

COCIR eHEALTH TOOLKIT
HEALTHCARE TRANSFORMATION
TOWARDS SEAMLESS INTEGRATED CARE **Third Edition**
MAY 2013

SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

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



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HEALTHCARE TRANSFORMATION – HOW eHEALTH CAN CONTRIBUTE?

The future of healthcare in Europe is uncertain. Healthcare faces the inevitability of having to find ways to deliver more services of higher quality at contained costs to meet increased demands for services and new ‘consumer’ expectations. In practice, there are massive changes to be made in the healthcare business and reimbursement mechanisms if the basic principles of universal coverage and solidarity in financing care provision are to be preserved.

Healthcare systems across Europe, and actually around the world, are facing challenges that cannot be met by a ‘business as usual’ approach. The continuous rise in demand, a cost explosion due to chronic and lifestyle diseases, staffing issues as baby boomer clinicians retire, and the need to reduce healthcare inequalities, make an even stronger case for the sustained innovation of healthcare systems. There is an urgent need to transform healthcare delivery at the patient level and to integrate currently fragmented processes. Hospitals are no exception and will play a critical role in participating in this paradigm shift.

Hospitals of Today must work as one element of an integrated healthcare delivery system where the hospital is the ‘hub’ through which patients and information flow. Enabled by innovative technologies coupled with electronic information and communication systems, connected and coordinated healthcare organizations provide numerous opportunities to deliver care for patients while offering greater transparency, flexibility and choice, and increasing access to the services available

In order to accompany such healthcare transformation, COCIR recognizes and support the efforts from the European Commission, in particular with their new eHealth Action Plan 2012-2020, entitled ‘Innovative healthcare for the 21st century’ as it provides a comprehensive roadmap for smart and sustainable healthcare in Europe.

We are pleased to note that the four pillars of the eHealth Action Plan - (1) Achieve wider interoperability in eHealth services (2) Support research and innovation and competitiveness in eHealth (3) Facilitate deployment and adoption of eHealth and (4) Promote international cooperation on eHealth at global level - are fully aligned with COCIR’s own vision and efforts developed to accelerate the deployment of eHealth.

Our industry has devoted significant efforts over the last years to improve systems interoperability in partnership with key stakeholders including user organizations and authorities and to supply the technologies required that will make eHealth a reality. Deployment and adoption at country level are crucial as it remains a major barrier to realizing the full benefits of eHealth.

The 3rd edition of the COCIR eHealth Toolkit will bring you an opportunity to better understand the industry trends and how mHealth and Electronic Patient Records (EHRs) in particular can truly contribute to a more sustainable healthcare system in Europe and beyond.

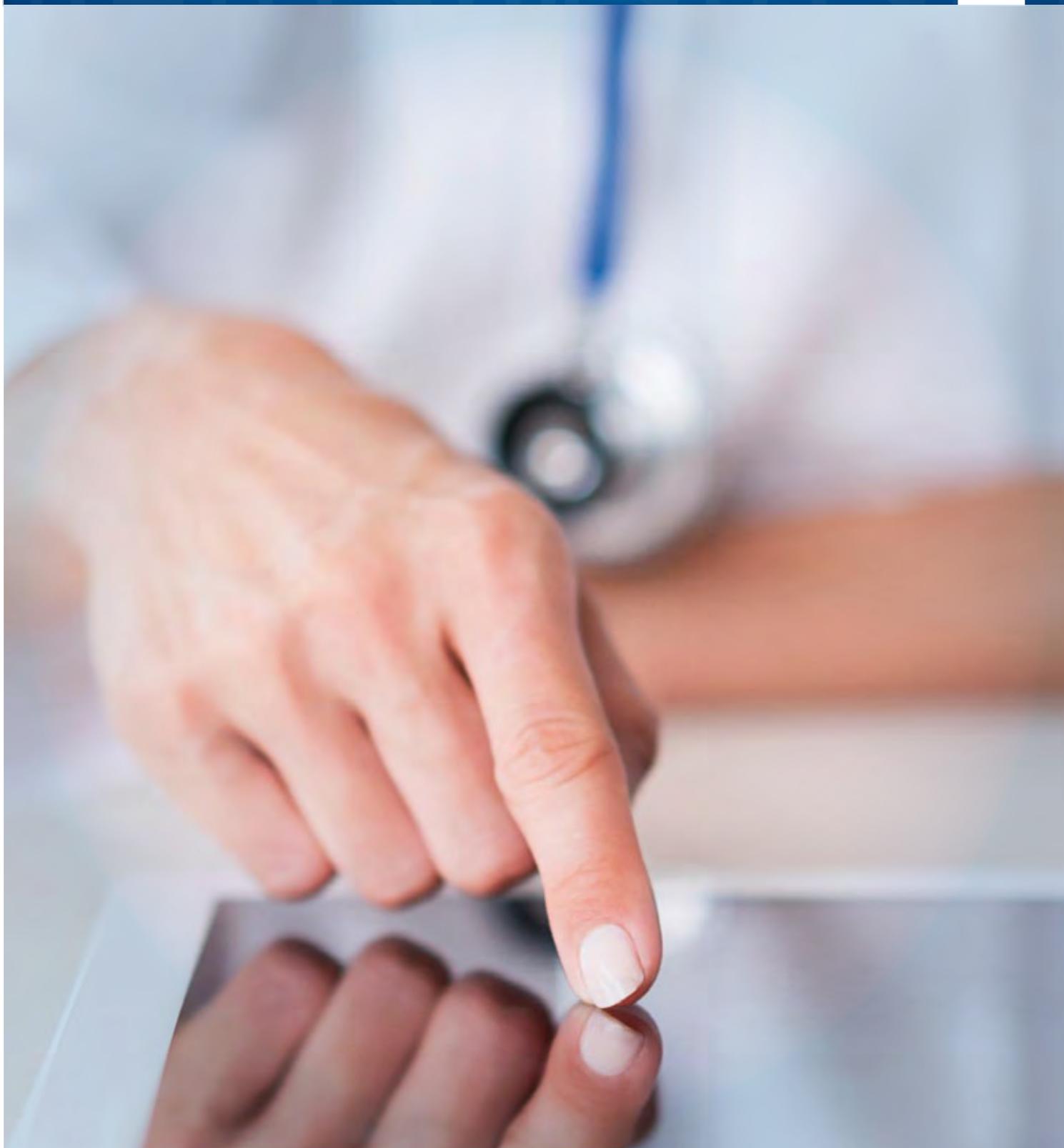
Nicole DENJOY

COCIR Secretary General



COCIR eHEALTH STRATEGY

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PART 1 COCIR eHEALTH STRATEGY 1

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eHEALTH STRATEGIC GOALS



At the crossroads of medical imaging, clinical processes and ICT Technology, COCIR develops and promotes strategies to move towards sustainable Healthcare systems in Europe and beyond.

COCIR is the only European Trade Association bringing together the traditional healthcare industry together with the Telecommunication and IT industries. COCIR and its members promote the use of advanced medical and ICT technology towards seamless care delivery and shared knowledge to build a better world with improved access to affordable, quality and safe healthcare. Established since 1959, COCIR brought important competencies in the eHealth domain since its creation and more intensively since the early years 2000 as one of the element brought in Europe was the introduction of the IHE methodology and concept of interoperability.

eHEALTH MARKET FOCUS AREA

Our activities are articulated around the 3 following areas:

- 1. ACUTE CARE ORGANIZATIONS:** their clinical information systems and the way they interact with their own eco-systems. COCIR aims to build awareness on the Digital Hospitals and its potential to improve the quality of care and connect hospitals to the wider health community for more efficient healthcare systems.
- 2. SHARED CARE WORKFLOW** (information and knowledge sharing) and the inter-professional collaboration mechanisms required to support HIE/her. COCIR aims amongst others to address the interoperability requirements (organization, semantic and technical).
- 3. INTEGRATED CARE:** COCIR aims to address the info structure requirements in the field of telehealth and mHealth and their related connectivity devices as well as supporting governance, regulation, value chain and business models.

eHEALTH ACTIVITIES

COCIR and its members have considerable knowledge in healthcare operations and related processes and are already positioned to provide a valid opinion on the future development and deployment of eHealth across Europe and beyond. This is the reason why COCIR structured its eHealth related activities as follows:



eHEALTH MARKET INTELLIGENCE CENTER: A UNIQUE PLATFORM

Since 2008, COCIR collects for its members reliable statistical data on the eHealth market (Imaging IT and Enterprise IT) to develop a better understanding of their availability and adoption in daily clinical routine practice as well as the size of the current market and its expected growth, trends and evolution in the coming years.

IMAGING IT: Data collected directly from COCIR members for the members on Radiology IT and Cardiology IT solutions in 54 countries in Europe and beyond.

ENTERPRISE IT: COCIR members gather and analyze data from acute care hospitals in specific European countries. In addition to country based reports, COCIR benefits from an exclusive Multi-country Comparison Tool developed by HIMSS Analytics Europe which automatically compares data collected in the countries for more than 45 eHealth applications giving the possibility to have a better understanding on how the market evolves. Last but not least, COCIR members raise consensus estimates on the size of the market and its expected development over a five-year forecast period.

