COCIR eHEALTH TOOLKIT

CONTRIBUTING TO THE EUROPEAN DIGITAL AGENDA

Second Edition
MAY 2012

COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

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

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HOW CAN COCIR CONTRIBUTE TO THE EUROPEAN DIGITAL AGENDA?

As the leading European trade organisation in the field of eHealth, representing the Radiological, Health ICT and Electromedical industry, COCIR welcomes activities and initiatives that developed around the Digital Agenda, one of the seven flagship initiatives of the EU's 2020 strategy for smart, sustainable and inclusive growth.

The objective of the EU's Digital Agenda is to maximise the social and economic potential of information and communication technologies (ICT), spur innovation, economic growth and improve daily lives of citizens and business.

Europe recognises that we need to continue our collective efforts towards the best use of ICTs to speed up economic recovery and lay the foundations of a sustainable digital future. It is key to concentrate on actions to remove current obstacles and focus on maximizing the potential of ICTs, with long-term investments to minimise future problems.

Although eHealth is considered to be a contributing factor in boosting economy and increasing sustainability of healthcare systems in Europe, its deployment remains limited in Europe. This is why COCIR launched in 2010 the concept of toolkits (telemedicine and eHealth).

Considering the great success of previous editions, we have decided to publish a new volume on eHealth in 2012, as a contribution to the Digital Agenda key actions on eHealth, namely:

- Give citizens secure access to their medical data online
- Foster international standards and interoperability
- Enable cloud computing in Europe

At the same time, this new edition also includes the COCIR ten recommendations on eHealth, outlines the benefits of eHealth, and provides recent figures on the eHealth market in Europe as well as an updated glossary of terms.

COCIR remains very active in all related EU projects linked to eHealth and is bringing additional key elements specifically on cloud computing and interoperability to share the COCIR competencies on these two strategic matters.

Nicole Denjoy

COCIR Secretary General

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COCIR VISION ON eHEALTH

PART 1
COCIR VISION ON eHEALTH 1

COCIR TEN RECOMMENDATIONS ON eHEALTH

While the potential benefits eHealth could bring are enormous, a number of barriers hinder the introduction of health ICT and eHealth solutions, or prevent from achieving optimal benefits. By clarifying the position of COCIR and its members supplying health ICT solutions and services, COCIR wishes to open dialogue with policy and decision makers, and users around 10 key recommendations, and call them for action.

COCIR CALLS FOR ACTIONS AND DIALOGUE ALONG TEN RECOMMENDATIONS:

1. **DEFINE A COHERENT VISION OF eHEALTH** at European, national and regional levels, and set long-term political goals able to deliver this vision.

2. **OVERCOME eHEALTH GOVERNANCE FRAGMENTATION** at all levels by stimulating 'outcomes thinking' and developing sustained investment planning and innovative business/procurement models supporting the new governance model.

3. **DEVELOP INNOVATIVE BUSINESS AND COMPREHENSIVE REIMBURSEMENT MODELS** to introduce financial accountability across the complete care cycle (prevention to care delivery to rehabilitation to home care), through eHealth technology and re-engineered process/workflow.

4. **BUILD TRUST AMONG ALL STAKEHOLDERS**, including the care professionals about eHealth technology, documenting benefits and understanding technology effects through evidence-based analysis.

5. **SUPPORT CITIZEN/PATIENT EMPOWERMENT** in line with developments for more customisation and personalised services.

6. **FOSTER INTERNATIONAL STANDARDS AND PROFILES FOR eHEALTH INTEROPERABILITY** and leverage self-declaration of interoperability performance based on conformance testing processes.

7. **ACHIEVE LEGAL CERTAINTY** and a framework to support cross-stakeholder and cross-border care services and address citizen's data privacy and security requirements in a coordinated manner across the European Union.

8. **ENABLE THE CREATION OF A LEADING AND COMPETITIVE eHEALTH MARKET** across Europe and removing administrative, financial, legal and technical barriers between EU Member States.

9. **STRENGTHEN THE POSITION OF THE EUROPEAN INDUSTRY INTERNATIONALLY** as an exporter of eHealth cutting-edge tools, skills and knowledge.

10. **STIMULATE INNOVATION AND RESEARCH AND DEVELOPMENT** and coordinate better research efforts at the crossroads of social, health, ICT and life science aspects.

BENEFITS OF eHEALTH

The benefits of eHealth are widely recognised. The European Council Conclusions[1] on 'Safe and Efficient Healthcare through eHealth' (December 2009) recognise "the importance of eHealth as a tool to improve quality and patient safety, to modernise national healthcare systems, to increase their effectiveness and make them better adapted to meet the individual needs of patients, health professionals and the challenges of an ageing society".

Below is a non-exhaustive list of the recognised benefits of eHealth.

1. FACILITATE ACCESS TO HEALTHCARE

eHealth can help deliver care to people located in remote places and who do not have access to a hospital, for example through a tele-consultation.

2. IMPROVE QUALITY OF CARE

eHealth can help improve the quality of care by providing easier, safer and faster access to patient data, thereby allowing the healthcare professional to access the right data at the right time and make an informed-based diagnosis.

3. IMPROVE QUALITY OF LIFE OF PATIENTS

eHealth in general and telemedicine in particular can help improve the quality of life of patients by, for example, monitoring the condition of the patient at distance at home, rather than in a hospital. This is particularly relevant for elderly, chronically ill persons and people living in remote regions.

4. IMPROVE PATIENT SAFETY

The availability of information on the patient – such as his medical history, past diseases and interventions, allergies, reaction to medications – in an electronic health record (EHR) allows healthcare professionals to deliver a treatment tailored to the needs of the patient and thereby reduce risks of complications, adverse drug reactions etc.

5. SAVE TIME FOR HEALTHCARE PROFESSIONALS AND RESPOND TO THE SHORTAGE OF QUALIFIED STAFF

Adequate eHealth tools such as electronic health records allow healthcare professionals to access information on the patient faster and thereby avoid losing time compiling information from different location/sources. By allowing healthcare professionals to save time, eHealth tools also address the issue of shortage of healthcare professionals. With the increase of chronic diseases and the ageing population, healthcare professionals will be required to monitor more patients. eHealth tools can help them work more efficiently, by storing patient information in a single location, taking medical decisions better and faster with the support of decision support systems.

6. SAVE COSTS

eHealth can help reduce costs (clinical and administrative costs) by, for example, avoiding the duplication of medical examinations and unnecessary visits to the general practitioners / hospitals.

1 European Council Conclusions « Safe and efficient healthcare through eHealth » (December 2009)

7. MODERNISE AND IMPROVE EFFICIENCY OF HEALTHCARE DELIVERY

Integrating eHealth in healthcare delivery brings a degree of sophistication to healthcare systems by allowing a faster flow of information and helping transform healthcare systems, from a fragmented approach (prevention, primary care, treatment, rehabilitation) to a seamless continuum of care where all these levels are closely interlinked.

8. IMPROVE AND SECURE TRANSFER OF PATIENT INFORMATION

Where patient data used to be stored on a hand-written piece of paper handled by nurses, doctors and administrative staff, it is now stored on a centralised electronic file, protected with adequate identification and authentication processes.

9. REDUCE CARBON FOOTPRINT OF HEALTHCARE

By using information technologies, eHealth allows the move from paper-based to electronic files. eHealth also reduces the need for travel for patients, healthcare professionals and other actors resulting in lower CO2 emissions.

10. CONTRIBUTES TO THE COMPETITIVENESS OF THE EU ECONOMY

eHealth is the fastest growing health sector in Europe and contributes to the creation of jobs and to the innovation capacity of the European economy, as recognised by the EU2020 strategy.

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ADVANCING HEALTHCARE DELIVERY WITH CLOUD COMPUTING

PART 2
ADVANCING HEALTHCARE DELIVERY WITH CLOUD COMPUTING

2

COCIR industry offers solutions that support the safe, fast and seamless transfer of medical data to support quality healthcare for the benefit of patients and medical professionals.

COCIR believes the cloud has a huge potential to modernise healthcare delivery, increases efficiency and reduces costs by pooling resources. COCIR therefore welcomes the Commission's initiative to leverage cloud computing to deliver the EU 2020 strategy for smart, sustainable and inclusive growth, and appreciates the opportunity to contribute to the debate as technology thought leaders. However, significant barriers need to be lifted before the cloud can realise its full potential in the healthcare domain.

This section aims to define the cloud, explains how it can be used in healthcare, and sheds light on on-going debates on security, privacy, regulatory trends and interoperability challenges. Hereafter, are eight recommendations to unleash the potential of cloud computing in healthcare.

COCIR EIGHT RECOMMENDATIONS FOR THE EU's CLOUD COMPUTING STRATEGY

1. Use public procurement to support the adoption and deployment of cloud solutions in healthcare
2. Do not delay investments
3. Accelerate digitalisation and provide online access to patient records
4. Adopt a legal framework that allows the flow of health data and accommodates the specific needs of the cloud business community
5. Foster standards and interoperability to support innovation
6. Balance regulation
7. Build IT skills among healthcare professionals
8. Streamline innovation in all policies and foster a cloud-friendly environment
   - Support SMEs' innovation capacity
   - Increase broadband coverage in Europe
   - Support research in high priority areas
   - Provide legal guidance to the cloud business community

DETAILED BRIEFING

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

WHAT IS A PUBLIC CLOUD?

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.

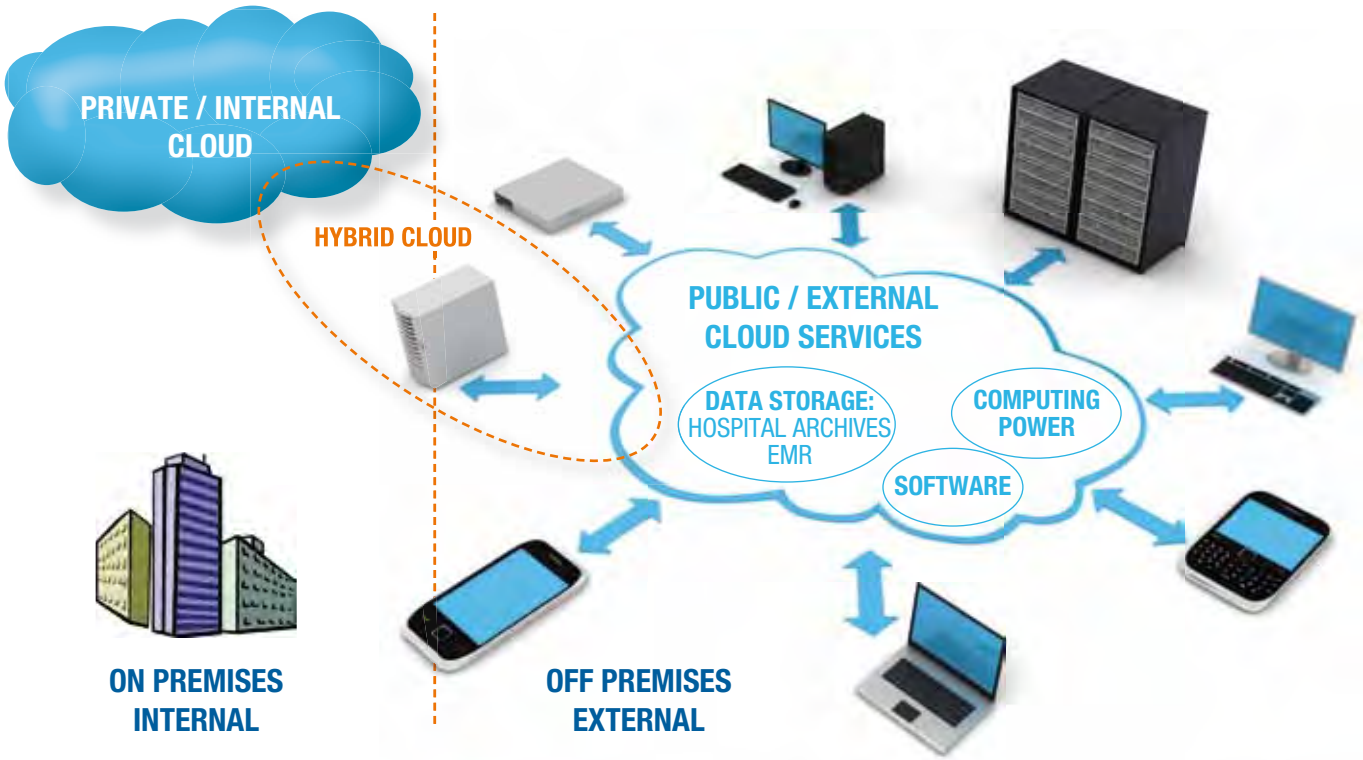
WHAT IS A PRIVATE CLOUD?

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.

WHAT IS A HYBRID 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.

FIG.1 CLOUD COMPUTING IN HEALTHCARE



EXAMPLES OF CLOUD APPLICATIONS

Although considered a recent technology, cloud computing has been with us since the mid-90s.

Hotmail is an example where data was stored and interacted with through a device. **iTunes** is another example where the internet became a new business model allowing the music industry to radically cut back its need for factories, land, materials and, more importantly, costs. This last example also demonstrates how an industry became more efficient thanks to cloud computing. Access to music became instant and ubiquitous, opportunities for the industry to collaborate increased, "green" initiatives became more effectively supported and geographical markets were bridged at an accelerated pace.

