL RECORD (EMR) / ELECTRONIC PATIENT RECORD (EPR)

Electronic Patient Record (EPR), Electronic Medical Record (EMR), Computerised Patient Record (CPR) are synonymous. They refer to an individual patient's medical record in digital format generated and maintained by a care provider, such as a hospital or a physician's office. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, and billing information. The purpose of an EPR/EMR can be understood as a complete record of patient encounters that allows the automation and streamlining of the workflow in health care settings and increases safety through evidence-based decision support, quality management, and outcomes reporting.

EMPOWERMENT¹²

A process through which people gain or are afforded greater control over decisions and actions affecting their lives.

ENCRYPTION

Encryption is the process of encoding messages or information in such a way that only authorised parties can read it. Encryption does not prevent hacking but it reduces the likelihood that the hacker will be able to read the data that is encrypted.

ENTERPRISE IT

Enterprise IT is synonymous with Hospital IT. See Hospital IT definition.

EPRESCRIPTION (ELECTRONIC PRESCRIPTION)

An ePrescription is an electronic prescription: a medicinal prescription, e.g. a set of data like drug ID, drug name, strength, form, dosage and/or indication(s), provided in electronic format.

The term 'ePrescription' may cover different functionalities, and depending on national viewpoints, the definition of ePrescription may vary. In general, the term 'ePrescription' may refer to the following features:

- Electronic medication record of an individual
- Informed prescription with electronic decision support
- Electronic transmission of a prescription.

In this framework, the ePrescription service is understood as the prescription of medicines using software, the electronic transmission of the prescription from the prescriber (the healthcare professional) to a dispenser (e.g. pharmacy), where the prescription is electronically retrieved, the medicine is given to the patient and information about the dispensed medicine(s) is reported electronically.

EVIDENCE-BASED MEDICINE¹³

Evidence-based medicine is a medicine that bases clinical decisions from evidence coming from the analysis of clinical data. It is defined in medical literature as the 'conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'.

12. Telescope http://www.telehealthcode.eu/images/stories/telehea/pdf/fp1_glossary_of_terms_v3_final.pdf

13. http://en.wikipedia.org/wiki/Evidence-based_medicine

GENOTYPE

Genotype refers to the genetic makeup of an organism, such as a human being.

HEALTH DATA¹⁴

Any information relating to the health of an identified or identifiable natural person. It can include demographics (age, sex, date of birth etc), clinical information (blood type, medication history, allergies, medical images, laboratory results, diet), genetic information (genotype, family disease history), disease information (cancer, HIV-AIDS, Alzheimer etc), medical interventions (delivery, abortion, surgery interventions), long-term care information etc.

HOSPITAL DIAGNOSIS IMAGING WORKFLOW

This use case supports the workflow related to imaging diagnostic tests performed inside a healthcare institution, for both identified orders and unknown orders, related to both identified patients and unidentified or misidentified patients.

HOSPITAL IT

Hospital IT – also often referred to as Enterprise IT – is a generic term referring to ICT-based products, systems, solutions and services used in hospitals to:

- Manage healthcare processes
- Manage the hospital administrative and business processes

Hospital IT includes Hospital Information Systems (Patient Administration Systems, Finance and Accounting Systems, Business Process Support, Logistics and Resource Systems) and Clinical Information Systems (Radiology Information Systems, Oncology Information Systems, Computerised Physician Order Entry Systems, Electronic Patient Records etc).

HOSPITAL LABORATORY WORKFLOW

This use case supports the workflow related to tests performed by a clinical laboratory inside a healthcare institution, for both identified orders and unknown orders, related to both identified patients and unidentified or misidentified patients.

EID

eID is the acronym for electronic identification. eID is enabled by the collection of identity attributes in an electronic form.

IDENTIFICATION

Performance of tests to enable a data processing system to recognise entities and individuals.

ELECTRONIC IDENTITY

Identity data (of a person) usable in electronic format.

IMAGING NETWORK

An imaging network is an ecosystem of connected care providers, allowing the seamless exchange of medical imaging and documents and related clinical data.

INFORMATION SYSTEM (IS)

An Information System (IS) is any combination of information technology and people's activities using that technology to support operations, management, and decision-making. In a very broad sense, the term information system is frequently used to refer to the interaction between people, algorithmic processes, data and technology. In this sense, the term is used to refer not only to the information and communication technology (ICT) an organisation uses, but also to the way in which people interact with. This technology in support of business processes.

INFOSTRUCTURE

eHealth Infostructure should be understood as the foundation layer containing all data structures, codifications, terminologies and ontologies, data interoperability and accessibility standards, stored information and data, as well as rules and agreements for the collection and management of these data and the tools for their exploitation. At European level, such a European infostructure may be composed of biomedical and health/medical research and knowledge databases, public health data repositories, health education information, electronic patient and personal health records systems, data warehouses etc.

14. http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

INTEGRATED CARE

Integrated care is a trend in healthcare reforms focusing on more coordinated and integrated forms of care provision. Integrated care may be seen as a response to the fragmented delivery of health and social services being an acknowledged problem in many health systems. WHO defines integrated care as a concept bringing together inputs, delivery, management and organisation of services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency. Furthermore, the WHO defines “integrated service delivery” as “the organisation and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money.”

INTEGRATED HEALTH INFORMATION NETWORKS

Networks supporting the exchange, processing and storage of health information. Integrated means that these networks are part of a broader IT infrastructure connecting different applications, servers or data centres, e.g. in a hospital or in a chain of hospitals, or even in local/regional or national IT infrastructure.

INTEGRATED PERSONAL HEALTH SYSTEMS¹⁵

Integrated Personal Health and Care Services address the health and social care needs of individuals outside of care institutions and support the work of care providers in an integrated fashion:

- They can integrate assistance, remote monitoring of chronic diseases, wellness and fitness
- They are produced as a result of integration of different institutional and information systems.