COCIR'S FOOT PRINT AT INTERNATIONAL LEVEL

- > **International Standards** (IEC and ISO): COCIR was granted liaison of category A with the international Technical Committee IEC TC 62, which allows COCIR to submit directly new work item proposals (NWIP) at international level.
- > **OECD:** COCIR holds the Chairmanship for the **Business and Industry Advisory Committee for the OECD** (BIAC) on Health policy.
- > COCIR is also cooperating with the **World Health Organisation** and the **World Bank**

COCIR does not act in isolation, and also aims to co-operate and joint forces with stakeholders.

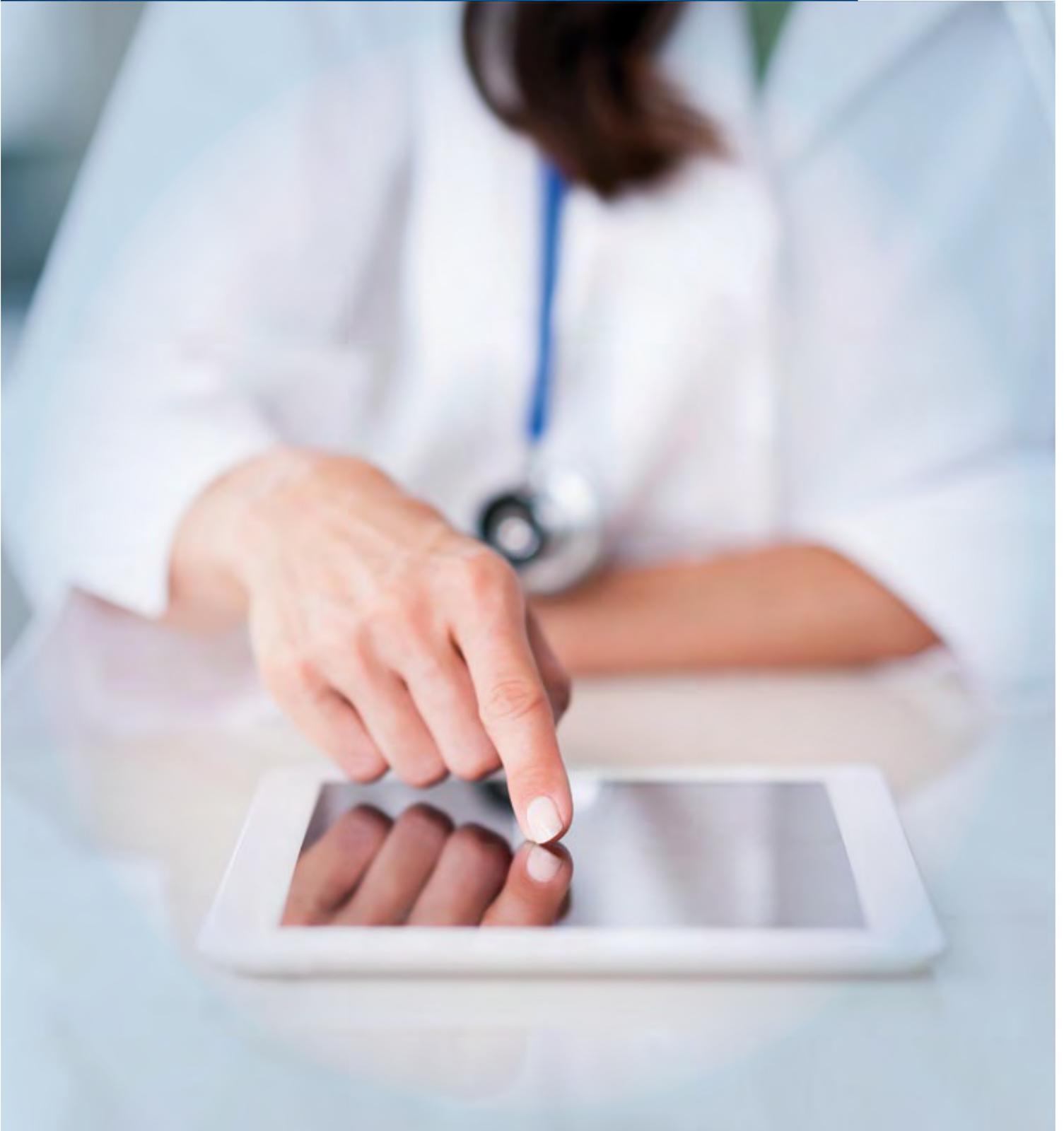
COCIR offers to be

- > "One-stop shop" for Europe's Medical and ICT technology industry
- > A trusted partner for national trade associations and other key stakeholders
- > Global outreach, experience and competence in the sector
- > Insight on new business models for healthcare systems

DIGITAL HOSPITALS

HEALTHCARE TRANSFORMATION:
FROM ELECTRONIC PATIENT RECORDS
TO FULLY CONNECTED HOSPITALS

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PART 2 DIGITAL HOSPITALS

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HEALTHCARE TRANSFORMATION: FROM ELECTRONIC PATIENT RECORDS TO FULLY CONNECTED HOSPITALS

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EXECUTIVE SUMMARY

eHealth has the potential to improve the quality of care and connect hospitals to the wider health community for more efficient healthcare systems.

Digital hospitals and clinical information systems (CIS) are directly contributing to improving and modernising healthcare delivery. Evidence has been gathered on the importance of clinical information systems and their impact on increasing accessibility, efficiency, quality of medical care and patient safety. Electronic Patient Records (EPR) and CIS implementation can generate cost saving by avoiding duplication of tests, better use of resources, streamlining processes and using information more efficiently.

The state of the industry illustrates the uneven availability of clinical information systems at the application level and across European countries. The adoption by clinicians, resistance to change, and level of investments can affect effective integration in clinical routine practices. There is a need for an incremental, step by step transformation of care organisations and to improve the exchange and sharing of patient information in the home and outside to develop more efficient clinical pathways.

COCIR outlines the **way forward** and on how the different stakeholders can align efforts and incentives to remove barriers, accelerate the adoption of advanced clinical systems and better integrate digital hospitals in the health information exchange platform of the future.

INTRODUCTION

The future of healthcare in Europe is unsustainable. Healthcare faces the inevitability of having to find ways to deliver more services of higher quality at contained costs to meet increased demand for services and new consumer expectations. In practice, there are massive changes to be made in the healthcare business and reimbursement mechanisms if the basic principles of universal coverage and solidarity in financing care provision are to be preserved.

There is an urgent need to transform healthcare delivery at the patient level and to integrate currently fragmented processes. Hospitals are no exception and will play a critical role in participating in this paradigm shift from care in 'silos' towards integrated healthcare delivery systems. Enabled by electronic patient records (EHRs) and advanced clinical information systems (CIS), connected and coordinated hospitals provide numerous opportunities to deliver care for patients while offering greater transparency, flexibility and choice, and increasing access to the services available.



However, and despite the role that electronic patient records and clinical information systems can play in improving the quality, safety and efficiency of healthcare delivery, investment across Europe has remained static over past few years. As stressed by European Commission Vice President Neelie Kroes during the eHealth Week 2012, this is far too little: 'Over the 5 years to 2015, some project the European market for health ICTs in hospitals growing by just 10% in absolute value. 10% over 5 years! That's tiny when you consider the massive scale of the digital revolution elsewhere. As ICT progressively transforms other sectors, healthcare is still a decade behind'.

COCIR aims to build awareness on digital hospitals and their potential to improve the quality of care and connect hospitals to the wider health community for more efficient healthcare systems. Today solutions exist to respond to tomorrow's challenges, from the sharing of information to decision support at the point of care through advanced analytics.

1 WHY ARE CLINICAL INFORMATION SYSTEMS SO IMPORTANT?

If implemented properly, the use of Electronic Patient Record (EPR) and advanced clinical information systems (CIS) can increase the efficiency of healthcare delivery, improve the quality of care and patient safety, and reduce costs.

There is a growing body of evidence on the outcomes of EPRs and associated CIS implementation in primary and secondary care¹. Below is a summary of the benefits and limitations reported in these articles.

However, readers will understand that it is quite hard to specifically align the benefits to a pure eHealth investment. The challenge is hidden in the section "It is all about technology, process and people", where we basically state that technology is one, but definitely not the only ingredient for hospitals to improve their performance. Our health ICT industries can bring the necessary tools and competencies to make the digital hospital become reality, reducing medical errors and enhancing the performance and safety of healthcare systems. However, this is only with the involvement of all stakeholders that the return on investment can be materialized and proven.

INCREASING EFFICIENCY OF HEALTHCARE:

The use of eHealth solutions can lead to a more efficient use of information and resources – lower number of X-ray examinations and radiation levels received by patients, faster triage in emergency rooms, reduction in time from prescription to medical administration, faster access to imaging results, elimination of paper records, etc².

¹ COCIR initiated a review of the existing literature in early 2012 and will continue on an ongoing basis

² Information and Communication technology adoption for business benefits: A case analysis of an integrated paperless system

In a survey of hospital executives (C level, VP and Directors) in American rural and community based hospitals (2007), 90% of interviewees report 'better patient care' after EPR and computerised physician order entry (CPOE) implementation and 75% report 'more efficient access to information' as the main benefit of EPR implementation³.

PACS and advanced image management tools are recognised as providing a useful way to improve the processing time (or overall 'throughput') of medical images and a cost-effective electronic alternative to conventional methods of storing and managing images. As pointed out by the OECD, increasing throughput means that turnaround time is shorter, and that there is less waiting around for both tests and results, which also means that there is less delay before treatment can be started. Data from 22 sites in British Columbia show that report turnaround time was reduced by 41% following the implementation of PACS.