Cloud computing offers similar benefits for the health industry, driving down costs, making administrative processes leaner and more efficient, reducing the time needed for patients to interact with health workers and providing increased access for patients to their health records. The cloud model also offers benefits specific to the health industry. It will allow healthcare companies, researchers and healthcare workers to share expertise, advance research through online collaboration and visualise, through geographic mapping, where problems are located, evaluate trends and health risks, and identify regions or municipalities not receiving satisfactory care.

WHY DO WE NEED THE CLOUD IN HEALTHCARE?

Cloud solutions can help us address certain societal challenges more efficiently and address the current lack of sustainability in healthcare systems.

RISING HEALTHCARE EXPENDITURE AND UNSUSTAINABLE HEALTHCARE SYSTEMS

Health spending continues to rise faster than economic growth in most OECD countries. Health spending reached 9.5% of GDP on average in 2009, up from 6.6% in 1980[2].

RISE OF CHRONIC DISEASES

Chronic diseases cost around 75% of healthcare budgets and account for 85% of premature deaths in Europe[3].

MEDICATION ERRORS

Over 5 million outpatient prescription errors could be avoided yearly through the use of electronically transferred prescriptions[4].

MEDICAL ERRORS DUE TO POOR COMMUNICATION[5]

Poor communication is the causal factor in over 60% of medical errors .

2 OECD Health at a Glance 2011 http://www.oecd.org/document/38/0,3746,en_21571361_44315115_48289894_1_1_1_1,00.html

3 http://www.healthcareeuropa.com/articles/janvanemelen

4 http://www.se2009.eu/polopoly_fs/1.8227!menu/standard/file/eHealth%20for%20a%20Healthier%20Europe.pdf

5 Joint Commission on Accreditation of Healthcare Organisations http://www.pathology.med.umich.edu/intra/AP%20Updates/ErrorsCommunicationEdit_MurphyCHEST2010.pdf

EXAMPLES OF FUTURE CLOUD COMPUTING HEALTHCARE SCENARIOS IN THE NEXT FIVE YEARS

- A German woman who lives in Berlin has been sent to a two-week conference in the United States. During the stay, her taxi has been hit by an oncoming car. She is rendered unconscious and needs immediate treatment including a blood infusion and several drugs. The doctor quickly scans a tag of one of her electronic devices (phone, tablet, watch etc). The tag connects the doctor to an online database available in the cloud that identifies the patient and instantly retrieves relevant information on her blood type and allergies to medication. Luckily a drug the hospital planned to use was detected and stopped as it could have killed her.
- A national disaster or healthcare epidemic occurs in Central Europe. The disaster relief team uses cloud services from outside the impacted area to quickly provision and make a healthcare information system securely available over public networks. This provides healthcare protocols and information to the professionals on the ground treating the impacted population. In addition, the existing healthcare systems use the elasticity of cloud services to rapidly increase capacity to deal with the additional load of users and data.
- A hospital in France struggles to process and store an increasing number of medical images in-house within the limits of its IT budget. The hospital contracts with cloud service providers to outsource the processing and storage of medical images. Although the images may be stored beyond French borders, they are accessible at all times, from all locations, with no delay, at reduced operating cost for the hospital.

BENEFITS OF CLOUD COMPUTING IN HEALTHCARE

1. CUT COSTS AND INCREASE EFFICIENCY

The use of information and communication technologies in healthcare is increasing dramatically; this means that keeping in-house systems up-to-date is both expensive and time consuming. Cloud computing can lower overall costs, increase access, and provide scalability and elasticity to the demand for health services. Cloud computing optimises server utilisation and drives down energy consumption by up to 30%[6]. This can lead to cost savings of up to 60% compared to traditional non cloud-based solutions[7].

EXAMPLE:

- *When embracing the cloud, the Swedish Red Cross was able to save 20% on their IT operating costs and increase collaboration and communications reliability, while freeing up to 25% of people's time to focus on more strategic tasks, better supporting the core mission of the organisation[8].*

2. HEALTH RECORDS AS A SERVICE: IMPROVE RELATIONSHIP AND CASE MANAGEMENT

The ability to provide end-to-end case management, rapid access to information for patients as well as members of the medical team and the extended circle of care stakeholders, is empowering citizens and patients to take responsibility for their health.

6 http://newsroom.accenture.com/article_display.cfm?article_id=5089

7 http://www.microsoft.eu/cloud-computing/case-studies/hospital-uses-cloud-computing-to-improve-patient-care-and-reduce-costs.aspx

8 http://blogs.technet.com/b/whymicrosoft/archive/2011/03/10/swedish-red-cross-saves-costs-with-microsoft-online-services.aspx

EXAMPLES:

- *The Socialist Mutualities in Belgium implemented a Case Management project to provide members with access to their personal health records, streamline internal administration processes by using a portal, improving complaint management, publishing vital information and managing the lifecycle of care and cure. The system has been adopted by 4,000 users covering 2.9 million members. It has provided a reduction in the range of 12-15% of previous administrative costs.*
- *The implementation of Patient Relationship Management for children with Type 1 diabetes at the University College London brought measurable results: 20% reduction in administration time and 68 new referrals to service in 2010 with no change in staff numbers. PRM enables the engagement of all care stakeholders around active and expert patients. In this case, 100% of patient children's schools put Medical Management Plans in place and as a result 70% of school children had 0.3% reduction in HbA1c following school study days.*
- *With just 16 weeks to develop a solution, the implementation of Patient Relationship Management at Guy's and St Thomas' Hospital, London, resulted in a reduction of referral time from 13 to 3 minutes, a reduction in development time\cost of 60% and a predicted annual saving of €590,000.*

3. ACCELERATE BUSINESS INTELLIGENCE AND DATA VISUALISATION

Health organisations need accurate, timely information to address escalating costs, ever-changing regulations, increased patients' and citizens' mobility and escalating demand for medical services in an ageing population.

Digitising patient information generates valuable knowledge, offering the baseline for generating efficiencies, providing better insights to support more informed decision making processes.

EXAMPLES:

- *In Germany, Eye on Health[9] stores and manages large amounts of data from 400 hospitals across the country. It brings together an updated and growing pool of demographic and clinical data, lists of physicians, and infrastructure availability data to help patients locate clinics and examine service portfolios. Payers can analyse market environments and plan future services. Due to easy visualisation techniques, health providers can identify efficiencies and opportunities for better services.*
- *The Danish eHealth portal[10] supports 92% of all General Practitioners with online access for all 78 hospitals and 330 independent laboratories. Citizens can access information about all hospitals through the internet and receive 81% of prescriptions electronically (around 1 million per month).*

4. CLOUD ALLOWS ENHANCED SECURITY SAFEGUARDS

Information security is possibly the biggest concern for using the cloud in healthcare: cloud computing providers hold massive amounts of customer data. Release of this data can be prejudicial to citizens.

Highly publicised data breaches have created disproportionate fears about security in the cloud. In fact the cloud's economies of scale and flexibility are both a friend and a foe from a security point of view[11]. The massive concentration of resources and data presents more attractive target to attackers, but cloud-based defenses can be more robust, scalable and cost-effective. Cloud operators can allocate more IT resources quickly if necessary, to avoid server break down or data loss in case of fire in one data center and ensure disaster recovery and continuity in line with business expectations.

In addition, many security measures are cheaper when implemented on a large scale so the same amount of investment in security buys better protection. This includes varieties of defensive measures such as filtering, patch management, hardening of virtual machine instances etc. Looking into the healthcare domain, it is worth noting that specialised cloud systems providers can provide better security than hospitals' IT services which may be less specialised and less well equipped.

9 http://www.eye-on-health.com

10 https://www.sundhed.dk

11 ENISA, Security and resilience in Governmental Clouds, January 2011

5. ACCESS TO IT EXPERTISE ON THE CLOUD

A wealth of expert and specialised IT services (e.g. data storage, data processing, software as a service, computing power, etc) can be accessed on the cloud. This enables healthcare providers to benefit from a large pool of expertise when and where needed, instead of developing ressources in-house.

REGULATING THE CLOUD

Cloud computing is an emerging field which is evolving faster than regulation. There are an increasing number of voices calling for regulation of the use of cloud in healthcare with a view to protecting patients' safety and privacy. How to regulate the cloud remains a headache for most regulators. The European Commission is currently assessing the risks posed by telemedicine and trying to determine whether telemedicine providers should be covered by the Medical Devices Directive (MDD). In the United States, the FDA is consulting to assess ways of regulating health-related mobile apps. To date, the cloud is not regulated as such but is nevertheless covered by certain EU regulations:

The Data Protection Directive (1995/46/EC) adopted in 1995 limits the flow of personal data across borders and to non-EEA countries. In addition, some national laws limit the exchange of data between different healthcare providers, medical disciplines, administrative bodies, regions etc. This limits the addressable market for cloud service providers and increases costs associated with compliance to various legal frameworks.

The 'cloud' is not a medical device under the Medical Devices Directive (2007/47/EC), but medical software proposed as a service on the cloud (SaaS) are covered by the Directive if intended to be used for medical purpose.[12] In this case, the cloud service provider needs to ensure the software or services comply with the essential requirements of safety and performance[13]. However, in a cloud scenario the software provider may be located outside the EU territory, and may not be aware of the Medical Device Directive while placing its services on the EU market through the cloud. In these conditions, enforcement and post market surveillance need to be radically transformed and updated to be effective.

STANDARDS AND DATA PORTABILITY IN THE CLOUD

Data portability and interoperability are essential for the cloud to be fair, open and competitive. The lack of interoperability and data portability standards result in customer lock-in and limited freedom of choice for customers. However, COCIR feels that regulation of interoperability and data portability at this early stage of the cloud is premature.

Instead cloud service providers and users would benefit from standards that:

- Ensure applications developed for one cloud service provider will work for another
- Enable the movement of a datastore (database or otherwise) from one cloud service provider to another. This should cover both protocols for data format and standard export provision within service agreements
- Support governance, functionality, topology and protocols for federated operations or cloud-to-cloud interoperability
- Enable reversibility, moving data from cloud to non-cloud environments

12 Medical Device Directive, art. 2- definition of a medical device

13 See EC guidelines on the qualification and classification of medical software

There are a number of market-led initiatives and forums in which stakeholders jointly explore the cloud standards landscape, including the various use cases and scenarios for which those standards (and others) are intended, and evaluate the need for interoperability and portability of existing and emerging cloud function. One such forum is the Cloud Standards Customer Council (cloud-council.org), where over 150 members have joined in such an exploration.

Other similar endeavours are being conducted by NIST, JTC 1 (SC38 SGCC), and other communities. Ideally, new standardisation initiatives will be influenced by the findings of such communities.

COCIR EIGHT RECOMMENDATIONS TO ADVANCE HEALTHCARE DELIVERY WITH CLOUD COMPUTING

The EU's cloud computing strategy should address the needs of end-users, protect the rights of citizens and allow for the development of a strong industry in this sector in Europe.

1. USE PUBLIC PROCUREMENT TO SUPPORT THE ADOPTION AND DEPLOYMENT OF CLOUD SOLUTIONS IN HEALTHCARE

Innovative technologies such as eHealth, telemedicine and cloud computing present many demonstrable benefits. However, their adoption and implementation can be lengthy for a variety of reasons: they require a change of habits, an initial roll-out cost and time to put new processes in place. Public authorities have a role to play in supporting this initial effort.

COCIR RECOMMENDS *that public authorities demonstrate how to support and invest in cost-saving, efficiency-gaining and scalable IT solutions such as the cloud, possibly through smart public procurement policies. The European Commission could support an informal working group composed of national authorities to share information and best practice in order to support governments' adoption of cloud computing infrastructures and services.*

2. DO NOT DELAY INVESTMENTS

In difficult economic times, minds are easily distracted by short-term fixes. Cutting costs today often means postponing those fundamental investments and opportunities to secure better care, provide broader access and faster delivery. Collectively, we must dare to provide better care through innovation and efficiencies with real impact, given the amount of money available in the system.

COCIR RECOMMENDS *that public authorities do not delay necessary investments to modernise healthcare through ICTs*

3. ACCELERATE DIGITALISATION AND PROVIDE ONLINE ACCESS TO PATIENTS RECORDS

If properly implemented, today's technologies would allow a full digitalisation of medical notes, medical records, laboratory results, prescription, etc. They would also enable patients' access to their medical records online, as called for by the Digital Agenda.

However too many medical processes are still handwritten (e.g. prescriptions, general practitioners' patient records). Laboratory results are often transmitted by postal mail, and scanned by the medical professional, instead of being transmitted

electronically.
COCIR calls for full digitalisation in healthcare. The banking sector achieved full digitalisation years ago and the same could be achieved in healthcare. The 2015 timeline proposed by the Digital Agenda to give Europeans secure, online access to their medical records is a reasonable timeline, provided the right change mechanisms are put in place. This requires political will and change management.

COCIR RECOMMENDS *that the European Commission fund targeted communications campaigns on successful regional or national eHealth/cloud implementation plans, to promote the feasibility and benefits of full digitalisation in healthcare.*

4. ADOPT A LEGAL FRAMEWORK THAT ALLOWS THE FLOW OF HEALTH DATA AND ACCOMMODATES THE SPECIFIC NEEDS OF THE CLOUD BUSINESS COMMUNITY

Trust in cloud is essential if there is to be significant take-up and adoption by end-users, especially when medical data may be stored, accessed and processed in remote locations. A clear legal framework on privacy and data protection and adapted governance models are needed to build trust.

COCIR welcomes the Commission's proposal for a regulation on data protection in Europe. It should create a single set of rules across the EU and facilitate the adoption of Binding Corporate Rules within companies to allow data flows beyond EU borders.