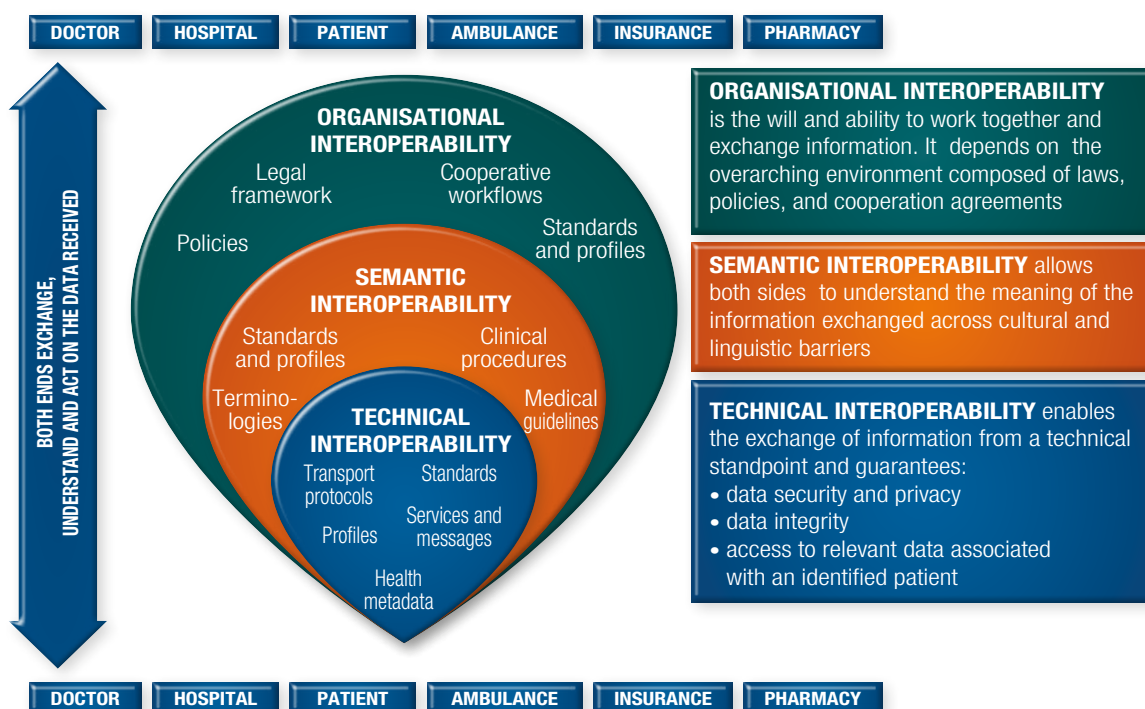
They are personal and possibly personalised in the way they gather, process and communicate data (for feedback/action).

INTEROPERABILITY

eHealth interoperability means the ability of two or more eHealth systems to use and exchange both computer interpretable data and human understandable information and knowledge.

There are three levels of interoperability - organisational, semantic and technical:

1. Organisational interoperability – also referred to as legal, process or cooperability interoperability – refers to the broader environment of laws, policies, procedures and bilateral cooperation needed to allow the seamless exchange of information between different organisations, regions and countries.
2. Semantic interoperability refers to the ability to ensure that the precise meaning of exchanged information is interpretable by any other system or application not initially developed for this purpose.
3. Technical interoperability means the ability of two or more ICT applications, to accept data from each other and perform a given task in an appropriate and satisfactory manner without the need for extra operator intervention.



15. Institute for Prospective Technological Studies – Strategic Intelligence Monitor on personal health Systems

LABORATORY INFORMATION SHARING

This use case supports the secured sharing (publishing, finding and retrieving) of laboratory reports and test results across a group of affiliated hospitals and practices within a region or nation. This use case provides ambulatory providers with online easy access to new laboratory test results for their patients, as well as comparison with earlier tests and prevents duplicated tests.

LEGACY SYSTEM

A legacy system is the existing technology, computer systems, application programmes and IT infrastructure that continues to be used, typically because it still functions for the users' needs, even though newer technology or more efficient methods of performing a task may be available.

MEDICAL IMAGING

The technique and process used to create images of the human body to reveal, diagnose, or examine a disease. Medical imaging is critical for early diagnosis and better evaluation of the treatment effect for improved outcomes. Medical Imaging has become a cornerstone of modern medicine in many disciplines: oncology; traumatology, musculoskeletal disorders, etc.

MEDICAL IMAGING INFORMATION SHARING

Imaging information sharing supports the secured sharing (publishing, finding and retrieving) of reports and imaging studies across a group of affiliated hospitals and practices within a region or nation. This use case provides ambulatory providers with easy online access to patients' imaging results, as well as to prior examinations of imaging departments (for comparison or to avoid duplicating imaging procedures).

mHEALTH – MOBILE HEALTH

Mobile health, or mHealth, is the provision of eHealth services and information that relies on mobile and wireless technologies. Similarly to eHealth, of which it is part, mHealth describes a broad set of technologies that can support a variety of health-related services, and is not a separate category of services in itself. Mobile technologies are utilised across the range of healthcare, social care, wellness and prevention, and form an integral part of telemedicine, telehealth and telecare.

MOLECULAR IMAGING¹⁶

Molecular Imaging is a discipline at the intersection of molecular biology and in vivo imaging. It enables the visualisation of the cellular function and the follow-up of the molecular process in living organisms without perturbing them. MI is used in the field of cancer, neurological and cardiovascular diseases. This technique also contributes to improving the treatment of these disorders by optimising the pre-clinical and clinical tests of new medication.

NEXT GENERATION SEQUENCING

Next generation sequencing (NGS) is a new method for sequencing genomes at high speed, at low cost and with great accuracy. It is also known as second generation sequencing (SGS).

OLOGIES

-ology, a suffix derived from the Greek logos, refers to the study of, or a speciality in a given scientific or medical field, e.g. oncology, pathology, radiology, etc.

-OMICS¹⁷

The English-language neologism -omics informally refers to a field of study in biology ending in -omics, such as genomics, proteomics or metabolomics. The related suffix -ome is used to address the objects of study of such fields, such as the genome, proteome or metabolome respectively. -Omics aims at the collective characterisation and quantification of pools of biological molecules that translate into the structure, function, and dynamics of an organism or organisms.

16. http://en.wikipedia.org/wiki/Molecular_imaging

17. <http://en.wikipedia.org/wiki/Omics>

PATIENT CENTRED CARE

Healthcare that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.