In addition, a widely recognised source of inefficiencies in healthcare systems is the fragmentation of the care delivery process and the poor transfer of information. As pointed out by OECD in its 2010 report, efficient sharing of health information is, however, indispensable for the effective delivery of care. This is particularly important for elderly people and those with chronic conditions, who often have several physicians and are shuttled to and from multiple care settings.

The sharing of information in health systems and the diversity of potential uses and benefits means that eHealth, ensuring the timely and accurate collection and exchange of health data, is likely to foster better care coordination and the more efficient use of resources.

IMPROVING THE QUALITY OF CARE AND PATIENT SAFETY:

The most recognised impact of eHealth is on quality of care and patient safety. Most of these are directly associated to CPOE implementation. Many studies reviewed by COCIR indicate a clear link between COPE implementation and reduced medication errors.

A study carried out in over 4 700 American hospitals concludes that CPOE decreases the likelihood of medication error by 48% in inpatient acute care settings. However the same study also reveals that CPOE implementation – when not accompanied by appropriate training and policies – can also lead to an increase in medication errors⁴.

A similar study in two Australian hospitals concludes that the use of ePrescription resulted in a 55% reduction in prescribing error rates⁵.

REDUCING COSTS:

EPR and CIS implementation can generate cost savings by avoiding duplication of tests, better use of resources, streamlining processes and using information more efficiently.

Although few studies measure the economic gains, a recent study published in the International Journal of Information Management shows that a Portuguese hospital achieved additional annual income of €3 million by increasing the number of outpatient appointments following the implementation of an EPR (of which 30% are attributable to the EPR)⁶.

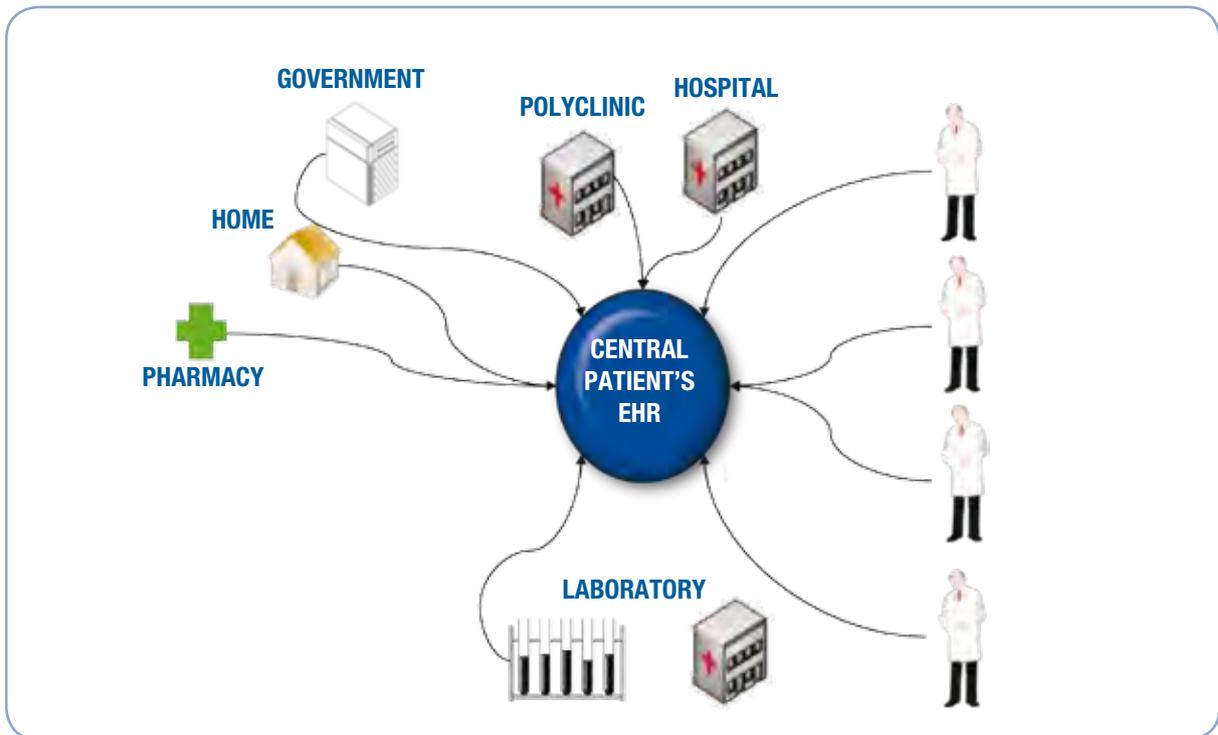
The hospital also reduced staff allocated to patient records from 25 to 15 people, resulting in an estimated €210 000 in annual savings.

3 EPR implementation in community hospitals: critical factors for success _ Sponsored by CPSI _ reported by Porter Research _ January 2007 IMPROVING HEALTH SECTOR EFFICIENCY: THE ROLE OF INFORMATION AND COMMUNICATION TECHNOLOGIES - OECD 2010

4 Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. David C Radley, Melanie R wasserman, lauren EW Olsho, et al. J Am Med Inform assoc 2013, 00:1-7. doi:10.1136/amiajnl-2012-001241

5 Westbrook JL, Reckmann M, Runciman WB, Burke R, et al. Effects of two Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: a Before and After Study. PLoS Med 9(1):e1001164. doi:10.1371/journal.pmed.1001164

6 Caldeira, M., et al. Information and communication technology adoption for business benefits: A case analysis of an integrated paperless system. International Journal of Information Management (2012)



Another study carried out in the US examines the relationship between the adoption of electronic patient records and hospital operating costs in thousands of American hospitals between 1996 and 2007⁷. It concludes – without providing figures – that EPR adoption is initially associated with a rise in costs and leads to a decrease in costs after three years in favourable conditions (e.g. urban hospitals).

...KEY SUCCESS FACTORS

Intelligence collected as of today identifies the following as key conditions for success:

- **Assessing benefits is an on-going process**, as some benefits are not immediate and only appear at a later stage once the system has been fully integrated within the hospital 'enterprise'.
- Successful implementation also largely depends on **widespread clinical adoption** and necessitates a number of **support policies and incentives**.
- Organisations that see a significant return on investment in eHealth also tend to enjoy good organisational and process support for their efforts. An **effective management of the process** and the **organisational change** to a digital system is essential.

⁷ The Trillion Dollar Conundrum: Complementarities and Health Information Technology David Dranove, Christopher Forman, Avi Goldfarb, and Shane Greenstein NBER Working Paper No. 18281 August 2012 JEL No. I10,L30 <http://www.nber.org/papers/w18281>

2 WHAT IS THE STATE OF THE INDUSTRY?

DIGITAL HOSPITALS STILL MATTER – FROM SILO CARE TO INTEGRATED CARE

The road to digital hospitals is not easy – it is a long process which started as long ago as the 1960s, when the concepts of ‘health informatics’ and ‘biomedical computing’ first began to find a permanent position amongst academic interest groups. However, at that time these concepts had little meaning for most hospitals and health professionals providing care in daily clinical routine practices.

The use of information – and, later, communications – technology to manage the complex and diverse work and service provision environment of hospitals became evident as long ago as 1970. Computer technology was considered an ideal way to keep track of patient notes, bed occupation and planning in a busy hospital. With the development of many stand-alone applications, the quest for an integrated record which could follow the patient in every interaction with the health service – providing a complete record of healthcare-related activities such as online advice-seeking, primary and secondary care provision, pharmacy services and other health and social care services – soon became the holy grail of eHealth.

Although the ultimate integrated and shared Electronic Health Record (EHR) has not yet been achieved, hospitals have made some progress over the last two decades – patient administration systems (PAS) are today very commonly used in European hospitals. These are followed by departmental systems such as laboratory information management, pharmacy department management and radiology information management.

TABLE 1 - INSTALLED BASE

	Germany	Italy	Poland	Portugal	Saudi Arabia	Spain	United States
Administrative Systems							
ADT/Registration	99.2%	94.4%	91.4%	96.2%	76.7%	98.2%	99.0%
Clinical Information Systems							
Laboratory							
Laboratory Information System*	94.7%	90.2%	50.6%	73.3%	77.2%	91.8%	97.4%
Pharmacy							
Pharmacy Management System*	57.0%	75.1%	77.5%	94.2%	74.2%	96.6%	97.0%
Electronic Medical Record / Electronic Patient Record							
Computerized Practitioner Order Entry (CPOE)	49.3%	50.1%	18.2%	38.6%	57.6%	75.7%	69.1%
Electronic Patient Record/Clinical Data Repository	88.5%	53.6%	51.7%	93.6%	71.7%	90.2%	92.5%
ePrescribing	34.8%	35.1%	7.6%	47.9%	68.1%	54.3%	n/a
Order Entry (Includes Order Communications)	79.3%	68.4%	19.3%	89.4%	78.9%	80.3%	93.8%
Physician Portal	19.4%	31.0%	0.9%	5.3%	35.2%	64.6%	51.7%
Radiology & PACS							
Radiology Information System*	80.7%	86.9%	46.8%	91.7%	69.9%	91.2%	95.1%
Radiology PACS*	75.0%	61.8%	42.8%	93.1%	54.6%	83.9%	85.9%

Source: HIMSS Analytics Europe - HAE (Country Comparison Report 2012)

While in some cases patient history remain recorded on paper in parallel to electronic ones, EPR solutions are now becoming more and more standard practice in almost the vast majority of hospitals across Europe. Not only is the number of hospitals using EPRs in Europe increasing significantly, but we observe more and more a changing balance of applications supporting more complex clinical systems such as close-loop medication, disease management and shared care workflows.