COCIR RECOMMENDS *that EU Member States, European Parliament and the European Commission:*

- *Harmonise the legal framework (adopt a regulation)*
- *Limit delegated acts that create legal uncertainty*
- *Clarify cooperation and responsibilities between data controller and data processor. Data processors intervene under the authority of data controllers. The responsibility should therefore lie on the controller*
- *Review new obligations for cloud service providers that do not seem realistic (e.g. delay to notify data breaches, impact assessment documentation, documentation for the data subject on the processing of his personal data, unrealistic fines, etc)*
- *The European Commission should engage with the international community to ensure that access to sensitive data e.g. health data is regulated effectively and takes into account patient interests in the safe and effective provision of healthcare, as well as data privacy concerns*

5. FOSTER STANDARDS AND INTEROPERABILITY TO SUPPORT INNOVATION

In this early stage of cloud computing, regulating interoperability, data portability and reversibility is premature.

COCIR RECOMMENDS *that the European Commission strive to achieve cloud computing interoperability by supporting the development of market-driven standards – or the use of existing standards – while avoiding strict technology mandates. The appropriate role for the Commission would be to call for global, open interfaces and standards, wherever and whenever they are available:*

- *Standards should be market driven to respond to the needs of users and manufacturers*
- *Standards should be global not local/European to support the global and scalable nature of the cloud*
- *New standards should only be created where they add real value and are aimed at solving real problems. In many cases, problems can be solved using existing standards*
- *Testing procedures to evaluate interoperability should be considered, for example through voluntary certification programmes*

Industry commits to ensuring that market-led initiatives respond to real needs and to participating in efforts to demonstrate interoperable solutions – even as work on relevant standards proceeds – and invites the European Commission and governments to join and monitor such initiatives.

Last but not least, COCIR recommends establishing a mechanism to track specific issues arising from interoperability within public sector operations, and puts forward requirements to the relevant standards bodies. A Commission-led exercise collating such requirements would be a significant step forward in ensuring public sector requirements that may otherwise not be brought forward to technical standards committees. At the same time, this would highlight public sector demand, ensure that public sector requirements are met by the market and prevent unnecessary fragmentation of standards between sectors.

6. BALANCE REGULATION

COCIR welcomes the debate on the potential risks to patients' safety and privacy by emerging technologies such as cloud computing and commits to engaging fully in the discussion. COCIR believes a balanced and concerted approach is needed to ensure that regulation serves both citizens and markets.

A thorough assessment of the risks, costs and benefits should be undertaken. Regulation should intervene when the risks outweigh the benefits brought by the cloud.

Any regulation should be technology-neutral, future-proof and should accelerate the adoption of enabling technologies and allow the internal digital market to exist:

- Allow the flow of data between countries and beyond the EU borders
- Harmonise the internal digital market rules

COCIR RECOMMENDS, *where possible, self-regulation and self-certification, two approaches that have proved effective in many domains.*

7. BUILD IT SKILLS AMONG HEALTHCARE PROFESSIONALS

Health professionals do not always have the necessary ICT skills to use eHealth solutions or leverage the benefits of cloud computing solutions. This can result in a significant barrier to the adoption of innovative technologies in the medical field.

COCIR RECOMMENDS *that public authorities use EU Cohesion Funds and Social Funds to:*

- *Embed ICT skills in the medical curriculum, including some training on existing healthcare IT solutions (RIS/PACS, CPOE, ADT, cloud computing)*
- *Provide adequate training to healthcare professionals and organise change management in healthcare institutions*
- *Develop certification schemes for ICT proficient healthcare professionals*
- *Launch new pilots to introduce the use of innovative solutions in healthcare organisations*

COCIR RECOMMENDS *that the eHealth Governance Initiative make eSkills a priority.*

8. FOSTER A CLOUD-FRIENDLY ENVIRONMENT

A global approach to eHealth innovation will bring real benefits to both citizens and the economy in Europe. Cloud computing is a tool that can accelerate innovation, cost-efficiency and modernisation in healthcare, but its development is hindered by an environment that is not adapted to its fast-moving and flexible nature.

A number of measures would help to create an environment more conducive to innovation in healthcare:

- **SUPPORT SMEs:** Industrial policies and EU Structural and Regional Funds need to be better aimed to address the needs of SMEs innovating in eHealth, with faster 'go-to market' support, internationalisation, industrialisation and funds for the deployment of innovative solutions and services on a wider scale.
- **INCREASE BROADBAND COVERAGE IN EUROPE:** COCIR recommends that the European Commission uses Cohesion Funds to support the provision of ultra-fast internet within a reasonable timeframe, by 2015, as proposed by the Digital Agenda.
- **SUPPORT RESEARCH IN HIGH PRIORITY AREAS:** COCIR encourages the European Commission to fund further research in a number of priority areas such as server resilience, data continuity, elasticity and portability, security (including authentication, authorisation, encryption), shared servers, cloud services infrastructure and multi-composition and data centre energy consumption.
- **PROVIDE LEGAL GUIDANCE AND CLARITY TO THE CLOUD BUSINESS COMMUNITY:** Under the current legal framework, the conditions for operating legally within the EU and beyond the EU are unclear. The cloud business community would benefit from legal guidance, in particular on contractual aspects and service level agreements.
  Companies, especially those operating in the B2B space, need flexibility to negotiate terms and conditions with their clients and customers. Service Level Agreements (SLAs) would be especially useful for Small and Medium Enterprises (SMEs) and new entrants into cloud services.

COCIR RECOMMENDS *that the European Commission encourages the organisation of industry-led sector standards and works in collaboration among sectors. SLAs should be voluntary and industry-led.*

COCIR INTRODUCTION TO INTEROPERABILITY

IMPROVING THE SEAMLESS FLOW OF INFORMATION BETWEEN MEDICAL DISCIPLINES, HEALTH SYSTEMS, REGIONS AND COUNTRIES, FOR BETTER HEALTHCARE

3

PART 3
COCIR INTRODUCTION TO INTEROPERABILITY 3

eHealth – or health ICTs – has the potential to revolutionise healthcare, but the lack of interoperability hinders the promised benefits of eHealth, as well as the development of the market. The European Commission has recognised the challenge and is developing efforts to achieve eHealth interoperability by the end of 2015. COCIR welcomes the initiative and aims to contribute to that process with this position paper.

This section sets out the 'interoperability challenge' in healthcare from the vendors' perspective and proposes a series of measures to move towards eHealth interoperability by 2015. It is accompanied by an Industry Guide to eHealth Interoperability (refer to section 4), aimed at national, regional and local eHealth project leaders

COCIR FIVE RECOMMENDATIONS TO ACHIEVE eHEALTH INTEROPERABILITY BY END-2015

1. Focus on priority use cases: patient summary, ePrescription, 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
4. Educate national, regional and local eHealth project leaders on interoperability
5. Address semantic interoperability step by step

DETAILED BRIEFING

WHAT IS 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[14].

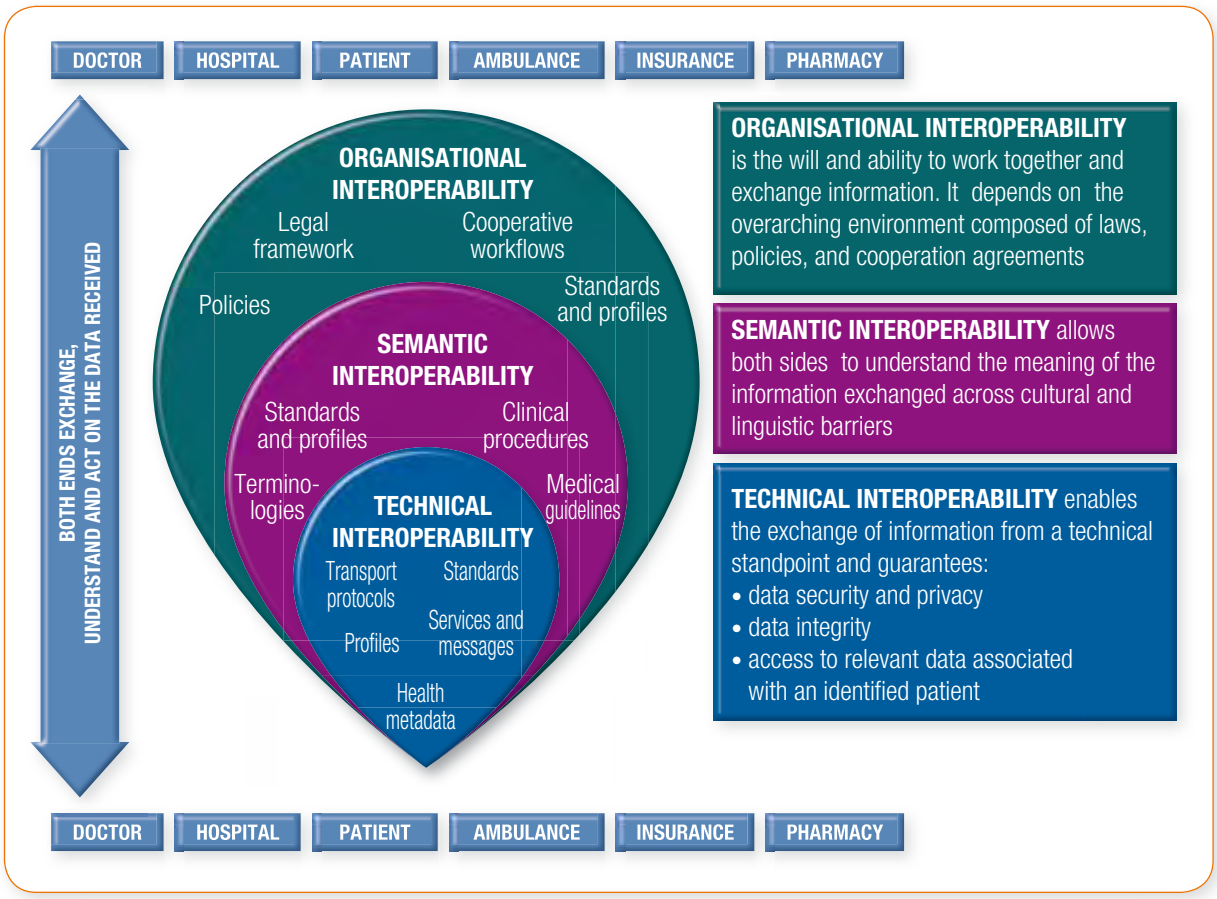
THERE ARE THREE LEVELS OF INTEROPERABILITY:

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 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.

FIG.2 THREE LEVELS OF INTEROPERABILITY



14 European Commission, Consultation for an eHealth Action Plan, Glossary of terms
http://ec.europa.eu/information_society/activities/health/glossary_of_terms

EXAMPLE OF AN INTEROPERABLE ELECTRONIC PRESCRIPTION[15]

Mr Smith lives in Germany. He suffers from a chronic condition and takes medication regularly. When on holiday in Spain, Mr Smith realises he has left his medication at home. He does not remember the name of the medication, nor the components. He goes to a local pharmacy to seek advice. The local pharmacist connects to an ePrescription portal and is able to identify Mr Smith. The pharmacist finds the ePrescription related to Mr Smith's condition and although he does not speak German, he can understand the medication Mr Smith requires.

Although this specific medication is not available in Spain, the pharmacist is able to read the medication's active components and recommended dosage and suggest a similar medication to Mr Smith.

This scenario is possible only if the three layers of interoperability are in place:

ORGANISATIONAL: Health authorities in Spain and Germany put in place an interoperable ePrescription system between their countries and finance its development. The data protection laws allow the transfer of patient information between the various entities involved and between the two countries.

SEMANTIC: The system was able to translate the information contained in the prescription into information understandable by a Spanish pharmacist, by using internationally-recognised terminologies and codes.

TECHNICAL: The IT systems used by the German medical professional, the ePrescription platform and Spanish pharmacist are able to exchange data by relying on an agreed interoperability specification.

BENEFITS OF eHEALTH INTEROPERABILITY

1. 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:

- Acceleration of communication
- Reduction in data (re-)capture errors
- Reduction in duplicate efforts
- Reduction in workload

2. BETTER DIAGNOSIS, BETTER QUALITY OF TREATMENT, BETTER PATIENT SAFETY

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

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

15 For more detailed description, view the epSOS eprescription page and related video: http://www.epsos.eu/epsos-services/eprescription.html

3. IMPROVED COST EFFICIENCY

Interoperability between systems reduces administrative costs through a reduction in manual data capture, duplicate efforts and in the workload for both clinical and administrative staff (as described in point 1 above).

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

4. INCREASED CONSUMER CHOICE AND ENHANCED COMPETITION

Interoperability between vendors and systems enhances the choice for consumers. If the solutions are interoperable, customers have more choice in buying what they need, while 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.

5. MORE END TO END SECURITY FOR DATA TRANSFERS

The exchange of patient data electronically requires privacy risks (identity theft, intrusion, alteration of data, and unauthorised access) to be addressed. Truly end to end interoperable IT systems with embedded privacy design reduce these risks through compatible security models, identification and authentication processes, data encryption etc.

OBSTACLES TO eHEALTH INTEROPERABILITY

While plug and play is a reality in other innovative domains (e.g. GSM or USB), interoperability is still a headache in healthcare. Healthcare is a large eco-system consisting of complex human organisations. Linking the different actors, IT systems and institutions across different medical disciplines, cultures, languages, jurisdictions and administrative entities is a challenge. The following paragraphs outline the main obstacles to interoperability in healthcare.

1. INCONSISTENT USE OF EXISTING ICT STANDARDS

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

However finding the standard that fits a desired purpose can be difficult.