PATIENT REGISTRY

Patient registries are collections of secondary data related to patients with a specific diagnosis, condition, or procedure. In its most simple form, a disease registry could consist of a collection of paper cards kept inside a box by an individual doctor. Most frequently, registries vary in sophistication from simple Excel spreadsheets which can only be accessed by a small group of doctors to very complex databases which are accessed online across multiple institutions. They can give healthcare providers (or even patients) reminders to check certain tests in order to reach certain quality goals. Patient registries are less complex and simpler to set up than Electronic Medical Records/Electronic Patient Records. An EMR/ EPR keeps track of all the patients a doctor follows while a registry only keeps track of a small sub-population of patients with a specific condition.

PATIENT SELF-MANAGEMENT

The systematic provision of education and supportive interventions by healthcare staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support. Self-management support programs may be able to help patients with conditions such as asthma, cardiovascular disease, depression, diabetes, heart failure, and migraine headaches (Pearson et al., 2007). In addition, self-management programmes may support patients in managing other health-related activities that may not be specific to a given condition, such as medication management or prevention and wellness.

PATIENT SUMMARY¹⁸⁹

A Patient Summary is a sub-set of an Electronic Medical Record. A Patient Summary is a concise clinical document which provides an electronic patient health data set applicable both for unexpected, as well as expected, healthcare contact.

The primary application of an electronic patient summary is to provide the healthcare professional with a dataset of essential and understandable health information needed in case of unexpected or unscheduled care (e.g. an emergency or accident) or in the case of planned care (e.g. the patient is in another area and needs to consult a healthcare professional other than their regular contact person).

The Patient Summary does not include a detailed medical history, details of the clinical condition, or the full set of the prescriptions and medicines dispensed but includes data such as:

- Patient's general information (mandatory)
- Medical summary (mandatory)
- Medication summary (mandatory)

A patient may have more than one electronic patient summary.

PERSONAL DATA¹⁹

Any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly; in particular by reference to an identification number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identity.

PRIVACY²⁰

In healthcare, privacy stands for the generic interest a patient has in being able to control who has access to his or her information, and keep his/her information away from public view.

18. epSOS definition: http://www.epsos.eu/faq-glossary/glossary.html?tx_a21glossaryadvancedoutput_pi1%5Bchar%5D=p&cHash=a6f1fa3be9712f8a355813734283d2ee

19. http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

20. WHO - Global Observatory for eHealth- Volume 5 – legal frameworks for eHealth – 2012

PERSONAL HEALTH RECORD

A personal health record – or PHR – is a health record that is initiated and maintained by an individual. Other health records such as Electronic Patient Record (EPR) or electronic medical record (EMR) are generated and maintained within an institution, such as a hospital, clinic, or physician's office.

PERSONAL HEALTH SYSTEMS (PHS)

Personal Health Systems (PHS) assist in the provision of continuous, quality controlled, and personalised health services, including diagnosis, treatment, rehabilitation, disease prevention and lifestyle management, to empowered individuals regardless of location. PHS consist of intelligent ambient and/or body devices (wearable, portable or implantable), intelligent processing of the acquired information and active feedback from health professionals or directly from the devices to the individuals.

PERSONALISED MEDICINE (NEW)

Personalised Medicine is an evolution from today's medical model of standardised clinical pathways and drugs licensed for an entire population, towards an approach which recognises the differences between individuals in their health risks, and their responsiveness to treatments. We have already embarked on this journey with Stratified Medicine, which attempts to cluster populations into smaller groups, based on their phenotypic characteristics. As more detailed knowledge becomes available, including genomic and proteomic data, we now need to consider how to evolve and adapt preventive, diagnostic, therapeutic and follow-up actions to each individual person. In addition, the adaption needs to take into account clinical information, the individual's specific epidemiologic and social context, personal preferences and lifestyle etc. Over time, as accuracy and confidence levels increase, we will move closer to the goal of Precision Medicine, completely customising the care to the individual, to optimise outcomes or prevent the incidence of any disease. In COCIR's view, although –omic information and corresponding research are very important, Personalised Medicine goes beyond using genomic information for personalising treatment. Personalised Medicine must be seen in the context of a holistic approach to healthcare, in which the patient becomes the central stakeholder.

PHENOTYPE

A phenotype is the composite of an organism's observable characteristics or traits, such as its morphology, development, biochemical or physiological properties, behavior, and products of behaviour. A phenotype results from the expression of an organism's genes as well as the influence of environmental factors and the interactions between the two.

PSEUDONYMISATION

Pseudonymisation is the process of disguising identities - the aim of such a process is to be able to collect additional data relating to the same individual without having to know their identity. This is particularly relevant in the context of research and statistics. Disguising identities can also be done in a way that no re-identification is possible, e.g. by one-way cryptography, which creates in general anonymised data.

PROFILE

A profile is a selection of specifications and options from existing standards, combined to serve a specific use case. Profiling is conducted in order to achieve interoperability between different products and implementations.

RADIOGENOMICS

Radiogenomics refers to non-molecular imaging biomarkers. Radiogenomics links radiological image information with genomic data, and together with the development and integration of imaging biobanks can be expected to be both integral and critical to the advance of Personalised Medicine.

SECONDARY USAGE NON-CLINICAL SYSTEMS

Secondary usage non-clinical systems include:

- Systems for health education and health promotion of patients/citizens such as health portals or online health information services.
- Specialised systems for researchers and public health data collection and analysis such as bio-statistical programmes for infectious diseases, drug development, and outcomes analysis

SOFTWARE AS A SERVICE (SAAS)

Software as a service, sometimes referred to as “software on demand” is software that is deployed over the internet and/or is deployed to run behind a firewall on a local area network or personal computer. With SaaS, a provider licenses an application to customers either as a service on demand, through a subscription, in a “pay-as-you-go” model, or at no charge. This approach to application delivery is part of the utility computing model where all of the technology is in the “Cloud” accessed over the internet as a service.

STANDARD

A standard is an agreed, repeatable way of doing something. It is a published document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition. Standards help to make life simpler and to increase the reliability and the effectiveness of many goods and services we use. Standards are created by bringing together the experience and expertise of all interested parties such as the producers, sellers, buyers, users and regulators of a particular material, product, process or service.

STRUCTURED DATA

Data organised in such a way that the different attributes, e.g. patient name, diagnosis and medication are interpretable by an IT system.

TELE-ASSISTANCE

Tele-assistance can be a medical act when a doctor remotely assists another doctor carrying out a medical or surgical act. The doctor can also assist another health professional who carries out an act of care or imaging, even within the framework of an emergency, to remotely assist a first aid worker or any person providing medical assistance someone in danger while waiting for the arrival of a doctor.