However, there is still a long way to fully connected hospitals as reflected in the model below.

TABLE 2 - CROSS REGIONAL EMR ADOPTION MODEL SCORE DISTRIBUTION

STAGE	GERMANY	ITALY	NETHERLANDS	SPAIN	POLAND	PORTUGAL	OTHER EUROPEAN COUNTRIES*	EUROPE	USA †	SHORT DESCRIPTION (HA EUROPE EMRAM)
STAGE 7	0,3%	0,0%	0,0%	0,5%	0,0%	0,0%	0,0%	0,1%	1,9%	Complete EMR; CCD transactions to share data; Data warehousing feeding outcomes reports, quality assurance, and business intelligence; Data continuity with ED, ambulatory, OP
STAGE 6	0,0%	0,6%	3,8%	4,3%	0,0%	0,0%	4,9%	1,4%	8,2%	Physician documentation interaction with full CDSS (structured templates related to clinical protocols trigger variance & compliance alerts), AND Closed loop medication administration
STAGE 5	8,3%	6,6%	34,6%	40,9%	0,0%	26,1%	32,0%	14,9%	14,0%	Full complement of R-PACS displaces all film-based images
STAGE 4	1,9%	1,8%	3,8%	6,7%	0,7%	4,3%	4,9%	2,8%	14,2%	CPOE in at least one clinical service area and/or for medication (i.e. ePrescribing); may have Clinical Decision Support based on clinical protocols
STAGE 3	8,3%	3,4%	1,9%	1,9%	0,0%	21,7%	0,0%	4,0%	38,3%	Nursing/clinical documentation (flow sheets); may have Clinical Decision Support for error checking during order entry and/or PACS available outside Radiology
STAGE 2	34,9%	26,7%	55,8%	18,8%	10,3%	4,3%	36,9%	27,2%	10,7%	Clinical Data Repository (CDR) / Electronic Patient Record; may have Controlled Medical Vocabulary, Clinical Decision Support (CDS) for rudimentary conflict checking, Document Imaging and health information exchange (HIE) capability
STAGE 1	0,6%	41,4%	0,0%	9,6%	13,0%	4,3%	6,8%	18,8%	4,3%	Ancillaries – Lab, Radiology, Pharmacy – All Installed OR processing LIS, RIS, PHIS data output online from external service providers
STAGE 0	45,7%	19,5%	0,0%	17,3%	76,0%	39,1%	14,6%	30,7%	8,4%	All Three Ancillaries (LIS, RIS, PHIS) Not Installed OR Not processing Lab, Radiology, Pharmacy data output online from external service providers
N	324	498	52	208	146	23	103	1.354	5.458	Institutions with valid EMRAM score (based on data from last 24 months, status as of Q1/2013)
MEAN	1,6941	1,6593	3,6592	3,4102	0,4268	2,5635	1,3456	2,0096	3,5115	

Source: HIMSS Analytics Europe - HAE (Country Comparison Report 2012)

Note: the EMRAM algorithm differs across different regions to reflect HIT implementation of that particular region

* This includes: Austria (19), Belgium (2), Denmark (4), Finland (3), France (32), Ireland (5), Norway (8), Sweden (2), Switzerland (3), United Kingdom (25)

While almost 45% of US hospitals have reached level three, Europe appears to lack behind with the exception of Spain (41% of hospitals having reached level 5). In Germany, for instance, 57% of hospitals surveyed were found at level 0. Italy reports a similar pattern with 48% of hospitals at level 0. Poland ranks below, with still 78% of hospitals at level 0.

The HIMSS Analytics survey also found large differences between European countries in their levels of sophistication within the different hospital segments – large, medium and small.

TABLE 3 - EMR ADOPTION MODEL - EUROPEAN OVERVIEW

STAGE	SMALL	MEDIUM	LARGE	PUBLIC	PRIVATE	TOTAL*	SHORT DESCRIPTION
STAGE 7	0,0%	0,2%	0,4%	0,2%	0,0%	0,1%	Complete EMR; CCD transactions to share data; Data warehousing feeding outcomes reports, quality assurance, and business intelligence; Data continuity with ED, ambulatory, OP
STAGE 6	0,8%	1,5%	3,0%	1,6%	1,1%	1,4%	Physician documentation interaction with full CDSS (structured templates related to clinical protocols trigger variance & compliance alerts), AND Closed loop medication administration
STAGE 5	10,5%	15,3%	26,7%	15,6%	13,9%	14,9%	Full complement of R-PACS displaces all film-based images
STAGE 4	2,7%	3,7%	1,3%	1,6%	4,6%	2,8%	CPOE in at least one clinical service area and/or for medication (i.e. ePrescribing); may have Clinical Decision Support based on clinical protocols
STAGE 3	3,3%	5,2%	3,4%	2,8%	5,8%	4,0%	Nursing/clinical documentation (flow sheets); may have Clinical Decision Support for error checking during order entry and/or PACS available outside Radiology
STAGE 2	22,3%	28,7%	37,9%	25,9%	29,1%	27,2%	Clinical Data Repository (CDR) / Electronic Patient Record; may have Controlled Medical Vocabulary, Clinical Decision Support (CDS) for rudimentary conflict checking, Document Imaging and health information exchange (HIE) capability
STAGE 1	21,9%	16,8%	14,2%	24,8%	9,8%	18,8%	Ancillaries – Lab, Radiology, Pharmacy – All Installed OR processing LIS, RIS, PHIS data output online from external service providers
STAGE 0	38,4%	28,7%	12,9%	27,5%	35,6%	30,7%	All Three Ancillaries (LIS, RIS, PHIS) Not Installed OR Not processing Lab, Radiology, Pharmacy data output online from external service providers
N (valid)	658	464	232	815	539	1.345	Institutions with valid EMRAM Score (based on data from last 24 months, status as of Q1/2013)

Source: HIMSS Analytics Europe – HAE (eHospital Census report)

* This includes: Austria (19), Belgium (2), Denmark (4), Finland (3), France (32), Germany (324), Italy (498), Ireland (5), Netherlands (52), Norway (8), Spain (208), Sweden (2), Switzerland (3), Poland (146), Portugal (23), United Kingdom (25)

In Germany, significant differences are observed, with 36% of the large hospitals (>750 beds) having reached level 5 as opposed to only 3.1% of small ones (>250 beds).

Finally patients, and citizens at large, are also far from receiving the full benefits deriving from rapid access to their EHRs. Only a relatively low proportion of European hospitals currently offer online access to patients' EHRs and related services such as online booking or ePrescription for pharmacies outside the hospital⁸.

IT IS ALL ABOUT TECHNOLOGY, PROCESS AND PEOPLE

One the key conditions for success lies not only in the mere availability on the healthcare providers' side but also in the level of actual adoption and use in daily clinical practice. As underlined by Van der Lei (2002), 'applying information and communication technology to a medical domain is not merely adding a new technique, it radically changes processes in that domain'.

Moving to shared, lifetime EHRs requires achieving various levels of progress and clear, strategic health objectives, along with their implications for workflows in clinical and business processes. There is now general agreement that business process

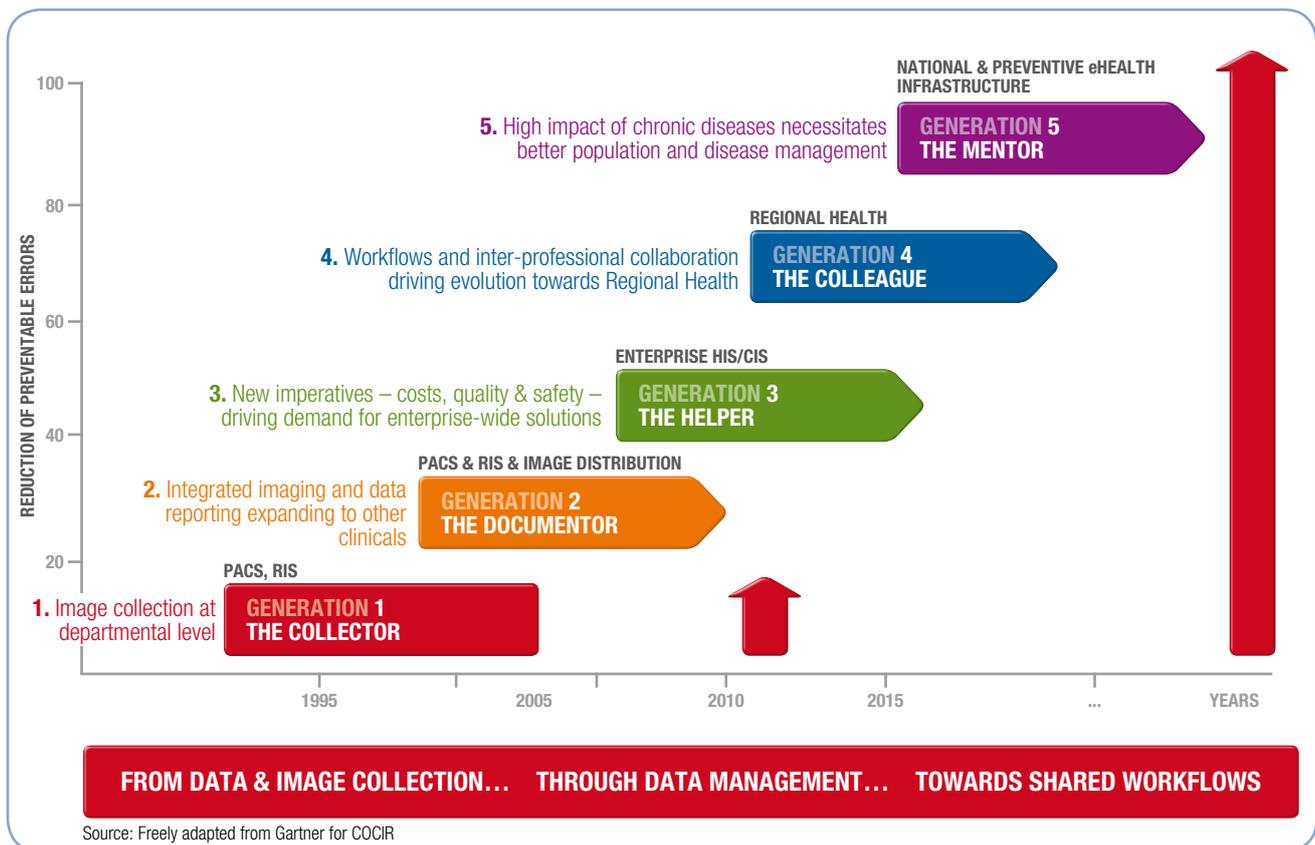
⁸ Deloitte and Ipsos Belgium for DG INFSO (2011), eHealth benchmarking (Phase III)