In addition the 'not invented here' syndrome and the desire to keep control over the technical specifications of one's IT system motivate many organisations to develop new proprietary custom solutions or adopt an isolated approach (e.g. a hospital electronic medical record developed in-house) rather than using existing standards. This culture creates unnecessary 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 that, in turn, deliver higher quality services while reducing costs.

2. EXTRA WORK FOR MEDICAL PROFESSIONALS

- **ENTERING STRUCTURED DATA IN THE SYSTEM:** The interoperability of data implies that medical professionals enter 'structured data' into the system. This requires additional time and complexity for the medical professional, who may not see the immediate benefi t for his personal use and is not rewarded for the extra effort.
- **CHOOSING THE RIGHT TERMINOLOGY FROM THE PROPOSED LIST:** Medical disciplines have different jargons which are refl ected in the use, vocabulary and structure of electronic clinical information. This requires an extensive mapping of existing vocabulary as information transitions across organisations and disciplines. This implies that the medical professional faces long vocabulary lists in scroll-down menus before he fi nds the term that best refl ects the information he want to communicate.

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.

3. FRAGMENTATION OF HEALTHCARE SYSTEMS ACROSS EUROPE

Europe is a fragmented field when it comes to healthcare: each country and even some regions have their own healthcare systems. Different national or regional health systems will use different laws, procedures, policies and terminologies. This further increases the complexity of communicating effectively and efficiently.

4. DIFFICULTY TO CAPTURE THE COMPLEXITY OF HEALTHCARE IN IT SYSTEMS

While a medical professional can easily put his thoughts on paper, it is more diffi cult to report them electronically. Several questions arise: what should be communicated to the other end? Should the medical professional report the basic clinical facts (e.g. colour of skin, blood glucose level, blood pressure etc), the symptoms, the cause chains and the holistic view on a patient or different levels of aggregated, consolidated health data? Should the medical professional include their reasoning to justify the diagnosis and clinical order?

Knowing which information will be necessary 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.

5. ENSURE PATIENTS' PRIVACY AND PROTECTION OF PATIENTS' DATA

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

- Healthcare providers may be reluctant to share patients' data because of the increased risk of a privacy breach and because of the complex rules around the processing, sharing and storage of health data.
- It means embedding additional measures and procedures at 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 ROLE OF STANDARDS TO ENABLE INTEROPERABILITY

STANDARDS PROVIDE COMMON AND RECOGNISABLE DATA FORMATS AND STRUCTURES TO ENABLE DATA SHARING

Using standards for data sharing is the first step of interoperability. Standards allow a common definition of data and data exchange formats which is essential to enable interoperability both at the technical and semantic level.

Using widely recognised standards e.g. European and international standards, helps create a wider network of consistent communications as integrated healthcare delivery continues to grow geographically. Two examples of widely-recognised standards:

- **HL7**[16] is a very successful standard for the intra-hospital communication of clinical, administrative and financial data. These message standards support the active management of key workflows within and across providers through data exchange, e.g. registration of patients, placement of orders and reporting of results.
- **SNOMED CT:** Another successful and internationally-accepted standard is SNOMED CT[17], (Systematized Nomenclature of Medicine - Clinical Terms). It is a systematically organised computer-processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, microorganisms, substances etc. It provides a consistent way to index, store, retrieve and aggregate clinical data across specialties and sites of care. It also helps organise the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research.

STANDARDS SHOULD HAVE THE FOLLOWING QUALITIES:

- **TRANSPARENT:** Standards should be easily available for all stakeholders
- **RELEVANT AND USER-DRIVEN:** Standards should be based on real-world business use cases
- **APPROPRIATE:** Standards should provide reasoning behind the choice of implementation technologies
- **EFFECTIVE:** Standards should reuse existing work (e.g. IHE[18] profiles) as well as global and ISO/IEC Base Standards as much as possible
- **THOROUGH:** Standards should address eHealth interoperability in relation to application functionality, data integrity and availability, patients' privacy and safety and performance aspects
- **COLLABORATIVE:** Standard setting procedures should maintain a cooperative spirit
- **TESTING AND VALIDATION:** Standards should have clear criteria that can be tested in order to validate interoperability

FROM INTERNATIONAL STANDARDS TO INTEROPERABILITY SPECIFICATIONS OF LOCAL eHEALTH PROJECTS

One size does not fit all: national or local extensions of international standards are needed to fit the exact needs and purposes of the local eHealth programme. Specific local or regional interoperability specifications - also called implementation guides - are needed to describe for each use cases (e.g. ePrescription) what messages and vocabulary should be used, what is minimally required etc. The development process of such implementation guides should be clear and open to ensure the engagement of all stakeholders.

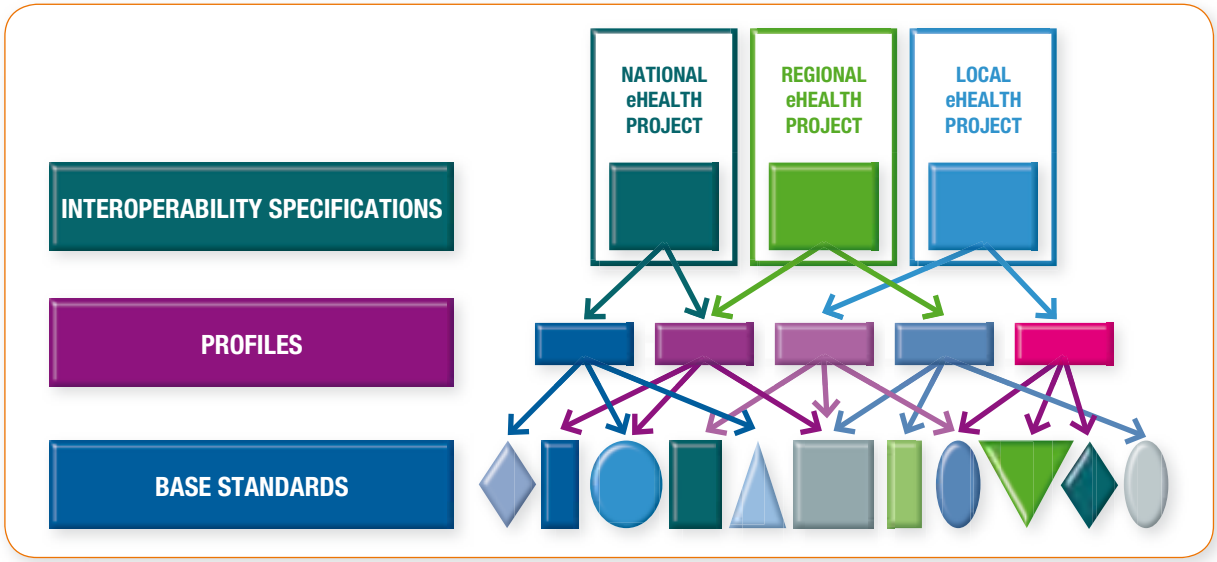
Authors of interoperability specifications should be aware of local needs, local medical settings and should consult standardisation experts to identify relevant standards. Interoperability specifications guides are based on Integration Profiles, which are themselves based on standards as described in figure 3.

16 HL7 family of standards www.hl7.org

17 http://www.ihtsdo.org/snomed-ct

18 Integrating the Healthcare Enterprise, http://www.ihe.net/

FIG.3 FROM INTERNATIONAL STANDARDS TO INTEROPERABILITY SPECIFICATIONS



Profiles developed by IHE* and the Continua Health Alliance[19] meet the quality criteria described in the previous paragraph and are considered the best practice in the field:

- **IHE** is a user-vendor initiative that engages numerous stakeholders, including care providers, medical and IT professionals, professional associations and vendors to advance interoperability in eHealth. IHE develops integration profiles based on existing standards following 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 requires the testing of these systems to verify that complex computer coding delivers the data.
  3. IHE promotes wider awareness and use of these methods for establishing local/regional interoperability specifications.

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

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

COCIR FIVE RECOMMENDATIONS TO ACHIEVE eHEALTH INTEROPERABILITY BY END-2015

1. FOCUS ON PRIORITY USE CASES

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

COCIR RECOMMENDS *focusing on a first step in seven use cases**:*

1. *Patient summary (at national and cross-border level)*
2. *ePrescription (at national and cross-border level)*

19 http://www.continuaalliance.org/index.html
* See IHE website for more information: http://www.ihenet.com/
** See definitions in annex

3. *Medical imaging information sharing (cross-regional)*
4. *Hospital diagnosis imaging workfl ow (intra-hospital)*
5. *Laboratory information sharing (cross-regional)*
6. *Hospital laboratory workflow (intra-hospital)*
7. *Telemonitoring*

Our observations on eHealth projects around the world and their benefit analysis show that these are the most frequently prioritised use cases. They have been identified and adopted by the EU eHealth Interoperability Mandate 403, and have been successfully implemented and profiles associated with these use cases are mature. They should constitute 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 should be to develop a legal environment that allows the exchange of information across care settings and across borders. In addition, the healthcare sector would benefit from a harmonised data protection legal framework in the EU, where a single and uniform set of rules applies to all 27 Member States. COCIR welcomes the Commission's proposal for a Regulation in the field and calls for caution on the use of delegated acts to specify conditions and requirements for data sharing which may result in legal uncertainty[20].

3. FOSTER USE OF INTERNATIONAL STANDARDS AND MARKET FOCUSED PROFILES

COCIR welcomes the Digital Agenda objective to foster EU-wide standards[21] and encourages the Commission to go one step further towards international standards and profiles.

COCIR RECOMMENDS THAT:

- *Clear requirements for internationally-recognised standards and profiles for interoperability be included in public procurement policies. This applies to EU funds as well (Horizon 2020, Structural Funds, Connecting Europe Facility etc).*
- *Standards be user-driven and market-focused for more effectiveness. All too often, the standard development process is slow and many published standards do not fulfill the requirements of the market players and users, as technology and users' needs have moved along while the standard was being developed. The effective use and adoption of standards needs to rely on a user-driven and market-focused profiling and implementation processes to deliver ready-to-implement specifications that result in successful interoperability (e.g. IHE profiling process).*
- *A process be established to recognise a specific list of profiles applicable to Europe driven by the requirements of the prioritised use cases (see below)*[22]
- *Standards and profi les be available on FRAND (fair, reasonable and non-discriminatory) terms to facilitate adoption*

4. EDUCATE LOCAL LEVEL ON eHEALTH INTEROPERABILITY

COCIR welcomes the progress that has been made in improving interoperability, through the work of various platforms such as Continua and IHE Europe. COCIR also welcomes the EU-driven initiatives in the field, such as the Recommendation for the Interoperability of EHR, the ISA study on an eHealth Interoperability Framework, the eHealth Governance Initiative, the establishment of the eHealth Network[23] etc. Unfortunately, local eHealth actors are not well-informed on these initiatives and tend to build local eHealth programmes in isolation.

20 See COCIR Position paper on the privacy and protection of health data for more information. http://www.cocir.org/uploads/documents/-63-cocir_position_paper_on_data_protection_14_nov_2011.pdf
21 Digital Agenda: Foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015, through stakeholder dialogue, page 30.
22 In line with HITCH and M403 phase I recommendations.
23 The 'eHealth high level network' was established by the Directive in Patient's Rights in cross-border healthcare to create a formal coordination mechanism on eHealth between Member States.

COCIR RECOMMENDS THAT *the European Commission funds awareness-raising and education campaigns to transfer the knowledge gathered at European level to the national, regional and local level, for better use and adoption of interoperable solutions.*
COCIR has developed a, Industry Guide to eHealth Interoperability in Six Steps (refer to section 4), aimed national, regional and local eHealth project leaders, to support this goal.

5. ADDRESS SEMANTIC INTEROPERABILITY STEP BY STEP

Semantic interoperability is a complex field that requires the marriage of health informatics with clinical practice. Semantic interoperability cannot be solved in one shot. On the contrary, it is so complex that it requires a step by step approach.

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

COCIR RECOMMENDS THAT *the selection of a small number of widely-needed terminologies as a starting point, for example a common approach across Europe for problems, procedures, diagnoses, vital signs (e.g. blood pressure) and medications. A standard common clinical data structure is also needed to embed the coded data in a semantically meaningful system (e.g. CDA - Clinical Document Architecture).*

INDUSTRY GUIDE TO eHEALTH INTEROPERABILITY IN SIX STEPS

4

PART 4
INDUSTRY GUIDE TO eHEALTH INTEROPERABILITY IN SIX STEPS

4

A number of interesting initiatives are striving to make eHealth interoperability a reality at European or international level[24]. They are delivering good processes that can be implemented in practice. However these best practices are not well-known and are not always implemented at local and national level.

COCIR has developed this guide to bring this knowledge where it really matters, to the local level where eHealth projects are defined, developed, financed and implemented.

This guide to eHealth interoperability in six steps is aimed at national, regional and local eHealth project leaders.

SIX STEPS TO ACHIEVE eHEALTH INTEROPERABILITY

1. IDENTIFY USE CASES
Describe the proposed eHealth functionality in medical terms (e.g. ePrescription), avoiding any technical language.

2. SELECT PROFILES AND STANDARDS
Identify existing profiles and standards that may support the eHealth use case.

3. REFINE DATA CONTENT
Design the messages and data structure required in the eHealth use case.

4. WRITE THE INTEROPERABILITY SPECIFICATIONS
Assemble the components and scenarios, building on existing standards.

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

6. EDUCATE END-USERS ON INTEROPERABILITY
Develop communication materials to familiarise end-users on the benefits and impact of interoperability.