TELECARE

Telecare designs systems and services capable of social alert and social services. Telecare is used mainly to monitor the situation of people dependent on external help (i.e. elderly or disabled people) in the home setting.

TELECARDIOLOGY

Telecardiology covers the remote collection of cardiology data, mostly ECG data, and their transmission to a service centre. In the centre, the data are evaluated by qualified staff who give advice to a patient or another healthcare provider. In emergencies, the service centre may also trigger rescue measures. Data transmission can either take place continuously or at clearly defined points of time. Data collection can take place either at the patient's home or mobile.

TELECONSULTATION

Teleconsultation is a medical act where the patient is present, and may be assisted by a healthcare professional. The healthcare professional may or may not be a medical doctor.

TELEDERMATOLOGY

Teledermatology describes the transmission of visible light images (photos or videos) of disorders of the human skin for classification and diagnosis. It can take the form of primary as well as secondary diagnosis. Detection and classification of skin cancers is a typical example. Since dermatology is a highly-specialised discipline and many patients will see a general practitioner first, the use of teledermatology offers great potential to shorten the diagnostic process and speed up the start of appropriate treatment.

TELE-EXPERTISE

Tele-expertise is a remote medical act between at least two healthcare professionals without the presence of the patient for decision purpose.

TELEHEALTH (Includes REMOTE PATIENT MANAGEMENT or “RPMT”)

The term telehealth covers systems and services linking patients with care providers to assist in diagnosing and monitoring, as well as the management and empowerment of patients with long-term conditions (chronic patients). Telehealth solutions use devices

(interactive audio, visual and data communication) to remotely collect and send data to a monitoring station for interpretation and to support therapy management programmes and improve patients' knowledge and behaviour. Telehealth solutions comprise systems and components (patient interfaces in hardware and software, sensors/peripherals, operating software and applications intended for care provider usage, clinical content and intelligence; data transmission, storage and intelligent routing) as well as supporting services (system operation, logistics, financial services etc).

TELE-INTERVENTION

Tele-intervention is a therapeutic medical act which is performed remotely by a physician on a patient, without or with the local presence of other healthcare professional(s) e.g. telesurgery.

TELEMEDICINE

Telemedicine is the overarching definition covering Telehealth, Telecare and teledisciplines. Telemedicine can be defined as the delivery of healthcare services through the use of information and communication technologies (eHealth), including wireless and mobile connectivity (mHealth), in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a healthcare professional and a patient (e.g. telemonitoring of the chronically ill such as those with diabetes and heart conditions, telepsychiatry etc). Telemedicine includes all areas where medical or social data is being sent/exchanged between at least two remote locations, including both care provider to patient/citizen as well as doctor-to-doctor communication.

TELEMONITORING

Telemonitoring refers to systems and services using devices to remotely collect/send vital signs to a monitoring station for interpretation.

Telemonitoring is the remote exchange of physiological data between a patient at home and medical staff at hospital to assist in diagnosis and monitoring (this could include support for people with lung function problems, diabetes etc). It includes (amongst other things) a home unit to measure and monitor temperature, blood pressure and other vital signs for clinical review at a remote location (for example, a hospital site) using phone lines or wireless technology.

TELE-OPHTHALMOLOGY

Tele-ophthalmology describes the remote diagnosis of medical conditions of the human eye. Similar to teledermatology, patients may not have immediate access to an ophthalmologist. Ophthalmology not only diagnoses typical diseases of the eye but can also generate useful information on other diseases, e.g. diabetes and cardiac conditions and related secondary symptoms. Data typically take the form of photos or videos.

TELEPATHOLOGY

Telepathology enables remote staff pathologists, and third-party providers, to securely share images of anatomical pathology specimens to complete primary and non-primary diagnostic evaluation, and to also seek expert second opinions, and primary interpretation of urgent cases, from operating rooms.

TELEPSYCHIATRY

Telepsychiatry is a form of teleconsultation by a psychiatrist of a patient suffering from mental disorder.

TELERADIOLOGY

Teleradiology Information Systems (IS) enables secure remote evaluation of digital diagnostic studies (CT scans, MRIs and X-Rays). This technology enables both remote staff radiologists and third-party providers to complete primary and non primary diagnostic studies from any location. It encompasses hospital-to-home teleradiology for out-of-hours healthcare coverage i.e. remote working for radiologists being part of the hospital radiology department. It also covers outsourcing to other imaging centers or commercial teleradiology companies that provide outsourcing services for image interpretation (night and/or day reads).

TELESCREENING

Telescreening describes the use of a first or second opinion through a remote connection in screening programmes. Either medical data is transferred to a remote specialist for primary evaluation, e.g. in the case that a specific medical qualification is required. Another scenario involves a second opinion in order to increase the quality of the screening process. An example in the form of teleradiology would be the use of screening centres in mammography screening. The data transmitted during telescreening can take any form from digital X-Ray images to video files or ECG or laboratory data.

TELESURGERY

Telesurgery describes the remote controlling of surgical apparatus, e.g. a surgical robot, by an experienced surgeon or the remote advice provided by an experienced surgeon to the surgeon on duty in the operating theatre. In the latter case, a live video connection and an audio connection between the two surgeons is sufficient. In the former case, a data link between the surgical apparatus on site and the remote manipulation tool is required.

UNSTRUCTURED DATA

Unstructured Data (or unstructured information) refers to information that either does not have a pre-defined data model or is not organised in a pre-defined manner. Unstructured information is typically text-heavy, but may contain data such as dates, numbers, and facts as well. This results in irregularities and ambiguities that make it difficult to understand using traditional computer programmes as compared to data stored in fielded form in databases or annotated (semantically tagged) in documents.

UNIQUE IDENTIFIER

In healthcare, unique identifier is a unique number that has been assigned to healthcare consumers (patients), and to healthcare providers and organisations that provide health services. The aim of unique identifiers is to ensure that individuals and providers can have confidence that the right health information is associated with the right individual.

USE CASE

In healthcare, a unique use case refers to a situation or a need for which eHealth information exchange needs to be developed. A use case helps to identify the relevant real world requirements. Use case descriptions are independent of technical details and focus on actions and information flow in the clinical world. Profiles are developed for each use case to ensure interoperability. The most common use cases referred to in eHealth are information exchange associated with patient summary, ePrescription, medical imaging exchange, laboratory results exchange.