reengineering (BPR) must be tackled early on in the life of any modernisation or change process – technology is not enough and needs to be combined with education, organisation and process change. These are key ingredients for successful eHealth developments and provide the opportunity for quantum improvements and savings through more effective workflow and business/clinical processes.

More emphasis should therefore be put on innovative business reengineering, combined with technology with clinical outcomes, health professional convenience and patient experience (and engagement) at the early planning stages.

...PROCESSES IN AND OUTSIDE THE HOSPITAL

As COCIR we advocate the incremental, step-by-step transformation of care organisation from simple data and image collection towards complex data management, ultimately leading to shared care workflows at local, regional, national and pan-European level.



Clinicians and other health professionals are unlikely to be the prime initiators of change – this is an area where public authorities need to guide and encourage others at senior management level in healthcare organisations to rise to the challenge.

The cost-containment policies and the changing reimbursement mechanism towards 'pay for performance' push indeed healthcare providers to start developing a 'care pathway' approach both in and outside the hospital. Developing care pathways in the hospital means changing the focus from departmental care delivery to patient-centred, seamless multidisciplinary care.

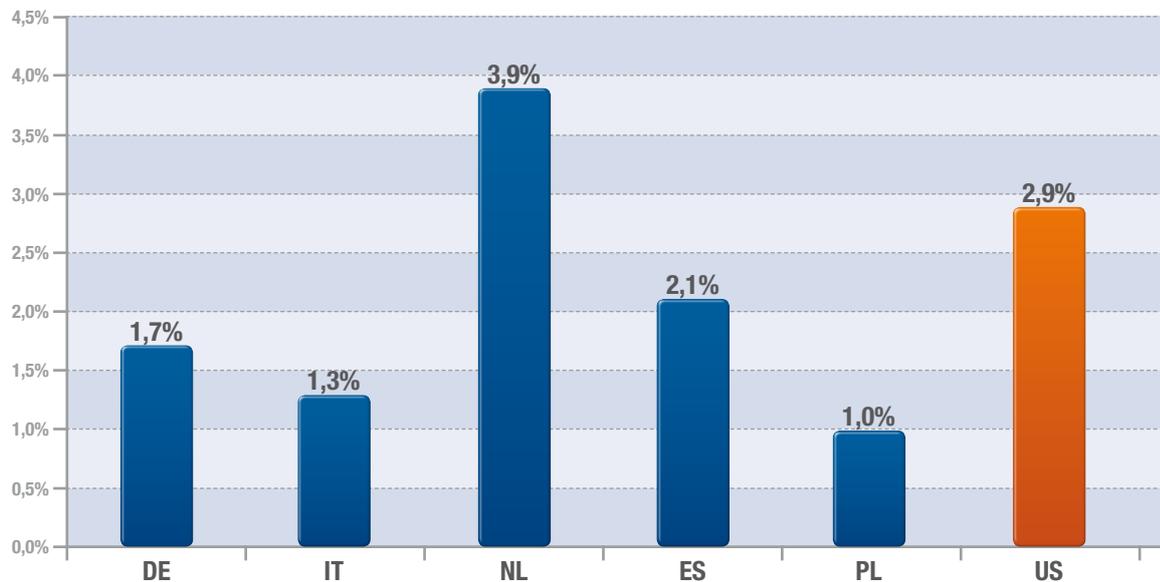
Moreover, major areas of improvement remain in enhancing the exchange and sharing of patient information in the home or outside of healthcare facilities so as to develop care pathways also outside the hospital. Mobile health (mHealth) is facilitating a growing array of telemedicine solutions that enable care providers to make better decisions, avoid patient errors, become more efficient and understand individual and population health more effectively. So far, however, reimbursement mechanisms do not favour the development of cooperation mechanisms between the single hospitals and other organizations, thus limiting change.

The drive to standardise and share care workflows is gaining momentum on a global industry scale, but will take time to reach fruition. With the completion of these steps, COCIR believes healthcare systems will be able to move towards advanced, predictive data analytics for various purposes, including public health management, disease management and clinical research.

CURRENT INVESTMENT CAPACITY IS TOO LIMITED

Hospitals will remain at the epicentre of new, integrated care delivery structures. The equipping of hospitals to meet the needs of eHealth is therefore essential for ensuring significant progress with advanced EHR evolution. However, progress towards digital hospitals is refrained by the current low levels of investment. While US hospitals spend on average 2.9% of their budget on IT (internal and external spend), most European countries are far below.

TABLE 4 - IT INVESTMENT (ANNUAL IT OPERATING EXPENSE IN % OF TOTAL HOSPITAL OPERATING EXPENSE)



Source: HIMSS Analytics Europe - HAE (Country Comparison Report - DE, IT, NL, US: data from Q1/2013; ES, PL: data from Q2/2012)

While European governments are concerned about how to speed up the evolutionary process as part of the move towards eHealth, we see – with a few exceptions – no clear overarching strategies, leaving hospitals alone in their efforts to modernise internally and with very limited resources to reach out outside the hospital setting.

3 THE WAY FORWARD

Digital Hospitals require a common vision and implementation strategy. Clear, strategic health objectives, together with their implications for workflow and the reengineering of clinical and business processes, are widely regarded as an ingredient for successful future development of digital hospitals.

Today, there is a perception that many national and regional eHealth plans or initiatives are not addressing hospitals anymore with the belief that ‘the work is done’. This report demonstrates **the Digital Hospitals still matter and ‘the work is not completed’.** **The digital hospital remains an essential building block towards seamless care delivery and shared knowledge, and is a response to the patient’s empowerment.** While many tools are now becoming available, amongst which EPRs, clinical adoption and use in daily clinical routine practices remain a challenge. With the vast majority of hospitals having failed to see technology as an enabler of internal transformational, integration in the wider social and health services delivery would remain too distant with current level of policies, investment and incentives.

In addition, **advanced clinical information systems have still a long way to go** and are far from having reach maturity, from the sharing of information, to decision support at the point of care through advanced and predictive analytics. While these tools are perceived as substantially increasing the safety of medical care by ‘generating a culture of safety’, improving clinical staff actions and workflows, and by bringing evidence-based, patient-centred decision support to the point of care, clinical availability remains limited.

Public authorities have a role to play. In some cases, healthcare authorities responsible for care in a particular country or region may not yet be convinced about the positive impact of digital hospitals and therefore are reluctant to commit. Where they are convinced, it takes time to generate strong evidence and support outcome thinking. Public authorities, therefore, need to steer and impulse the effective use of ICTs to implement new directions for health system change and redesign.