24 e.g. HITCH project, IHE, European eHealth Interoperability Framework, Continua Health Alliance, etc

DETAILED BRIEFING

THE INTEROPERABILITY LANDSCAPE

ONE SIZE DOES NOT FIT ALL: MODELLING AND IMPLEMENTATION GUIDELINES

A perfect interoperability scenario in healthcare delivery assumes an environment in which systems can seamlessly exchange the information while preserving the meaning of data, render the information in localised forms, comply with data protection laws and offer sustainability of business and process models.

In that scenario, the ideal standard(s) for a health information exchange solution would unambiguously define all fields, values and structures representing the data, support the transfer based on a variety of protocols, be universally-applicable and enable plug-and-play interaction of systems.

However, since healthcare delivery is always subject to local processes, laws, language and cultural behaviours, one immediately understands that there is no 'one size fits all' approach. Hospitals' Chief Information Officers (CIOs) and health executives will not achieve interoperability just by selecting all the 'best of breed standards' for health data exchange. Interoperability cannot be bought. It is a process rather than merchandise with a price tag on it.

An important step in achieving interoperability is indeed the selection of best of breed standards that will secure value for the money and the sustainability of projects. The most advanced health information exchange standards take the 'use case approach', which means trying to formally map real-life scenarios to the data exchange models and transactions. This process, although proven to be the best approach possible, results in rather broad and abstract specifications, which cannot be directly implemented in any scenario. For CIOs and health executives, this means that the selection of best of breed standards is just the first step of many to be taken.

Experience shows that implementation guidelines, localisation of standards and profiling of existing models requires hard work, a good understanding of both local processes and standards to be adopted, educated project teams and finally collaboration with the medical community. This is where unfortunately many attempts at achieving the interoperability of systems fall apart and people start questioning their decisions and investments.

There are however many good examples of how to deal with these issues. This document will outline some of the best practice in the interoperability landscape. It will not only set out some of the widely-accepted standards and profiling techniques in health information exchange, but will also serve as the cookbook on how to go about further steps in a journey towards successful and interoperable eHealth solution deployment.

EXISTING STANDARD AND PROFILING ORGANISATIONS

There are several standards organisations where healthcare stakeholders define a use case model based on which an implementation guide is developed. These implementation guides profile existing standards and put them together to serve the use case at stake, e.g. ePrescription. Therefore, it is possible to distinguish between core standards organisations such as HL7 and DICOM and standards profiling organisations such as IHE and Continua who profile core standards.

Another dimension worth noting is electronic health record (EHR) standards, both functional and informational standards. EHR information standards have been developed by CEN/ISO with extensions made by openEHR. In projects which aim to sustain longitudinal, cross-institutional and patient-centric EHRs, it is important to assess the contribution of each standards organisation to the emergence of such EHRs.

Listing all standardisation and profile platforms here would be too lengthy and complex. Here we propose an introduction to two recognised standard profiling organisations:

- **IHE** brings together stakeholders to define a use case model from which an implementation guide is developed (IHE Profiles, see http://www.ihe.net/About/index.cfm). These profiles may not be fully constrained (meaning fully defined), in which case local implementations would apply the final constraints based on local agreements.

  IHE International also organises cross-manufacturer testing events (Connectathon) where vendors can demonstrate their ability to implement a profile 'who?'. Vendors can then publish so-called IHE Integration Statements for their products to assert that their product passed the Connectathon test for a defined profile 'which product?'

  IHE conformance criteria and the cross-manufacturer testing events create a higher level of confidence in the market. More and more eHealth project leaders require IHE Profiles conformance when purchasing IT applications for hospitals and other care settings.

  National and regional users can then configure the IHE Profile to their needs by writing an 'Implementation Specification' which constrains the profile, defines clinical vocabularies and enforces security measures like signature, encryption, login etc.

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

A COOKBOOK TO eHEALTH IMPLEMENTATION IN SIX STEPS

This section describes how to write an implementation guide, so that different IT systems cooperate, reuse existing standards and reflect the local needs of their setting.

The overall objectives as well as the long-term goals need to be assessed in order to design the best suitable implementation.

Among the most important criteria for this assessment are the following:

1. IDENTIFY USE CASES

The eHealth project leader should identify the use cases required e.g. ePrescription. Use cases describe an application scenario from a user's perspective e.g. the medical professional, typically as a list of events and actions. A basic flow of events (interactions, messages) should be drafted for the initial steps of the project and alternative flows can be extended later as the project matures.

A few questions can help in drafting these use cases, depending on the focus of the national/local strategy, e.g. focus on health, costs, risks, etc and similar strategic questions. These questions are:

- To what extent does the integrated data need to be longitudinal: covering a short episode or up to the lifetime of the individual patient?
- In projects where a personal health record is the main target, how important is the expected synergism with providers of EHR systems?

Once the use cases are identified, the following steps should be undertaken for each use case:

- **AGREE ON A MEDICAL GLOSSARY** so that all stakeholders, e.g. users and implementers, have a common understanding of the concepts used by the eHealth implementation.
- **WRITE SCENARIOS THAT CONSTITUTE THE USE CASE** but do not specify technology at this level
- **IDENTIFY THE ACTORS** participating in the scenarios. These are the IT systems and devices supporting the patients and the health professionals, hospitals, special medical departments, payers, authorities (statistics, regulation, public health etc).
- **DESIGN PRIVACY:** compare use case needs against data protection laws and introduce required controls and enforcement (non-technical).
- **IDENTIFY INTERNAL VARIATIONS** e.g. regional changes in languages, currency or changes across user communities to understand constraints.

The resulting use case should describe the interactions and participants in the proposed eHealth application.

2. SELECT PROFILES AND STANDARDS

The eHealth project leader should consider the legacy system and select the existing standards e.g. IHE or Continua Profiles that can be built on the legacy. In the different IHE 'medical' domains, there are specifications called 'IHE Integration Profiles' which describe special IHE Profiles that can be tailored to any practical application in the respective medical field. In IHE, there are profiles for general use in eHealth in PCC (the patient care coordination domain) and ITI (the IT infrastructure domain). eHealth project leaders should start in the PCC domain and then go to the infrastructure level (ITI). Profiles need to be selected in five categories: patient identification, servicing for information exchange, security/privacy, data content and terminology value set.

3. REFINE DATA CONTENT

Based on the use cases selected and available profiles, certain data in records and messages must be customised to specific projects. The following must be considered:

- Scope of the health data to be integrated, e.g. whether it is summative in nature or more granular data such as discrete clinical documents, patient charts, medical imaging etc.
- The proportion of narrative versus structured data: to what extent does the integrated data need to be machine-processable as well as human readable? In particular, the goals should be assessed in light of possible decision support applications.
- To what degree does the integrated data needs to reach out to all sources of data?
- How much control is given to the patient?

Each local project has its own vocabulary e.g. concept terms for diseases, treatments, medical disciplines. Identifiers for documents, doctors, patients, hospital/department, payers, authorities or their respective IT systems are also local and need to be documented. The defined data may be the placeholder for a term from a clinical vocabulary or an object identifier: in this step administrative vocabularies, clinical terminologies, ontologies or identifier types are also selected.

4. WRITE THE INTEROPERABILITY TECHNICAL SPECIFICATIONS

The eHealth project leader should write the interoperability specifications: assemble the use case implementation for communication, storage and access control as designed in Step 1 using the profiles (e.g. IHE Profile) from Step 2 and insert selected useful Base Standards plus vocabularies and identifiers for data as defined in Step 3. The result is a technical specification that enables the implementation of the use case across the various IT systems and devices. The vendors that have already implemented the support for the profiles specified in the interoperability specifications have only to make minor efforts to customise their products to become interoperable in the context of the project. This is a major time and cost gain as well as reducing risk for the project.

5. ORGANISE TESTING

An important step is the interoperability testing. The eHealth project leader should organise a cross-implementer connectivity testing to provide empirical evidence of the application's integration capacity and functionality to the project stakeholders. This is an important means to assess implementation knowledge among developers and establish confidence among users.

The following steps are recommended[25]:

1. Leverage available profile-level testing to drive potential vendors' compliance with the project selected profile. This has been identified by the HITCH project[26] as a necessary foundation at the European level and the IHE Connectathon is a good example of testing. The testing should be open to all implementers and vendors through a public call for participation. The results should be made publicly available to enable eHealth project leaders to identify the most mature products and vendors.
2. As a second step, the project should establish a test environment based on its interoperability specification, as this builds upon the profile level testing (Step 1) by focusing on the project specific extensions. Several organisations provide guidance, tools or even operate such tests in support of a specific project (e.g. IHE services for a projectathon).
3. As a third step, the project should establish a virtual test environment to support the testing of the actual system installed by the healthcare providers in their organisation. This verifies that the healthcare provider is ready to connect to the eHealth project, including its security and privacy requirements.

The testing should include at each step a mix of conformance testing and system-to-system testing and should rely on robust test data.

This process relates to interoperability testing only. Other tests related to software characteristics such as performance, ease of use, reliability etc need to be addressed separately by the project and its vendors.

6. EDUCATE USERS ON INTEROPERABILITY

The eHealth project leader should develop communications materials to familiarise the end-users e.g. patient, doctor, pharmacist, payers, administrators, etc on the benefits and impact of health information exchange.

25 The three-step testing process has been validated by the epSOS project. It is also consistent with the recommendations of the EU-funded HITCH project.

26 http://epractice.eu/en/cases/hitch and http://www.hitch-project.eu

ANNEX A
BASE STANDARDS FOR eHEALTH

Some organisations develop standards that are not specific to healthcare but are used in ICT infrastructure for eHealth, supporting security and performance aspects.

ETSI is a recognised European Standardization Organization (ESO) which makes its standards available for its members and for implementers. ETSI standards are available on a FRAND basis to all interested implementers. The FRAND regime gives flexibility to both the implementer and the patent owner in negotiating the terms and conditions of the license, to the extent that these terms are fair, reasonable and non-discriminatory. They can be based on the sales of ICT products implementing the standard, or on other factors. This type of up-front business model - together with methods and tools for strict conformity testing - may be the reason for the success of the ETSI specifications (e.g. GSM, LTE).

MITA[27] is a branch of NEMA[28] and manages the development of DICOM[29], the most successful standard in medical imaging. DICOM specifications are available for free access and commercial implementation to MITA members (FRAND licensing). Small implementing entities are not forced into MITA membership. The DICOM standard is released each year. MITA hosts working groups for many topics to innovate and extend the standard, while the basic format and database structure remains stable.

HL7 International[30] developed the Clinical Document Architecture (CDA) and continues to develop specific document types in collaboration with IHE. There are many common document types like discharge summaries, referral letters, operative notes, consultation or progress notes and more. These common types have been harmonised in a consolidated CDA package, where section and entry level templates are shared among the documents. A template is a set of constraints applied to the generic CDA specification .

There are document templates (types) as well as document section templates e.g. the medications section template. In addition to the common document types, there are special types, the most notable has been the Continuity of Care Document, representing a snapshot-in-time summary of the patient's health history for the purpose of care continuity and coordination. A similar document is being used in epSOS for the medical summaries service and is the result of constraining the CDA to the specific requirements of epSOS. Other important document types are the Diagnostic Imaging Report that could serve as a bridge between clinical information systems and medical imaging archives, as well as a Personal Healthcare Monitoring Report reaching out to the homecare devices world and the Healthcare Associated Infection Reports type.

The following organisations publish specifications available online. They are widely implemented in many different ICT products covering telecommunications systems, medical devices and operating systems. Interested stakeholders can contribute or comment on these specifications. Comment resolution is transparent and published.

- IETF - Internet Engineering Task Force
- OASIS - Advancing Open Standards for the Information Society
- UN/CEFACT - United Nations Centre for Trade Facilitation and Electronic Business
- W3C - World wide web consortium

27 http://www.medicalimaging.org
28 http://www.nema.org/prod/med
29 http://medical.nema.org
30 http://www.hl7.org

ANNEX B
EXISTING IHE PROFILES* AND CONTINUA IMPLEMENTATION GUIDELINES** FOR MOST COMMON USE CASES

To support the implementation of interoperable IT systems and devices enabling the deployment of the priority use cases proposed in this document, the table below lists some of the main supporting profiles.

- The profiles listed in the middle column have been developed by IHE and Continua and are identified by the acronym used by the parent profiling organisation. IHE and Continua liaise actively to ensure their profiles can be easily combined to support the same business use case.
- The third column lists some of the key Base Standards upon which these profiles are based. An exhaustive list may be found in the reference section of these profile specifications accessible on the website listed below the table.