CLINICAL USE CASE: A clinical use case refers to scenarios and terms of the clinical world rather than mentioning computer-related terms.

TECHNICAL USE CASE: A technical use case is a use case that refers to application scenarios, but already assumes some technical measures or components. Technical use cases typically help in the selection of existing specifications and design of solution components.

VITAL SIGN MONITORING²¹

Vital signs are to be understood as a set of physiological indicators, which reflect the overall status of the body. With the help of technologies they can be checked regularly to assess body functions of an individual making it possible to remotely monitor the patient or user status, without the need of a care giver to be present. The measurement and the resulting data are either collected discretely meaning at predetermined intervals called spot checking or continuously. Originally automated vital signal monitoring was used in Intensive Care Units (ICUs), Cardiac Care Units (CCUs) and Operating Rooms (ORs). Today spot checking certain parameters forms part of the procedures for most medical physical examinations. In addition, it can be used to determine training effects.

VENDOR NEUTRAL ARCHIVING (VNA)²²

A VNA provides image storage, management, archiving and routing functions for one or more medical imaging documentation and archiving systems. It may also include integration to a clinical viewer offering secure access to standard imaging data from existing workstations anywhere on the network. The viewer is generally considered an external component to the VNA.

21. Institute for Prospective Technological Studies – Strategic Intelligence Monitor on personal health Systems

22. See Part 2 on VNA for a more detailed definition.

PART 3: HOSPITAL INFORMATION SYSTEMS (HIS)

Hospital Information Systems manage the administrative and financial aspects of a hospital (patient administration, finance, accounting, logistics, human resources, materials management etc). This includes paper-based information processing as well as data processing machines. Hospital Information Systems include business process support systems, finance and accounting systems, logistics and resource systems, patient administration systems.

3.1. BUSINESS PROCESS SUPPORT

Systems designed to support the business processes of a hospital. They collect, integrate, analyse and present business information to improve business decision-making.

BUSINESS INTELLIGENCE SYSTEMS (BI)

Business Intelligence (BI) systems refer to technologies, applications and practices for the collection, integration, analysis, and presentation of business information to improve business decision-making by using fact-based/data-driven decision support systems. BI systems provide historical, current and predictive views of business operations using data from a (clinical) data warehouse and operational data. The emerging integrated clinical/financial BI systems approach therefore combines traditional sources (such as human resources, cost accounting and financial reporting) with rich clinical data from computer-based patient record/medical records (EPR/EMR).

However, a BI system is much more than a data warehouse. Its purpose is to provide insights that affect and improve business/clinical processes and all the associated outcomes (clinical, financial etc.) BI also has a real-time, immediate dimension. Results can be either predictive or correlative in nature.

CLINICAL DATA WAREHOUSING SYSTEMS (CDW)

Data Warehousing Systems (CDW) are integrated systems of patient-related clinical data allowing the collection and normalisation of data from disparate clinical sources into a database designed to support management clinical decision-making, performance analysis purposes or research. CDW can be standalone solutions based on database platforms and integration standards, or integrated with an Electronic Patient Record/Electronic Medical Record (EPR/EMR) solution or built at regional level as is the case in Norway and Sweden. In all cases, CDW are usually tied to the Master Patient Index (MPI).

QUALITY MANAGEMENT SYSTEMS (QMS)

Also called Assurance Information Systems, QMS support the monitoring of the overall performance and quality of clinical care by analysing, comparing and treating information of detailed clinical practices patterns and parameters. Quality Management / Assurance IS might also include compliance/audit features, for example by asking if the care which was documented matched the care given). It also has a real-time, immediate dimension. Results can be corrective and preventive in nature.

3.2. FINANCE & ACCOUNTING SYSTEMS

Information systems designed for the finance and accounting departments of hospitals to manage financial and accounting processes. They include – amongst others – Coding Information Systems, Financial Accounting and Controlling Information Systems.

CODING INFORMATION SYSTEMS

Coding Information Systems are used to collect and code clinical service information for patient billing, insurance claims, activity analysis and cost accounting. They may include DRG-Management features. They enable personnel to find and use complete and accurate codes and code modifiers for procedures and diagnostics to optimize billing and reimbursement. They are rarely a standalone system and can be part of Patient Administration System either directly or through the Electronic Patient Record / Electronic Medical Record (EPR/EMR) depending on each country's coding workflow specificities (in Germany, for example, coding is performed by physicians). Coding Information Systems are usually associated with care administration but have also clinical relevance with specific code for clinical purposes or research.

FINANCIAL ACCOUNTING & CONTROLLING INFORMATION SYSTEMS

Financial Accounting & Controlling Information Systems record and process accounting transactions within a variety of functional modules, including Accounts receivable (AR), Accounts payable (AP), General ledger (GL), Billing, Stock/Inventory, Purchase Requisition and Purchase Order (PO), Debt Collection (DC), Expenses, Inquiries, Payroll, Timesheets, and Controlling and Financial Reporting. Coding Information Systems might be part of this or provided as a separate Information System. Financial Accounting & Controlling Information Systems can be stand-alone systems or part of an Enterprise Resource Planning (ERP).

3.3. LOGISTICS AND RESOURCE SYSTEMS

Logistics and resource systems are information systems designed to manage the logistics and resources of a hospital. They include – among others – enterprise resource planning systems, Human Resources management systems, supply chain management systems etc.

ENTERPRISE RESOURCE PLANNING SYSTEMS (ERP)

Enterprise Resource Planning Systems are business management systems that integrate multiple business applications including human resources and payroll management, materials management, supply chain management, financials and accounting management as well as customer relationship management (CRM) by providing an automated and integrated view of business information and reports of data from several operational areas.

FACILITY & EQUIPMENT MANAGEMENT SYSTEMS

Facility & Equipment Management systems control and monitor facilities and equipments, describe and track their deployment, maintain the clinical infrastructure and optimise resource utilization. Additionally, they can manage the interactions and activities from the selection and acquisition, inspections / maintenance through to the eventual retirement/disposal of medical equipment governed by related policies and procedures. Available as standalone tools/systems (e.g. Medical Equipment Management System - MEMS; Facility Management System - FMS) or as part of an Enterprise Resource Planning (ERP) system or a Hospital Information System. Such systems require integration with key clinical systems (orders etc).