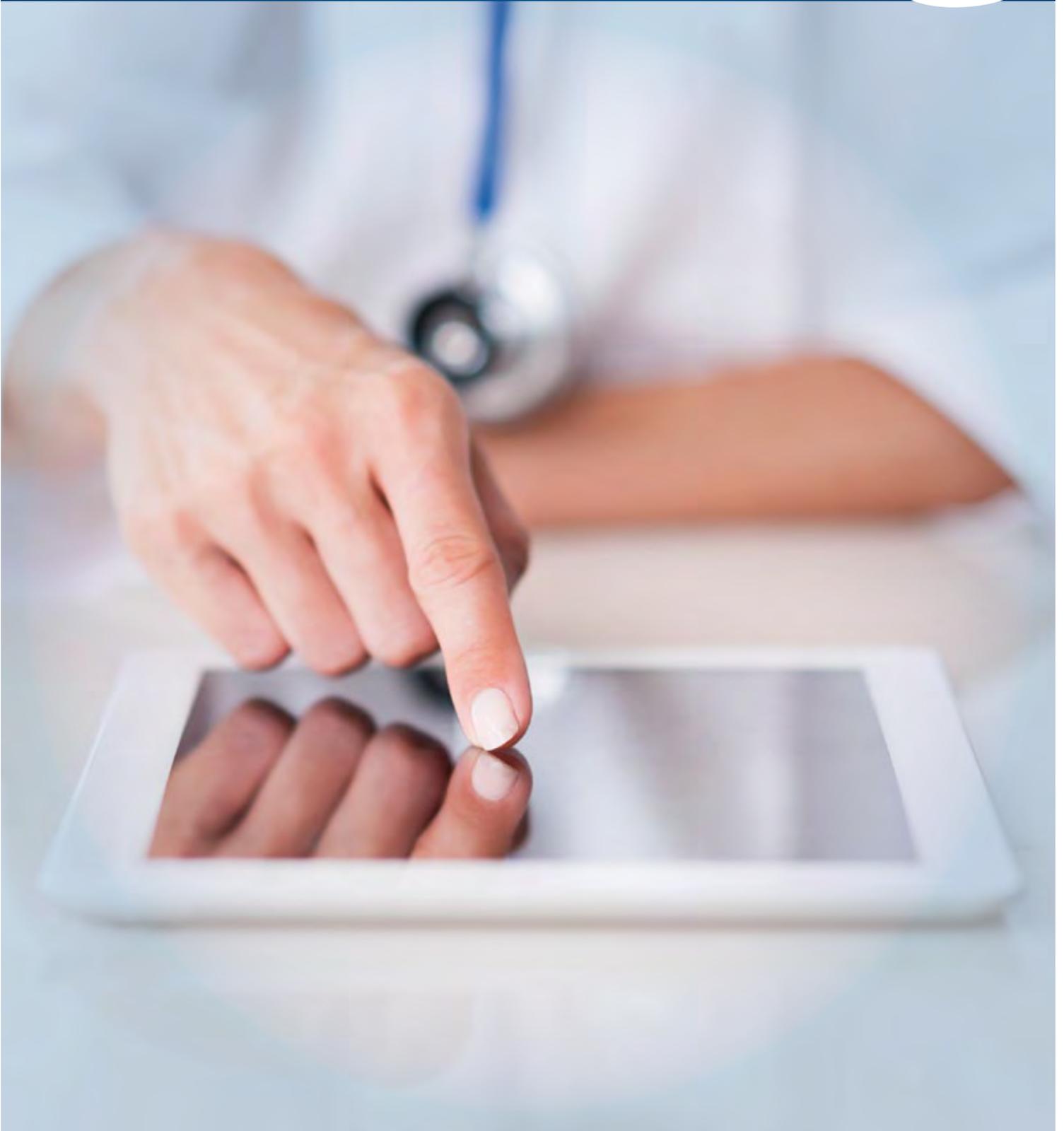
As an investment, Digital Hospitals has a good return, but achieving healthcare modernisation objectives requires **immediate actions and investment at hospital level and longer-term organizational incentives for transformation towards integrated care** and fair allocation of benefits and costs. At a COCIR event in Brussels mid-April on ‘Digital Hospitals, speakers from the European Commission, OECD, hospitals and industry came together and concluded that it is a worthwhile investment. We all need to act as “ambassador”.



MOBILE HEALTH

ADVANCING HEALTHCARE WITH mHEALTH

3



PART 3 MOBILE HEALTH

3

ADVANCING HEALTHCARE WITH mHEALTH

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In recent years mobile health (mHealth) has emerged as an additional way of delivering healthcare services that builds on the ubiquitous connectivity provided by mobile networks. The proliferation of smartphones and tablets, the increasing number of connections to the internet on the mobile platform and the wealth of mHealth apps available on the market increasingly attract the attention of patients, healthcare professionals, the business community, policy makers and regulators.

COCIR aims to shed light on mHealth from an industry perspective: What is mHealth? What is the size of the mHealth market in Europe? What are the challenges and benefits of mHealth solutions? How can we accelerate mHealth deployment? What policies and regulations are needed to support a faster adoption of mHealth?

Improving healthcare delivery is a priority that can be achieved in large part through the use of mobile broadband technology. COCIR has started to collect case studies of successful mHealth deployment in Europe (refer to Annex) and will continue to work with policy makers and with all other public and private sector stakeholders to ensure that mobile broadband technologies, devices, services and applications are used to improve the delivery of healthcare.

COCIR ENCOURAGES POLICY MAKERS AND STAKEHOLDERS TO WORK TOGETHER WITH INDUSTRY TO IMPROVE HEALTHCARE WITH mHEALTH BY ACHIEVING THE FOLLOWING GOALS:

1. INTEGRATE mHEALTH INTO HEALTHCARE DELIVERY STRUCTURES

A committed, integrated governance structure is necessary for successful mHealth deployment – mHealth is a natural evolution of healthcare delivery, not an addition to it.

2. ENABLE CITIZENS' ACCESS TO THEIR DATA

Citizens should be given secure online access to their medical information – EHRs accessible on the mobile platform can increase patient engagement and improve healthcare delivery.

3. DEVELOP APPROPRIATE REIMBURSEMENT STRATEGIES

mHealth cannot be fully integrated in healthcare delivery unless there is a clear understanding of 'who invests and who pays' – discussions on mHealth reimbursement must continue

4. ESTABLISH A HARMONISED DATA PROTECTION REGIME THAT ENABLES INNOVATION

The data protection framework for healthcare, at both EU and Member State level, must make it possible for innovative forms of healthcare delivery to be brought to citizens.

5. SUPPORT MOBILE BROADBAND POLICIES THAT SUSTAIN INVESTMENT IN CONNECTED DEVICES

The right incentives to invest in high-speed mobile broadband are needed to support quality mHealth services.

6. PROVIDE CLEAR AND SIMPLE REGULATORY GUIDANCE FOR mHEALTH

mHealth is a young market that is largely made up of small businesses – regulation (for instance, on apps) should be as lean as possible to support this new ecosystem

7. FOSTER THE USE OF WIDELY RECOGNISED INTERNATIONAL STANDARDS

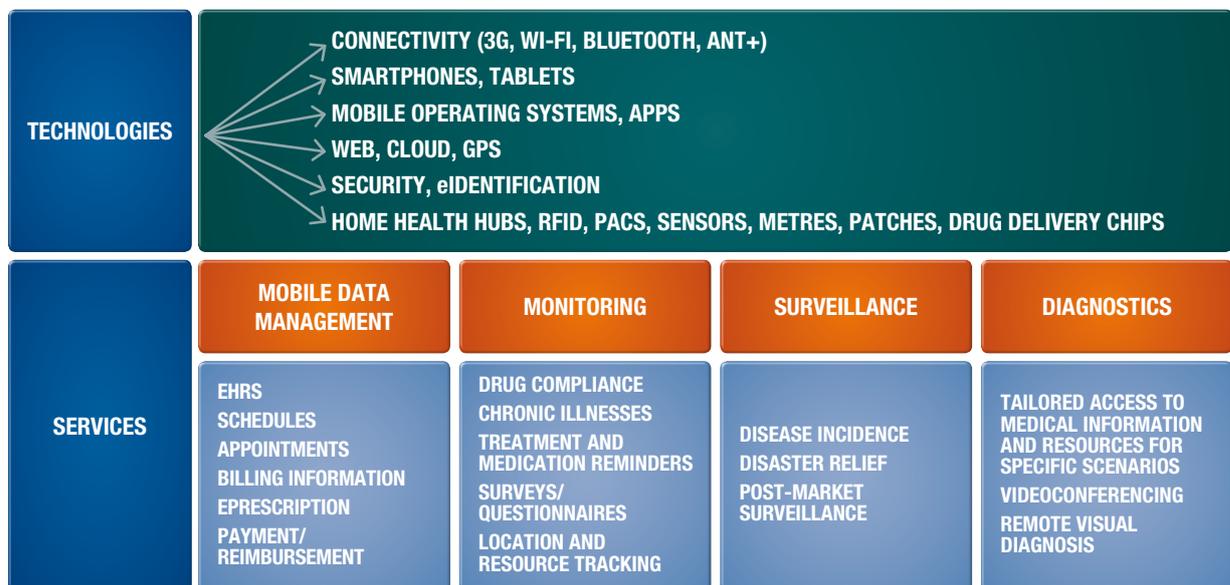
International standards and profiles must be implemented to create consistent, integrated care in Europe and worldwide

WHAT IS mHEALTH?

Within integrated health information systems, eHealth applications can be implemented both on fixed workstations and on the mobile platform. Mobile health, or mHealth, is the provision of eHealth services and information that relies on mobile and wireless technologies.

Information technologies are increasingly using wireless functionality to transmit raw data, diagnostic health information, critical aspects of care, emergency services and personalised information in hospitals, in the home and outside the home. These services increasingly utilise broadband technologies over wireless wide area networks (WWAN, e.g. UMTS and LTE) or wireless local area networks (WLAN, e.g. Wi-Fi) to seamlessly provide information and connect healthcare professionals, caregivers, patients/citizens and healthcare authorities⁹.