BUSINESS USE CASES	SUPPORTING PROFILES	KEY BASE STANDARDS IN PROFILES
PATIENT SUMMARY IN CROSS-BORDER	XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*, XPHR*	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA
PATIENT SUMMARY IN REGIONAL OR NATIONAL	PIX* OR PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*, XDS-MS* OR XPHR*	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA
ePRESCRIPTION AND eDISPENSATION IN CROSS-BORDER	XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*, PRE*, DIS*	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA
ePRESCRIPTION AND eDISPENSATION IN REGIONAL OR NATIONAL	PIX* OR PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*, XDS-MS* OR PRE*, DIS*	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA
LAB RESULTS IN REGIONAL OR NATIONAL	PIX* OR PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*, XD-LAB*	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA
MEDICAL IMAGING IN REGIONAL OR NATIONAL	PIX* OR PDQ*, XDS*, CT*, ATNA*, BPPC*, XUA*, XDS-I*	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA, DICOM
TELEMONITORING	PIX* OR PDQ*, XDS* OR XDR* OR XDM*, CT*, ATNA*, BPPC*, XUA*, HRN+, WAN+ OR DEC*/RTM*, LAN+ OR PAN+	HL7 V2 OR V3, OASIS EBRS, OASIS SAML, NTP, IETF, HL7 CDA, IEEE1073

* For IHE Profiles see:
- For an overview wiki.ihe.net/index.php?title=Profiles
- For complete specifications www.ihe.net/technical_frameworks

** For Continua Implementation Guidelines see:
http://www.continuaalliance.org/products/design-guidelines.html

5

MARKET INTELLIGENCE OVERVIEW

HOSPITAL's USE AND INVESTMENT PLANS FOR HEALTH ICTs

PART 5
MARKET INTELLIGENCE OVERVIEW

5

In 2011, COCIR launched the COCIR Market Intelligence Overview, which was published for the first time in the COCIR "eHealth Toolkit – May 2011". It provided figures on the 2008 health ICTs (information and communication technologies) market, along with a forecast for 2012. One year later, this second edition gives an overview of the availability and use of health ICTs in European hospitals in 2010, along with a forecast for 2015.

COCIR KEY FINDINGS

1. The European hospital health ICTs market totaled €2.5 billion in 2010 and is estimated to grow to €2.8 billion by 2015.
2. The level of equipment of European hospitals in health ICTs varies greatly between types of systems and between countries.
3. While hospitals are relatively well equipped with administrative information systems, they are insufficiently equipped with clinical information systems and show modest investment plans for these technologies which are crucial to improve healthcare delivery.

COCIR RECOMMENDATIONS

1. COLLECT EVIDENCE ON THE CLINICAL AND ECONOMIC BENEFITS OF HEALTH ICTs

Given the low adoption of health ICTs by medical professionals, healthcare providers and payers, it is urgent to encourage adoption by demonstrating the benefits of these technologies both in clinical and economic terms. The shortage of studies documenting the economic benefits of health ICTs, clinical information systems in particular, is a challenge. Industry encourages governments and payers to finance such studies and to look into existing evidence when considering investments in health ICTs.

2. BUILD IT SKILLS AMONG HEALTHCARE PROFESSIONALS

Even when health ICT solutions are available in hospitals, healthcare professionals are not always equipped with the right set of IT skills to use those solutions. This can be explained - amongst other things - by resistance to innovative information technologies and a lack of time to learn how to use these new tools. This should be addressed by embedding IT skills in the medical curriculum and by providing IT training to healthcare professionals, including healthcare managers.

3. INVEST IN CLINICAL INFORMATION SYSTEMS TO INCREASE EFFICIENCY OF HEALTHCARE DELIVERY

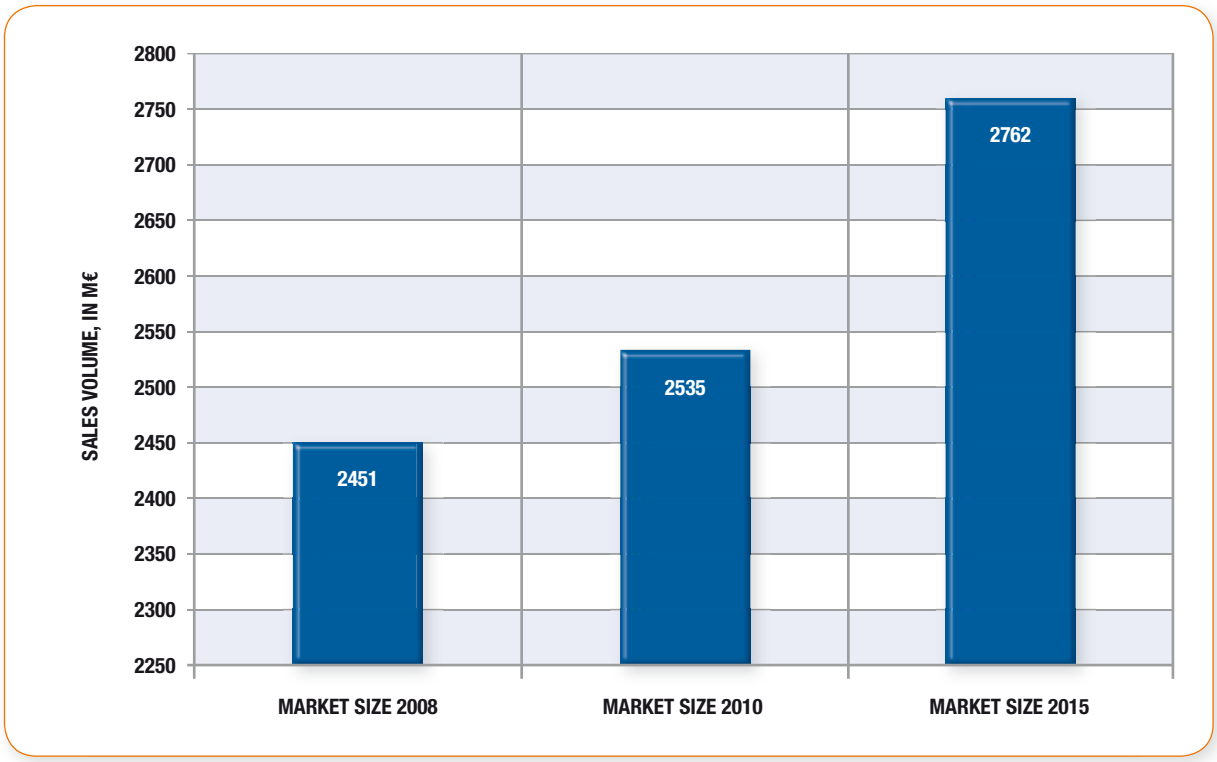
Clinical information systems are enabling tools: they increase the efficiency of healthcare delivery by supporting data transfer, workflow and decision-making. More investment in clinical information is needed to move today's healthcare delivery models to the next level of efficiency and quality. Industry calls for more investment in order to move to integrated, more efficient, safer and patient-centered healthcare systems.

HEALTH ICTs IN EUROPEAN HOSPITALS: GENERAL OVERVIEW OF THE MARKET (2008-2015)

A MARKET WORTH €2.5 BILLION IN 2010

The European hospital health ICTs market totaled €2.5 billion in 2010. Moving forward, COCIR anticipates this market to reach €2.7 billion by 2015. These figures cover ICT solutions used in hospitals in Western and Eastern Europe: administration information systems, clinical information systems, laboratory information systems and imaging information systems (in the field of radiology and cardiology).

GRAPH 1 HEALTH ICTs IN EUROPEAN HOSPITALS: MARKET'S EVOLUTION FROM 2008 TO 2015 (M€)



HEALTH ICTs: A VARIETY OF SYSTEMS SUPPORTING HOSPITALS' MULTIPLE DEPARTMENTS AND FUNCTIONS

Health ICTs offer five types of information systems serving different purposes in hospitals:

ADMINISTRATIVE INFORMATION SYSTEMS

Market size in 2010: 940 M€.
Estimated market size by 2015: 971 M€.
Availability: 90% of hospitals are equipped with administrative IS. The market is saturated and moving towards a replacement cycle.

CARDIOLOGY IT (CARDIOLOGY INFORMATION SYSTEMS AND CARDIOLOGY PACS)

Market size in 2010: 55 M€.
Estimated market size by 2015: 69 M€.
Availability: Cardiology IT is still limited, with 10 to 30% of hospitals equipped. COCIR expects this small market to develop in the short- to mid-term.

CLINICAL INFORMATION SYSTEMS

Market size in 2010: 787 M€.
Estimated market size by 2015: 936 M€.
Availability: The availability of clinical IS is uneven, both between countries and between systems. The growth of this market is expected to be limited in the coming years.

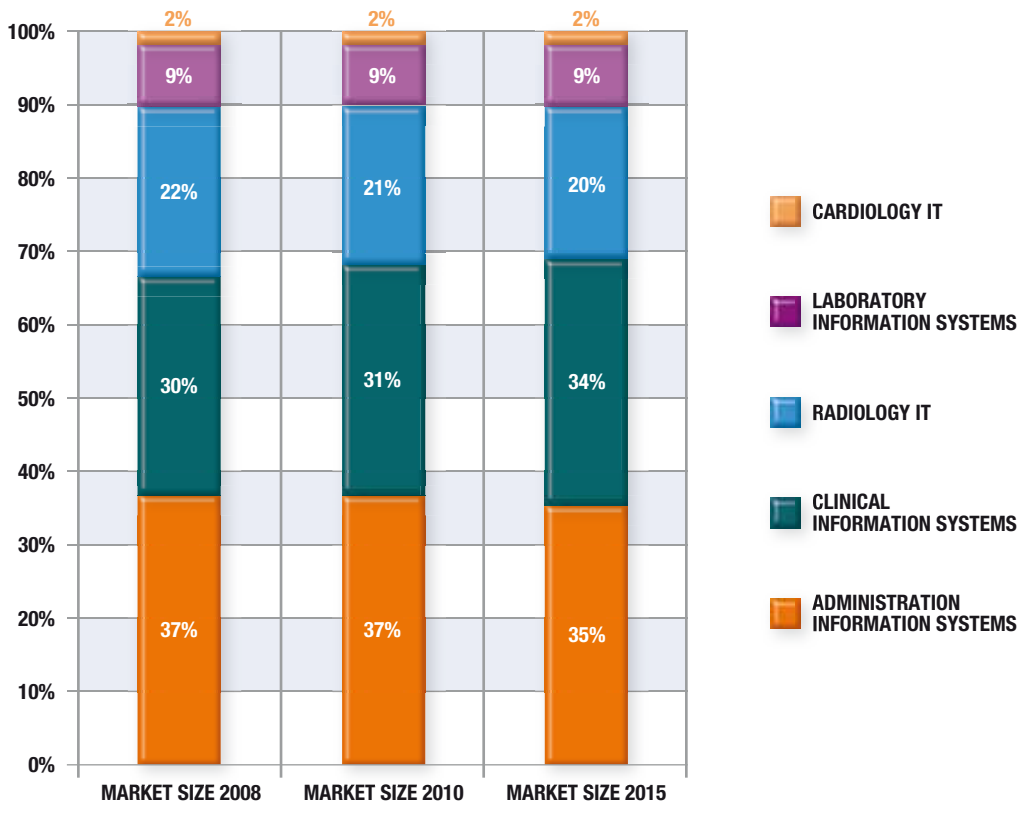
LABORATORY INFORMATION SYSTEMS

Market size in 2010: 220 M€.
Estimated market size by 2015: 242 M€.
Availability: 80 to 100% of hospitals are fully equipped. The market is saturated and moving towards a replacement cycle.

RADIOLOGY IT (RADIOLOGY INFORMATION SYSTEMS AND PACS)

Market size in 2010: 533 M€.
Estimated market size by 2015: 544 M€.
Availability: The availability of radiology IT varies from country to country. UK and German hospitals are well equipped (70-95%), while France lags behind with 30% of hospitals equipped. 5% growth is expected in France over the period 2010-2015, perhaps more if national and regional plans under the "France sans film" programme are confirmed.

GRAPH 2 HOSPITAL HEALTH ICTs MARKET PER MARKET SEGMENT IN 2008 AND 2010, AND PROJECTED FOR 2015



INVEST IN CLINICAL INFORMATION SYSTEMS TO INCREASE EFFICIENCY OF HEALTHCARE DELIVERY

WHAT ARE CLINICAL INFORMATION SYSTEMS?

Clinical information systems are integrated systems designed to support the clinical functions of a hospital across departments. They are complex systems composed of one or more software components (e.g. electronic patient record information systems, medical document management information systems, computerised physician order entry, etc.) 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, etc.)

WHY ARE CLINICAL INFORMATION SYSTEMS SO IMPORTANT FOR IMPROVING AND MODERNISING HEALTHCARE DELIVERY?

The use of clinical information systems increases the efficiency of healthcare delivery by:

- Archiving patient data in an automated manner
- Providing healthcare professionals and hospital departments with faster access to patient data
- Guiding healthcare professionals when making medical decisions

LIMITED AVAILABILITY OF CLINICAL INFORMATION SYSTEMS

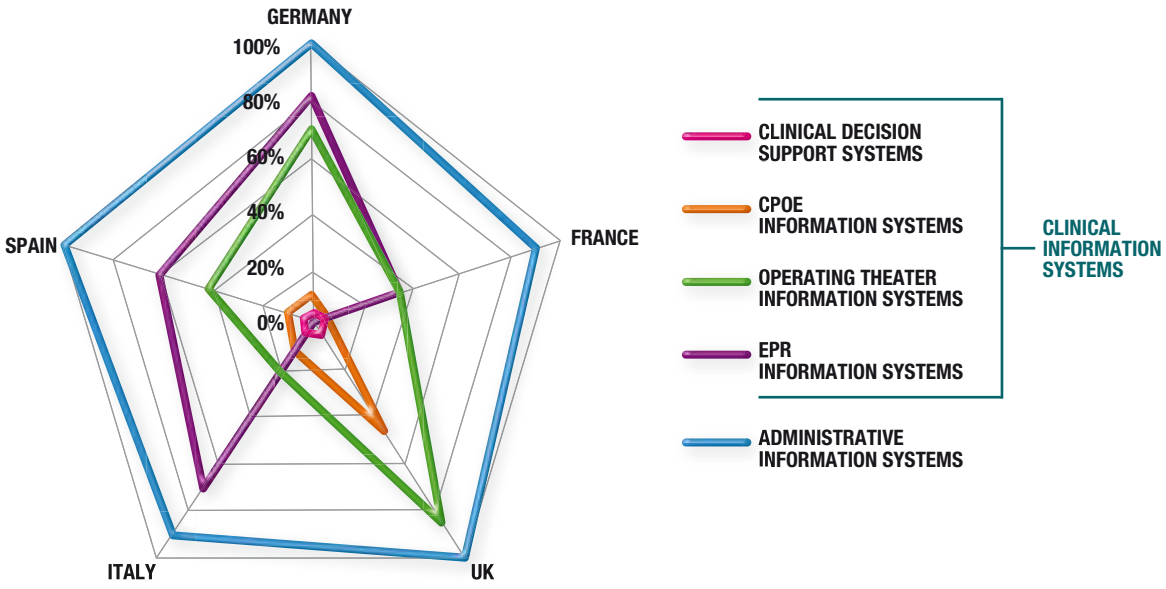
The availability of Clinical IS is uneven both at the application level and across countries, as reflected in the five largest European markets (see Graph 3).