HUMAN RESOURCES MANAGEMENT SYSTEMS (HRM)

Human Resource Management Systems manage the administration of personnel, including personnel planning/staff/nurse scheduling, employee time and attendance tracking/labour time assessment, payroll and controlling. Individual functions may be stand-alone solutions or part of an Enterprise Resource Planning (ERP) system including Payroll and Human Resources. In healthcare delivery systems operated by government (e.g. national health systems), HRM systems may reside on government systems.

SUPPLY CHAIN MANAGEMENT (SCM)/MATERIALS MANAGEMENT SYSTEMS

Supply Chain Management Systems manage the processes of planning, implementing and controlling all movement and storage of materials and inventory from point-of-origin to point-of-consumption. Key functionalities include: purchase order processing, inventory management, warehouse / materials management, supplier relationship management/sourcing. SCM are available as standalone tools/systems or as part of an Enterprise Resource Planning (ERP) system. Standalone systems/tools may also be integrated with Enterprise Resource Planning (ERP) solutions. SCM require the integration with key clinical systems (orders etc.)

3.4. PATIENT ADMINISTRATION SYSTEMS

A patient administration system is one of the earliest components of a hospital computer system which manages the administrative side of the relations with a patient.

Patient administration systems include - among other things - admission, discharge and transfer systems, master patient index systems, patient relationship management systems, scheduling of critical resources or facilities systems.

ADMISSION, DISCHARGE & TRANSFER SYSTEMS (ADT)

Also called registration systems, ADT systems include pre-registration, patient history (administrative), patient admission and discharge transfer functions. They are rarely standalone systems and are mainly part of an overarching Patient Administration System (PAS).

MASTER PATIENT INDEX SYSTEMS (MPI OR EMPI)

MPI systems maintain a unique patient identifier and a single master index of all patients, which references all patient indices within a single facility (e.g. hospital or a group of hospitals) to correctly identify and share patient information across linked IT systems with multiple authorised users. MPI systems also provide additional search functionality for specific patients including full name, partial names, address, ID numbers, etc. MPI systems are rarely a standalone system and are very often an integral component of a Patient Administration System (PAS) or electronic patient records (EPR)/electronic medical records (EMR). MPI is for a single facility whereas EMPI is a unique patient identifier for multi-facilities (who may each identify patients non-uniquely across facilities). To accurately match and link records across systems, a standalone EMPI has proven integration with these systems, scalability to support real-time identification across millions of records and most importantly a matching algorithm that can take data from different systems and create a unified view.

PATIENT RELATIONSHIP MANAGEMENT SYSTEMS (PRM)

PRM refers to the use of IT for identifying and anticipating patient needs and preferences by providing a centralised view on patient demographic information in order to tailor communications and programmes accordingly. PRM introduces the principles of customer relationship management (CRM) into healthcare. It can be a standalone system (e.g. standard CRM solutions), part of a Patient Administration System (PAS) or an ERP system (Enterprise Resource Planning), but it can also be a mix of standalone solutions for individual aspects (e.g. patient questionnaires, direct marketing activities such as mailings etc.)

SCHEDULING OF CRITICAL RESOURCES OR FACILITIES SYSTEMS

Patient scheduling systems coordinate scheduling of all care providers resources for a specific patient (inpatient or outpatient) and identify conflicts with other appointments for the patients or provider resources. It may include staff, critical resources (beds, surgery rooms, etc.), materials (diagnostic equipments) as well as preparation requirements (anesthesia consultation). It is rarely a stand-alone system and is mainly part of a Patient Administration System (PAS). It may also be part of an Enterprise Resource Planning (ERP) system including features which support clinical and enterprise scheduling. Patient scheduling systems are general and therefore differ from specialised scheduling systems such as Emergency/Operating Room/ICU scheduling systems. They also differ from resource planning or departmental scheduling.

PART 4: CLINICAL INFORMATION SYSTEMS (CIS)

Clinical Information Systems refer to comprehensive, integrated information systems designed to manage the clinical functions of a hospital.

Clinical Information Systems aim to increase the efficiency of healthcare delivery by archiving patient data, providing faster access to patient data between healthcare professionals/hospital departments and guiding healthcare professionals when making medical decisions.

Clinical Information Systems can be composed of one or more software components with core functions such as electronic patient record information systems, medical document management information systems, computerised physician order entry as well as a large variety of sub-systems in medical specialties (e.g. oncology information systems, orthopedic information systems, etc.) and service departments (e.g. Laboratory Information System, Radiology Information System).

Clinical Information Systems include clinical knowledge and decision support systems, clinical order communication management systems, medical record systems, medico-technical service department systems.

4.1. CLINICAL KNOWLEDGE, DECISION & PROCESS SUPPORT INFORMATION SYSTEMS

Systems designed to assist health professionals with decision-making by linking dynamic individual patient health observations with a common clinical knowledge management system. They include among others clinical decision support systems, clinical workflow management systems etc.

CLINICAL KNOWLEDGE MANAGEMENT & CLINICAL DECISION SUPPORT SYSTEMS (CDSS)

Clinical Decision Support Systems are an interactive computer programme designed to assist doctors and other healthcare professionals with decision-making tasks by linking dynamic individual patient health observations (e.g. monitored in an Electronic Patient Record) with a common clinical knowledge management system (e.g. a set of rules derived from experts and evidence-based medicine). Decision support systems are based on knowledge management systems also named Rules Engines. Rules Engines maintain complex rule sets designed by end-users and acquired from extra knowledge sources. Rules Engines are critical to extending Electronic Patient Record systems beyond the capabilities of human cognition and enhancing collaboration. Because medical knowledge has moved beyond the ability of unassisted human to track all relevant information, the use of clinical decision support implemented in a Rules Enging is now necessary to practice state-of-the art medicine.

CLINICAL WORKFLOW MANAGEMENT INFORMATION SYSTEMS (CWMS)

Clinical Workflow Management Information Systems optimally coordinate the multidisciplinary clinical processes from admission to discharge for each patient based on a single individual care plan by linking a complete view of the patient's movement through the hospital to clinical decision support. It involves the use of workflow engines which support explicit clinical and operational workflows created by users and supported by scientific literature using graphical design tools. It supports the practice of evidence-based medicine and provides the infrastructure necessary for an organisation to optimise its clinical activities. These systems can be standalone solutions from basic Therapy Planning software to departmental solutions integrated with the different clinical information solutions or ultimately integrated solution with Knowledge Management Systems and Decision Support Systems in an Hospital Information Systems/Clinical Information Systems (HIS/CIS).