FIGURE 1 - EXAMPLES OF mHEALTH

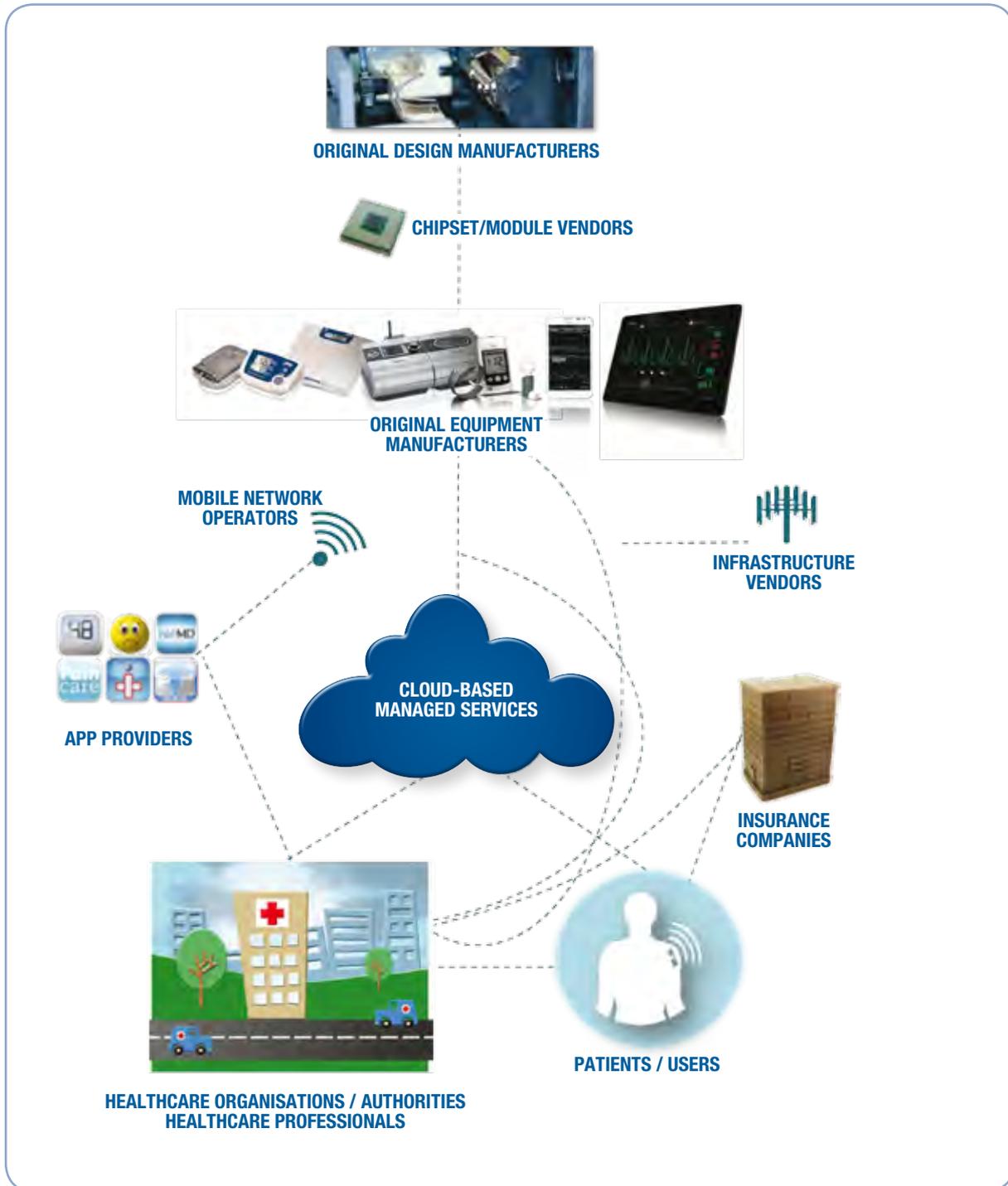


Similarly to eHealth, of which it is part, mHealth describes a broad set of technologies that can support a variety of health-related services, and is not a separate category of services in itself. Mobile technologies are utilised across the range of healthcare, social care, wellness and prevention, and form an integral part of telemedicine, telehealth and telecare. As a consequence, the mHealth value chain is complex and involves participants from several different segments¹⁰.

⁹ For a comprehensive overview of mHealth categories and trends, see Informa (2009), Mobile healthcare: markets and trends for mHealth applications.

¹⁰ For a seminal overview of the mHealth market and its relationship with telemedicine, telehealth and telecare, see JRC-IPTS (2012), Strategic Intelligence Monitor on Personal Health Systems phase 2 (SIMPHS 2): market developments – remote patient monitoring and treatment, telecare, fitness/wellness & mHealth.

FIGURE 2 - mHEALTH VALUE CHAIN



WHAT ARE THE BENEFITS OF mHEALTH?

Healthcare systems are striving to respond to rising demand for better services with fewer resources. mHealth can enable new models of care that improve access and quality, empower patients and make healthcare systems more sustainable in the long term. As multi-standard chipsets and low-energy wireless technologies continue to emerge at increasingly commercially viable prices, and as higher network capacity becomes available, more advanced mobile uses in hospitals, in the home and outside the home will be possible.

INCREASING ACCESS TO HEALTHCARE

Today, mobile is the most pervasive communications platform. Citizens are increasingly taking advantage of the many capabilities that are packed into mobile broadband-enabled devices, including smartphones and tablets. According to the International Telecommunication Union, the number of mobile cellular subscriptions will reach 6.8 billion in 2013, corresponding to a global penetration of 96%, making the cellular network the most pervasive platform that exists today¹¹. Worldwide, there are more people who have access to a cellular network than to running water or electricity. The industry has proved to be a highly competitive environment where investments continue to improve coverage while ensuring an enhanced and affordable user experience. A 2010 poll has shown that about 70% of people worldwide are interested in mHealth applications, and are willing to pay for them¹². There is therefore less of a need to build devices from scratch – the smartphone platform is becoming a more attractive and popular way to build.

FACING ESTABLISHED DEMOGRAPHIC TRENDS

The age structure of the European population will change dramatically in the coming decades. While in proportion people aged 0-14 will remain fairly constant by 2060 (around 15% of the population) and those aged 15-64 will decrease (from 67% to 56%), people aged 65 and over will become a much larger share (from 18% to 30%) and those aged 80 and over (from 5% to 12%) will be almost as many as the younger age segment¹³. This means that healthcare expenditure is expected to grow to 8.5% of GDP in 2060 (from 7.2% in 2010) as a result of demographic ageing alone, and to higher levels if additional factors are taken into account.

Europe needs to ensure that healthcare systems keep pace with the changing healthcare challenges. The pervasiveness and economies of scale of the mobile computing platform can enable more low-cost and personalised healthcare. mHealth technologies, sustained by a solid healthcare information system backbone, can replace the static, high-cost rescue and disaster-recovery model that too often typifies chronic disease care with an iterative course-correction model that is better suited to manage diseases and help avoid expensive complications.

MODERNISING AND IMPROVING EFFICIENCY OF HEALTHCARE DELIVERY

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

The anywhere/anytime availability of information on patients enabled by the mobile platform, including medical history, past diseases and interventions, allergies and reaction to medications, is a key component in increasing the efficiency and quality of healthcare management: better management of medical data, faster access to data, faster communication between patients and healthcare professionals, reduction of unnecessary visits to hospital and immediate alerts in case of deterioration.

¹¹ ITU Statistics, Global ICT developments 2001-2013.

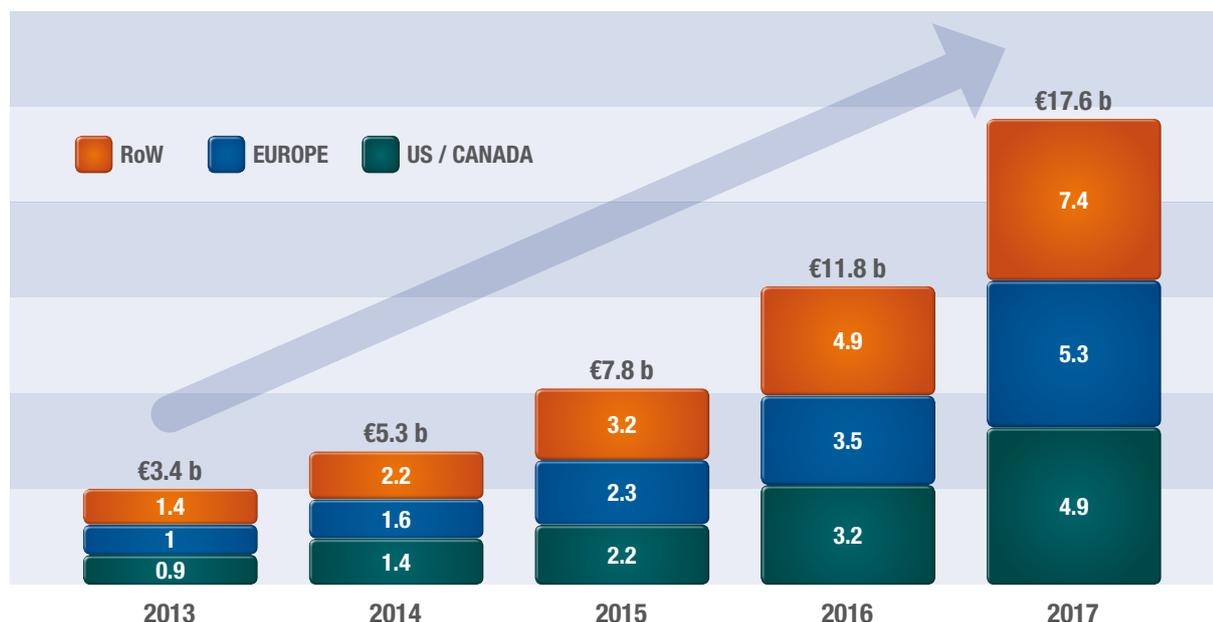
¹² Pyramid Research (2010), Health check: key players in mobile healthcare

¹³ DG ECFIN and AWG (2012), The 2012 ageing report: economic and budgetary projections for the 27 EU Member States (2010-2060).