COMPUTERISED PHYSICIAN ORDER ENTRY (CPOE) are extremely useful systems for the placement of clinical orders for patient services, medications, procedures, examinations, nursing care, diets, laboratory tests, etc. - with subsequent automated distribution of the clinical documentation in the relevant departments.
However, figures show that CPOE is not yet a reality in most hospitals, with up to just 10% of hospitals equipped - with the exception of the UK.

ELECTRONIC PATIENT RECORD INFORMATION SYSTEMS (EPR IS) present the benefit of grouping all information relative to a patient in a central, easily accessible location, allowing better cooperation between healthcare professionals, as well as diagnosis, treatment and follow-up. EPR IS can thus be considered the basis of a modern, efficient patient-centered healthcare system.
More than half of European hospitals are equipped, with the exception of France ranking behind with 35% and the UK with 5 to 10% of hospitals equipped. Even when available, wide clinical adoption remains a challenge.

CLINICAL DECISION SUPPORT SYSTEMS (CDSS) are designed to assist doctors and other healthcare professionals with decision-making by linking 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).
These systems are of great help to doctors in sorting information overload, and therefore deliver better and safer diagnosis, treatment and follow-up on the basis of most the relevant information only. Nevertheless, the figures demonstrate that CDSS are almost nonexistent in European hospitals (less than 1% of hospitals are equipped).

GRAPH 3 LEVEL OF EQUIPMENT OF HOSPITALS IN CLINICAL IS COMPARED TO ADMINISTRATIVE IS, IN FIVE EUROPEAN COUNTRIES



It is worth noting that the availability of clinical information systems is much lower than that of more conventional information systems such as administrative information systems (e.g. billing information systems or admission information systems), as reflected in Graph 3.

This reveals a lack of investment in recent, clinical oriented solutions (e.g. electronic patient record systems).

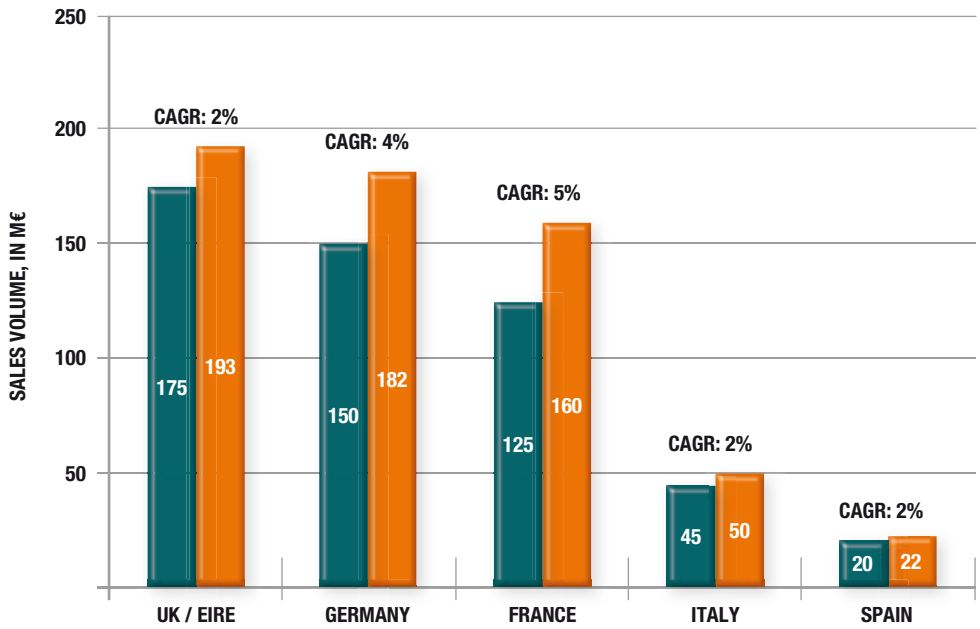
MORE INVESTMENT NEEDED IN CLINICAL INFORMATION SYSTEMS TO IMPROVE AND MODERNISE HEALTHCARE DELIVERY IN EUROPE

Despite the role that clinical information systems can play in improving the efficiency of healthcare delivery, investment in these systems has remained static over the past few years. Hospitals' total spending on clinical information systems progressed from 735 M€ in 2008 to 787 M€ in 2010. COCIR estimates that it will reach 936 M€ by 2015.

This translates into a modest 3.5% compound annual growth rate. None of the Western European countries show growth prospects over 5% (see Graph 4) when COCIR estimates double-digit growth (above 10%) would be required to significantly modernise healthcare delivery.

By comparison, the market for Electronic Patient Record (EPR) in the United States is expected to grow at an average compound annual growth rate of 18.1% between 2009 and 2015 , partially driven by federal initiatives to expand EPR adoption.

GRAPH 4 ESTIMATED SIZE OF THE CLINICAL IS MARKET IN 2010 AND ESTIMATED GROWTH FOR 2015 IN FIVE EUROPEAN COUNTRIES (M€)



COCIR believes that the current situation of the CIS market (limited availability, limited adoption by healthcare providers and modest investment) will not allow healthcare systems to deliver more patient safety, more efficiency and more patient-centered healthcare, all of which are necessary improvements in healthcare.

Real healthcare transformation cannot happen without scaling up the availability of information at the health professionals' level. Focus should be placed on in-depth institutional solutions to allow information cross-sharing and decision support at the point of care.

It is worth noting that the United States adopted an incentive programme in 2009 to support the adoption of health ICTs by the healthcare sector over a five-year period. The industry recommends that the European Commission and Member States closely monitor the impact of this stimulus plan for the eHealth market and eventually draw learnings which can be applied to the EU market.

COCIR METHODOLOGY

Since 2008, COCIR has been monitoring the availability, use and investment plans for health ICTs in European acute care hospitals.

The figures provided in this paper are based on a survey conducted among CIOs (Chief Information Officers) from acute care hospitals in Europe. CIOs were interviewed about the availability, use, replacement and investment plans for 41 types of information systems in their hospitals. The data collected through the survey has been analysed by COCIR members.

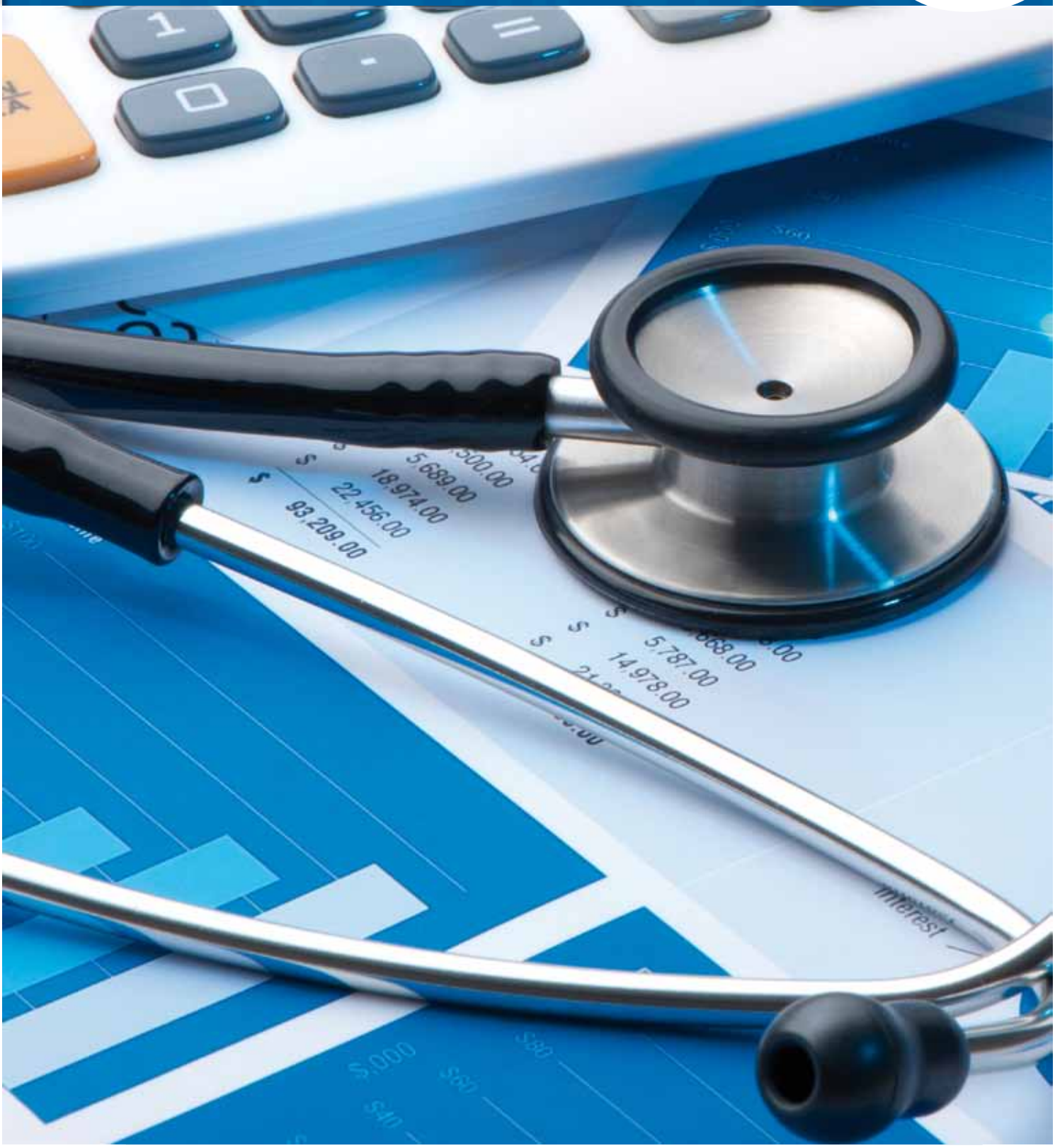
The methodology was tested through a pilot project in 2008. The ongoing research programme started in 2009, focusing on Western European countries and one emerging market, Poland.

DATA COLLECTION METHODOLOGY

- The data is collected by an external market research company (HAE) on the basis of interviews with hospital CIOs (Chief Information Officers).
- The interviews consist of online questionnaires and a follow-up telephone interview to ensure completeness and accuracy. The data is collected from acute care hospitals only.
- The questionnaire has been developed by COCIR in partnership with the market research company and is refined on a regular basis to reflect market evolution.
- The definitions for each of the 41 information solutions identified in the survey have been developed by COCIR members and are updated on a continuous basis. They are available in the COCIR eHealth Glossary of Terms.
- The research sample is randomly drawn from the total number of acute care hospitals in each country: it includes small, medium, large, public and private hospitals and represents a minimum of 16% of the total number of acute care hospitals in the country.

COCIR GLOSSARY OF TERMS

6



PART 6
COCIR GLOSSARY OF TERMS

6

INTRODUCTION: SEEKING CLARITY ON HEALTH ICTs

COCIR advocates the deployment of health ICTs as being crucial for improving healthcare in Europe. Before going any further, it is important to define health ICTs.
eHealth, healthcare IT, health ICTs, health informatics are synonymous. While eHealth is the term most commonly used, COCIR and organisations such as the OECD use preferably the term 'health ICTs'. Despite these semantic habits it is worth noting that these terms represent the same concept and refer to the application of information and communication technologies to deliver healthcare.

Health ICTs is a fast-evolving field, with many new ICT based solutions appearing on the market. It can be difficult to keep track with these developments, understand the purpose of each new solution and to put the right name on the right product. What is an Electronic Patient Record? What is the difference with Electronic Health Record? What is a PACS? What is a Decision Support System? What do we mean by Clinical Information Systems?

The lack of common understanding makes the dialogue between healthcare stakeholders difficult.
COCIR has developed a set of definitions to bring clarity to the field. The COCIR Glossary of Terms provides the following definitions:

- a general definition for health ICTs / eHealth (part 1)
- definitions for terms commonly used in relation to eHealth (part 2)
- definitions used in relation to interoperability (part 3)
- technical definitions for systems used in hospitals : clinical information systems (part 4) and hospital information systems (part 5)
- definitions for telemedicine (part 6)

The COCIR glossary of terms aims to be a founding block for a better dialogue and cooperation between stakeholders to improve healthcare delivery in Europe and worldwide. It is a living document which will be updated on a regular basis.

PART 1: DEFINING HEALTH ICTs / eHEALTH

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, institution-to-institution transmission of data, or peer-to-peer communications between patients and/or health professionals; it can also include health information networks, electronic health records, telemedicine services, and personal wearable and portable communicable systems for assisting prevention, diagnosis, treatment, health monitoring and lifestyle management.