DISEASE MANAGEMENT INFORMATION SYSTEM

Disease Management Information System support healthcare professionals to manage patients who have one or more chronic conditions. Such systems, unlike Electronic Patient Records, do not document the entire patient's encounter, but rather focus on chronic disease and preventive care. The use and concept behind Disease Management Information Systems are not widespread, hence relatively new with unclear boundaries. They might often be confused with "disease-specific registry".

eLEARNING APPLICATIONS AND ONLINE TRAINING OF STAFF

eLearning enables the distribution and presentation of teaching materials for professional education and training. eLearning can be based on a range of technologies and media (generally all digital media, here defined as computer and web-based) and covers a broad range of forms and applications.

4.2. CLINICAL ORDER COMMUNICATION MANAGEMENT INFORMATION SYSTEMS

Systems designed to place and share clinical orders between healthcare professionals and hospital departments.

CLINICAL ORDER ENTRY & RESULT REPORTING/COMPUTERISED PHYSICIAN ORDER ENTRY (CPOE)

Clinical Order Entry/Results Reporting information systems allow for the placement of clinical service orders for patient services or medications, including medications, procedures, examinations, nursing care, diets, laboratory tests, etc. with subsequent automated distribution of the clinical documentation processed as a result of this order. Order entry and result reporting can be a standalone solution or part of RIS, LIS or HIS. CPOE systems have the same functionality as a Clinical Order Entry/results reporting IS but in addition include special electronic signature, workflow, and rules engine functions.

ELECTRONIC TRANSMISSION OF PRESCRIPTIONS INFORMATION SYSTEM (ETP)

Electronic Transcription of Prescriptions Information System (ETP IS) facilitates the end-to-end medication management including ordering, dispensing and administration. They are point-to-point systems and do not include decision support functionalities. ETP IS can be a standalone solution or a module of Pharmacy information system.

ePRESCRIBING SYSTEM

ePrescribing Systems facilitate the end-to-end medication management including ordering, dispensing, and administration. Compared to the ETP, it goes further and updates the Medication Administration Record. It addresses large-scale benefits of decision support allowing physicians to review patient history and recommended dosage. Very often, it works in conjunction with other technologies, such as mobile devices, bar coding and automated dispensing machines. ePrescribing can be stand-alone solutions or modules of Pharmacy Information Systems.

4.3. MEDICAL RECORDS / ELECTRONIC PATIENT RECORD INFORMATION SYSTEMS

Systems that record and/or host information about the patient on an electronic file. They include digital dictation and transcription information systems, electronic patient records and medical document management systems.

DIGITAL DICTATION & TRANSCRIPTION INFORMATION SYSTEM

A Digital Dictation Information System facilitates the management of voice-recorded notes and reports. It converts voice-recorded notes and reports as dictated by physicians and/or other healthcare professionals into computerised text format (i.e. Medical Transcription). It can be standalone digital sound recording software and speech recognition software or integrated digital dictation and transcription workflow software.

ELECTRONIC PATIENT RECORD (EPR)/ELECTRONIC MEDICAL RECORD (EMR)

Electronic Patient Record (EPR), Electronic Medical Record (EMR), Computerised Patient Record (CPR) are synonymous. They refer to an individual patient's medical record in digital format generated and maintained in a healthcare institution, such as a hospital or a physician's office (as opposed to a personal health record – PHR – that is generated and maintained by an individual). Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, and billing information.

The purpose of an EPR/EMR can be understood as a complete record of patient encounters that allows the automation and streamlining of the workflow in healthcare settings and increases safety through evidence-based decision support, quality management, and outcomes reporting. EPR/EMR are made up of electronic medical records from many locations and/or sources and a variety of healthcare-related information to enable complete patient-centered documentation from initial diagnosis and therapy through to continuity-of-care planning. A graphical user interface on the clinical workstations allows authorised healthcare providers to retrieve/access, review and update a single patient's record at any linked department or facility. Medical technical devices may feed data automatically into the patient record. EPR/EMR are included in an application environment which is composed of the clinical data repository, clinical decision support, controlled medical vocabulary, order entry and results reporting/CPOE and clinical documentation applications.

MEDICAL DOCUMENT MANAGEMENT INFORMATION SYSTEM (MDM)

Medical Document Management systems mean a central repository system for disparate electronic/digital medical patient documents/files (e.g. care episodes, test results, diagnoses, referrals, discharge letters etc.) Documents may have been digitised (e.g. scanned) or created in digital format (e.g. by information systems). Key functions of medical document management systems include computer-aided document/file entry, indexing, administration, storage and access/retrieval of individual documents/files. Some systems include image archiving functions. Medical document Management systems might be integrated in a Hospital information system/Clinical information system (HIS/CIS).

4.4. MEDICO-TECHNICAL SERVICE DEPARTMENT SYSTEMS

Specialised systems designed to support clinical processes in the various service departments of a hospital. They include – amongst others – laboratory information systems, radiology information systems and picture archiving communications systems.

ADVANCED VISUALISATION INFORMATION SYSTEM

Advanced Visualisation Information Systems (IS) or advanced image processing tools, e.g. 3D MPR/MPI, CT/MR matching, Computer Aided Decision (CAD) support the decision-making processes and visualisation of the areas of interest for physicians in radiology, cardiology, oncology, neurology, pathology, orthopedics etc. Advanced Visualization Information Systems may imply a variety of techniques and methods such as extracting more information from existing datasets, providing a richer display of anatomic information than conventional section, volumetric interpretation of image data, Computer Aided Decision (CAD) and other advanced imaging techniques.

CARDIOLOGY PACS

Cardiology Picture Archiving and Communications Systems (PACS) are defined as a coherent system including a networked digital archive with online and nearline storage components, dedicated reading workstations, and all the associated software required to store, manage and view cardiology images. As for radiology, Cardiology PACS and Cardiovascular Information Systems (CVIS), the two systems are continuously becoming more integrated.

CARDIOVASCULAR INFORMATION SYSTEM (CVIS)

Cardiovascular Information Systems (CVIS) automate processes within the cardiology department, supporting scheduling, ordering, documentation and data capture. CVIS can be standalone solutions or integrated with a Cardiology Picture Archiving and Communications Systems (PACS) or as a module of a HIS/CIS (Hospital Information System/Clinical Information System).

ELECTRONIC HEALTH RECORD (EHR)

An Electronic Health Record (EHR) is a record in digital format containing medical information about a patient. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, vital signs, personal statistics like age and weight and billing information.

EMERGENCY INFORMATION SYSTEM

Emergency Information Systems support emergency department clinicians, nurses and staff in the critical task of managing patients quickly and efficiently. They provide features for care management and instant access to up-to-date patient information. They ensure a smooth transition for patients including triage and tracking as they are admitted to hospitals or discharged. Emergency IS can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

IMAGING DATA CENTERS (IDC)

Imaging Data Centers (IDC) provide a central imaging data repository (in-house or off-site) for a multi-site environment (e.g. a hospital chain), region or country. Very often based on a hub and spoke model, IDC provide a redundant central data repository to store and archive radiology and non-radiology diagnostic images often including relevant key image notes/post processing measurements combined with relevant reports. Outside the sharing of information based on secure access and authorisation, IDC offer resilience against network interruptions, centralised long-term archive and disaster recovery services.

INTENSIVE CARE UNIT INFORMATION SYSTEM (ICU IS)

Intensive Care Unit Information Systems provide automated functions for the automated documentation and protocol intervention management by the intensive care unit. Intensive care unit information systems also capture the data output from all medical devices monitoring the patient's clinical status. They include order entry, clinical documentation and flow charts, decision support and results reporting. They often summarise large amounts of observations to feed into the electronic medical records. ICU IS can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

INTERNAL MEDICINE INFORMATION SYSTEM

Internal Medicine Information Systems provide automated functions in the internal medicine department. Internal medicine Information Systems can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

LABORATORY INFORMATION SYSTEM (LIS OR LIMS)

Laboratory Information Systems (LIS) provide complete support for the laboratory department from an operational, clinical and management perspective. LIS can cover a number of different laboratory or pathology systems including different specialties such as Hematology, Histopathology, Microbiology, etc. The system provides an automatic interface to laboratory analytical instruments to transfer verified results to nurses' stations and even to remote doctors' offices. The system allows the user to receive orders

from any designated location, process the order and report results, and maintain technical, statistical and account information. Laboratory Information Systems are available as standalone solutions or as module(s) of Hospital Information Systems/Clinical Information Systems (HIS/CIS).

NURSING INFORMATION SYSTEM

Nursing Information Systems document nursing notes which describe the nursing care or services provided to a patient. It provides observations, decisions, actions and the outcomes of these actions. Nursing Information Systems track what occurred and when it occurred. They can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

ONCOLOGY INFORMATION SYSTEM

Oncology Information Systems comprise a set of systems which manage advanced clinical, administrative and financial processes in a completely integrative environment. Oncology Information Systems automate the clinical decision-making and complex communications needs of the medical oncology care team. It provides the ability to share information across venues for complex, multi-encounter chemotherapy protocol management. Oncology Information Systems can be a standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

OPERATING THEATRE IS (OT IS)

Operating Theatre Information Systems provide automated functions in the operating theatre department. OT IS can include peri-operative, post-operative and pre-operative functionalities. They might also include OT scheduling functionalities. OT IS can be stand-alone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

ORTHOPAEDICS INFORMATION SYSTEM

Orthopaedics Information Systems provide automated functions in the Orthopaedics department. When associated with a PACS, they include image acquisition, storage, distribution and viewing to preoperative planning using digital implant templates. Orthopaedics Information Systems can be standalone solutions or modules of Hospital Information System/Clinical Information System (HIS/CIS).

PHARMACY INFORMATION SYSTEM (PHIS)

Pharmacy Information Systems provide complete support for the pharmacy department from an operational, clinical and management perspective. It also allows the pharmacist to enter and fill physician orders, and as a by-product, performs all the related functions of patient charging, distribution of drugs and re-supply scheduling, pharmacy stock control, tracking of usage at ward level and post-hoc checking of prescriptions. PHIS may be associated with CPOE for prescriptions (CPOE or ePrescribing). PHIS can be standalone solutions or modules of Hospital Information Systems/Clinical Information Systems (HIS/CIS). Patient safety imperatives are driving a trend to tighter and tighter integration within HIS/CIS.

RADIOLOGY INFORMATION SYSTEM (RIS)

Radiology Information Systems are used by radiology departments to store, manipulate and distribute patient radiological data and imagery. The system generally consists of patient administration, scheduling, examination, reporting, accounting, statistics and system administration. The RIS can be standalone or integrated in a Picture Archiving and Communication System (PACS) or the Hospital Information System (HIS).

RADIOLOGY PACS

Radiology Picture Archiving and Communications Systems (PACS) address providers' storage, retrieval, distribution and presentation requirements for radiography imaging. While older PACS implementations do not include Radiology Information Systems (RIS), the two systems are becoming ever more integrated, moving away from standalone systems and towards combined PACS and RIS. While Radiology PACS has traditionally been located within the radiology department, the importance of these systems to other

clinical areas, including cardiology and pathology, continues to grow. PACS can be available as standalone solutions (modality PACS – basic solution integrated with the imaging device; mini-PACS – scaled-down/entry-level departmental solution), hospital-wide general or speciality, (e.g. Radiology PACS) or integrated RIS/PACS.

TELERADIOLOGY INFORMATION SYSTEM

Teleradiology Information Systems enable the secure remote evaluation of digital diagnostic studies (CT scans, MRIs and X-Rays). This technology enables both remote staff radiologists and third-party providers to complete primary and non-primary diagnostic studies from any location. It includes hospital-to-home teleradiology for out-of-hours health care coverage e.g. remote working for radiologists who are part of the hospital radiology department. It also covers outsourcing to other imaging centres or commercial teleradiology companies that provide outsourcing services for image interpretation (night and/or day reads).

VENDOR NEUTRAL ARCHIVING (VNA)

A VNA provides image storage, management, archiving and routing functions for one or more medical imaging documentation and archiving systems. It may also include integration to a clinical viewer offering secure access to standard imaging data from existing workstations anywhere on the network. The viewer is generally considered an external component to the VNA.



GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

COCIR COMPANY MEMBERS:



NATIONAL TRADE ASSOCIATIONS MEMBERS:



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