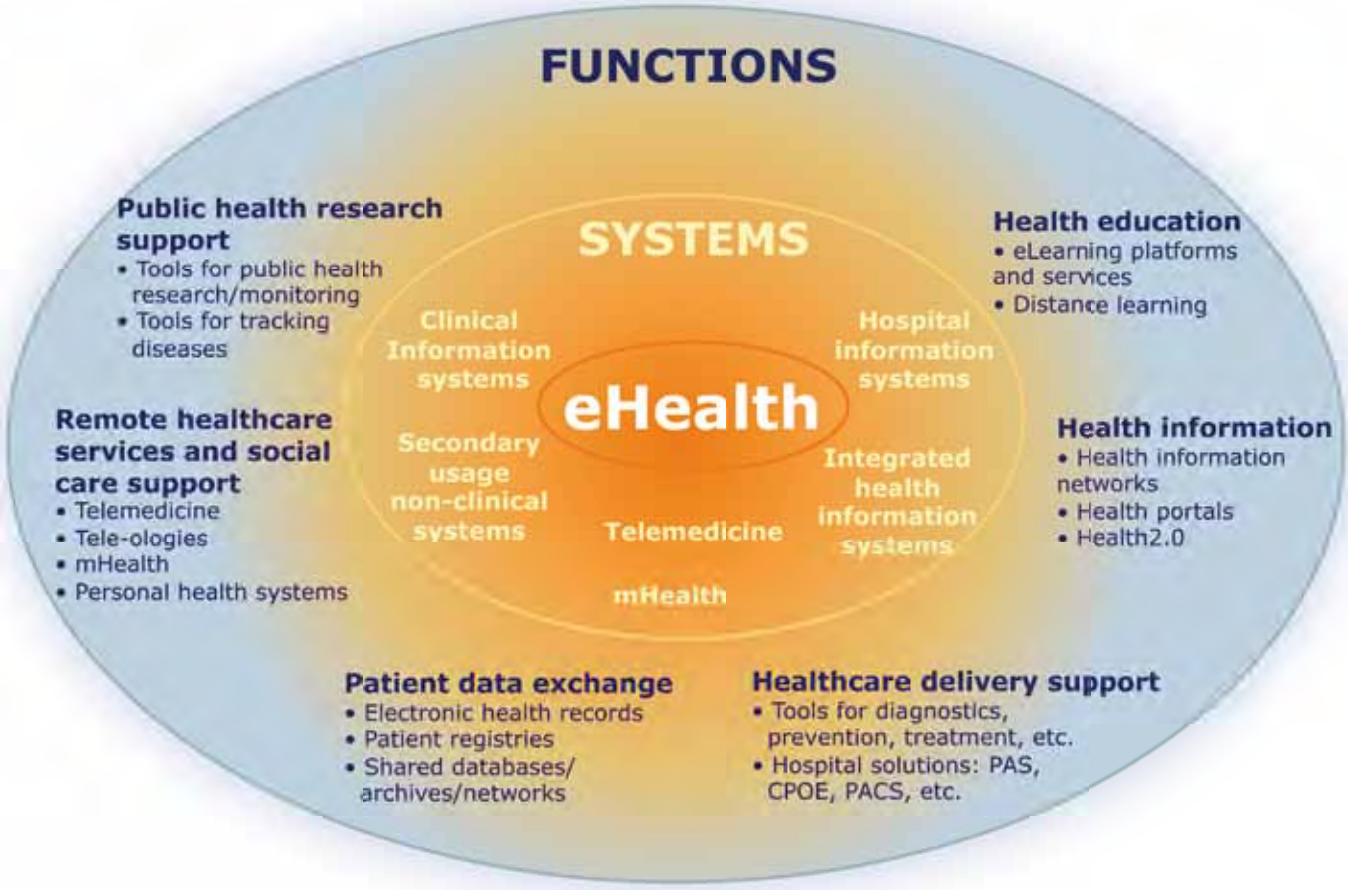
eHEALTH COMPRISES SIX TYPES OF SYSTEMS:

1. Hospital information systems (HIS)
2. Clinical information systems (CIS)
3. Telemedicine
4. mHealth
5. Integrated health information networks
6. Secondary-usage non-clinical systems

EHEALTH COVERS THE FOLLOWING SIX FUNCTIONS:

1. Data exchange
2. Health education
3. Health information
4. Public health research support
5. Healthcare delivery support
6. Remote healthcare services social care support

eHealth is the application of ICTs across the whole range of functions that affect the health sector.
It encompasses five types of systems and covers various functions:



PART 2: GENERAL eHEALTH RELATED DEFINITIONS

ACTIVE AND HEALTHY AGEING

Active and healthy ageing is the process of optimizing 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 well being. '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 home[31].

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 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?".

CARE COORDINATION

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 health care services. Organising care involves the marshalling of personnel and other 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[32].

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.

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

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

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.
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.

OECD definition: http://www.oecd.org/dataoecd/39/47/43933771.pdf
USA National Institute of Standards and Technology definition: http://csrc.nist.gov/publications/nistpubs/800-145/SP800-145.pdf

COMPOUND ANNUAL GROWTH RATE

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

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 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, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.

There are different types of electronic health 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 in a healthcare institution, 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.

COCIR proposes a more detailed and technical definition describing EPR/EMR systems, as used in hospitals, in part 3 of this glossary.

EMPOWERMENT

A process through which people gain or are afforded greater control over decisions and actions affecting their lives[33].

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[21].

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, Computerized Physician Order Entry Systems, Electronic Patient Records, etc.).

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 recognize entities and individuals.

ELECTRONIC IDENTITY

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

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

33 http://www.telehealthcode.eu/images/stories/telehea/pdf/fp1_glossary_of_terms_v3_fi nal.pdf legacy

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 Info-structure 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.

INTEGRATED CARE

Integrated care is a trend in health care 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 organization 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 organization 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 centers, e.g. in a hospital or in a chain of hospitals, or even in local/regional or national IT infrastructure.

INTEGRATED PERSONAL HEALTH SYSTEMS

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 an fitness;
- they are produced as a result of integration of different institutional and information systems.

They are personal and possibly personalised in the way the gather, process and communicate data (for feed-back/action)[34].

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

INTEROPERABILITY

Interoperability is a property referring to the ability of diverse systems and organisations to work together (inter-operate) without any restricted access or implementation.

Health system interoperability means the ability, facilitated by ICT applications and systems to exchange, understand and act on citizens/patient and other health related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors and organisations within and across health system jurisdictions in a collaborative manner.

Technical interoperability means the ability of two or more 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.

Semantic interoperability means ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose. It also refers to the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

mHEALTH – MOBILE HEALTH

mHealth (also written as m-health or mobile health) is the use of mobile communications – such as personal digital assistants, smart phones, mobile phones and wireless communication networks– to deliver information and services in the fields of public health, healthcare, social care and well-being. mHealth services are used by citizens, patients, healthcare professionals, healthcare authorities, elderly and disabled persons.
Applications range from fall detection alarms, lifestyle coaching programs, SMS medication reminders, data collection and exchange, medical images viewing to remote monitoring of vital signs.

PATIENT SUMMARY[25]

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, health care 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.

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) with reminders to check certain tests in order to reach certain quality goals.
Patient registries are less complex and simpler to setup 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.

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

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 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

Personalised medicine is a medical model emphasising the customisation of healthcare, with all decisions and practices tailored to individual patients. Recently, this has mainly involved the systematic use of genetic or other information about an individual patient to select or optimise the patient's preventative and therapeutic care.
Traditionally, personalised medicine has been limited to the consideration of a patient's family history, social circumstances, environment and behaviours in tailoring individual care. It is now extended to the individual's genomes to understand the individual's susceptibility to diseases and possible reactions to treatment.
Fields of Translational Research termed «-omics» (genomics, proteomics, and metabolomics) study the contribution of genes, proteins, and metabolic pathways to human physiology and variations of these pathways that can lead to disease susceptibility. It is hoped that these fields will enable new approaches to diagnosis, drug development, and individualized therapy.

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.

UNIQUE IDENTIFIER

In healthcare, unique identifier is a unique number that has been be 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.

VIRTUAL PHYSIOLOGICAL HUMAN (VPH)

Virtual Physiological Human (VPH) is a methodological and technological framework, targeting multi-scale models and simulation aiming at personalised, predictive and integrative medicine and information infrastructures. Once established, it will enable collaborative investigation of the human body as a single complex system.

VITAL SIGNAL MONITORING

Vital signals 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[35].

PART 3: INTEROPERABILITY RELATED DEFINITIONS

IHE

International user - vendor cooperation (based in Chicago, www.ihe.net) aiming to develop reusable profiles for interoperability in the healthcare sector.

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.

CONTINUA HEALTH ALLIANCE

Continua Health Alliance is an organisation bringing patients, caregivers and healthcare providers together whose aim is to establish a system of interoperable personal telehealth solutions. Continua develops interoperability guidelines and a product interoperability certification program with a consumer-recognisable logo. Continua also engages with regulatory authorities and governments to address cost, safety and security issues in personal health systems.

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.

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 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.

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.

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).

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.

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[36].

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.

USE CASE

In healthcare, a use case refers to a situation or a need for which eHealth information exchange needs to be developed. A usecase 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.

36 BSI, http://www.bsigroup.com/en/Standards-and-Publications/About-standards/What-is-a-standard/

PART 4: 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.

4.1. 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 stand-alone 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.

4.2. 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 the 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 stand-alone 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).

4.3. LOGISTICS AND RESOURCE SYSTEMS

Logistics and resource systems are information systems designed to manage the logistics and resources of a hospital. They include – amongst 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 optimize 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 stand-alone 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 stand-alone tools/systems or as part of an Enterprise Resource Planning (ERP) system. Stand alone systems/tools may also be integrated with Enterprise Resource Planning (ERP) solutions. SCM require the integration with key clinical systems (orders, etc.).

4.4. 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 stand-alone 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 stand-alone 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 stand-alone 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 stand-alone 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 stand-alone 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 5: 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.

5.1. 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 program 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 rule engine is now necessary to practice state-of-the art medicine.

CLINICAL WORKFLOW MANAGEMENT INFORMATION SYSTEMS (CWMS)

Clinical Workflow Management Information Systems optimally co-ordinate 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 stand-alone 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.

5.2. 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 & result reporting can be a stand-alone 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 stand-alone 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.

5.3. 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 computerized text format (i.e. Medical Transcription). It can be stand-alone digital sound recording software and speech recognition software or integrated digital dictation & 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, 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.
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 authorized 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 digitized (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).

5.4. 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 the 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 stand-alone 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).

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 stand-alone 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 stand-alone 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 stand-alone 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 stand-alone 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 stand-alone 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 stand-alone 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 theater 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 stand-alone 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 stand-alone 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 stand-alone 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 stand-alone solutions (modality PACS - basic solution integrated with the imaging device; mini-PACS - scaled-down/entry-level departmental solution); hospital-wide general or specialty, (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).

PART 6: TELEMEDICINE

Telemedicine is the overarching definition covering Telehealth, Telecare, mHealth and Teledisciplines.

Telemedicine can be defined as the delivery of healthcare services through the use of Information and Communications Technologies (ICT) 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 health care 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 caregiver to patient/citizen as well as doctor to doctor communication.

6.1. GENERAL TELEMEDICINE RELATED DEFINITIONS

mHEALTH
See mHealth definition in part 1.

PERSONAL HEALTH SYSTEMS (PHS)[28]
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.

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 healthcare professional providing care or imaging services, even within the framework of an emergency, to remotely assist a first-aid worker or any person providing medical assistance to someone in danger while waiting for the arrival of trained medical professionals.

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, e.g. elderly or disabled people in the home setting.

TELECONSULTATION
Teleconsultation is a medical act which is carried out in the presence of the patient who dialogues with the physician and/or the physicians consulting at distance as necessary.

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).

28 European Commission definition http://ec.europa.eu/information_society/activities/health/glossary_of_terms/

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).
Input data sources are typically patients' self-assessments ("subjective data") as well as dedicated peripherals to measure vital parameters ("objective data").
Telehealth solutions address healthcare delivery, diagnosis, consultation and treatment as well as education/behavioural modifications and transfer of medical data.

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).

TELEMONITORING

Telemonitoring designs 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 a hospital to assist in diagnosis and monitoring. This could include support for people with chronic diseases. It includes among 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, at a hospital site, using phone lines or wireless technology.

6.2. TELEDISCIPLINES

The term «telediscipline» is being introduced as an umbrella to describe various approaches to provide medical services over a distance with the help of ICT. It covers various medical disciplines performed at a distance between two healthcare professionals using ICT. A «telediscipline» typically is restricted to a specific medical discipline. In contrast to a «telediscipline» the terms «telemedicine» or «telehealth» have a more general meaning.

TELECARDIOLOGY

Telecardiology covers the remote collection of cardiology data, mostly ECG data, and its transmission to a service centre. In the centre, the data is 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 in time. Data collection can take place either at the patient's home or in a mobile way.

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 first see a general practitioner, the use of teledermatology offers great potential to shorten the diagnostic process and speed up the start of appropriate treatment.

TELEOPHTHALMOLOGY

Teleophthalmology describes the remote diagnosis of medical conditions of the human eye. Similar to teledermatology, patients may not have immediate access to an opthalmologist. 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 takes 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 off-hours health care 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.

GENERAL INFORMATION ABOUT COCIR

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide.

COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens.

COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users.

We encourage the use of advanced technology to support healthcare delivery worldwide.
COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

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