HOW BIG IS THE mHEALTH MARKET?

An analysis conducted jointly by GSMA and PwC anticipates that the global market for mHealth will reach the equivalent of €17.6 billion in five years, with Europe and the Asia-Pacific (approximately €5.4b or 30% each) leading over the North American market (28%)¹⁴. Previously, Frost & Sullivan calculated in 2008 that the European mobile and wireless healthcare technologies market was worth just over €1 billion at the time¹⁵.

FIGURE 3 - ESTIMATED mHEALTH REVENUE, 2013-2017



Sources: Commonwealth Fund, 2009; CSC, PhRMA, ANA, AHA, 2011; Deloitte, CMS, 2012; GSMA 2012

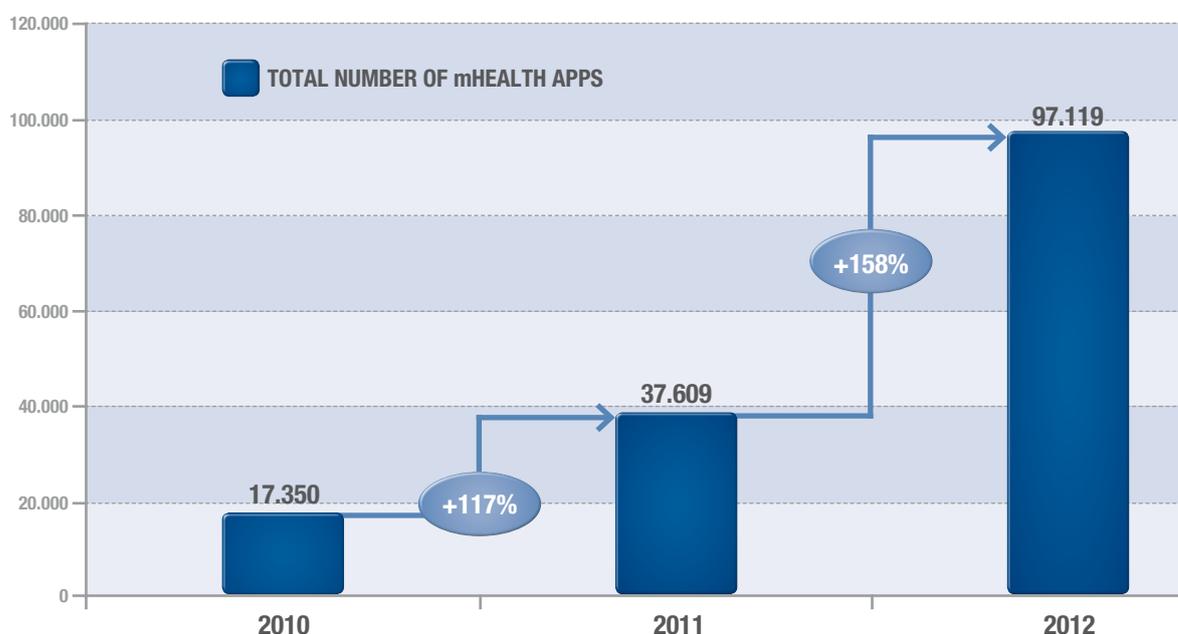
One thing that the Frost & Sullivan analysis could not factor in is the advent of mobile applications (or apps), i.e. software applications designed to run on smartphones and tablets, that have exploded in more recent years and have been a key driver of mHealth facilitated by smartphone penetration, a shift towards a more patient-centric care model and patient demand. Research2Guidance estimates that as of 2012 there were more than 97,000 mHealth applications across all app stores (including Android, iOS and Windows Phone) that have generated millions of free and hundred thousands of paid downloads –comparatively, there were only 17,000 in 2010¹⁶. They include apps for fitness and nutrition (38%), health tracking (21%), wellness (13%), continuing medical education (6%), medical reference (5%), alerts and diagnosis (1-2%), among others. The research shows that currently as many as 60% of healthcare professionals and 52% of patients in developed countries are using mHealth applications.

¹⁴ GSMA and PwC (2012), Touching lives through mobile health: assessment of the global market opportunity. The mobile health market calculated in this study includes charges paid for mobile calls, data connectivity, value-added services, licence/usage fees for applications and special devices with mobile connectivity (e.g. for monitoring). It does not include expenditure on mobile phones and services that are not closely associated with healthcare but can be used in other industries as well.

¹⁵ Frost & Sullivan (2008), Mobile/wireless healthcare technologies in Europe. The mobile and wireless healthcare technologies market calculated in this study includes mobile infrastructures, software applications, client software, devices and services developed for healthcare.

¹⁶ Research2Guidance (2013), The mobile health global market report 2013-2017: the commercialisation of mHealth apps (Vol. 3).

FIGURE 4 - GROWTH OF mHEALTH APPS BETWEEN 2010 AND 2012



Source: Research2Guidance, 2013

While the general sophistication of today's mHealth apps is still low to medium, there are many examples of advanced solutions. Some of these were identified in the first European Directory of Health Apps, which contains facts about 200 mHealth apps recommended by European patient groups¹⁷. The most cited app specialisations include communication disability, diet, medication reminders, diabetes, cancer (e.g. symptoms, diary), exercise, deafness, visual impairment and mental health. The survey shows that out of the 200 listed apps 41 are also available in French and Spanish, 39 in German, 33 in Italian, 24 in Dutch, 16 in Swedish, 15 in Danish and 14 in Portuguese, among others.

Interestingly, solo developers and small companies app innovation has been fuelled. 30% of mobile app developer companies are individuals, while 34.3% are small companies (defined as 2-9 employees)¹⁸. The fact that nearly two-thirds of all mobile apps are developed by individuals or small companies shows the potential for European SMEs and European competitiveness in this fairly new industry.

BARRIERS HINDERING THE DEVELOPMENT OF mHEALTH

While the potential benefits of mHealth are enormous, a number of barriers continue to hinder its full deployment.

INSUFFICIENT AWARENESS AND CONFIDENCE

Consistent evidence tells us that, at the very least, eHealth does not diminish the quality of healthcare, although not all conditions benefit from eHealth solutions in the same way. Indeed, evidence on impacts is overwhelmingly positive, resulting in fewer emergency admissions, hospitalisations and bed days per intervention as well as reduced mortality, sometimes dramatically and beyond expectations¹⁹.

¹⁷ PatientView (2012), European Directory of Health Apps 2012-2013: a review by patient groups and empowered consumers.

¹⁸ IDC (2011), Worldwide and US mobile applications, storefronts, developer, and in-app advertising 2011-2015 forecast: emergence of postdownload business models.

¹⁹ JRC-IPTS (2012), Strategic Intelligence Monitor on Personal Health Systems phase 2 (SIMPHS 2): evidence consolidation – report on best practices and key drivers of success.

Many medical professionals, however, are not yet convinced of the benefits of eHealth and mHealth, and tend to be particularly sensitive about the availability of health information to their patients. Many clinicians and healthcare authorities partially question the economic evidence and do not trust eHealth and mHealth to support and improve the delivery of quality healthcare.

SLOW DIGITISATION AND HEALTH INFORMATION EXCHANGE

While medicine keeps progressing, the way it is delivered and administered needs to transform. In 2013, modern medicine still relies heavily on paper systems, rooted in manila folders and administered through manual entry of patient data. The often forgotten casualty is the patient, who continues to have little access, if any, to relevant data, electronic health records and ongoing instructions from their clinicians, care providers or hospital. As of April 2011, only 4% of European hospitals allowed patients online access to their electronic health records (EHRs), and only 11% offered online booking options; ePrescription services were offered by 30% of hospitals, but only 29% of these connected to pharmacies outside the hospital²⁰. This exposes healthcare systems to delivery risks, reduced patient choice and wasted resources.

MARKET FRAGMENTATION

Fragmentation is preventing scalable deployment of mHealth services. Many markets are still grappling with the creation of locally integrated eHealth systems, mostly at regional level, while developers are required to duplicate work on a variety of legacy platforms to cater for the different choices made by different healthcare organisations. Telehealth solutions, in particular, remain in the domain of pilot projects and are not integrated into clinical practice, including for billable services (reimbursement, billing code, incentives based on outcome, etc.).

DATA PROTECTION REGIMES

mHealth service providers need to comply with the Data Protection Directive for the collection, processing and storage of patient data. This Directive 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 hampers the use of mHealth, reduces the dimension of the addressable markets and substantially increases compliance costs for mHealth service providers.

BUDGET RESTRICTIONS

The current austerity climate forces healthcare organisations to postpone, if not abandon, the adoption of innovative technologies that are perceived purely as an unnecessary cost in the short term. Regrettably, this has very direct repercussions on citizens and the availability of quality healthcare services.

²⁰ Deloitte and Ipsos Belgium for DG INFSO (2011), eHealth benchmarking (Phase III).

COCIR RECOMMENDATIONS

Improving healthcare delivery is a priority that can be achieved in large part through the use of mobile broadband technology. COCIR has started to collect case studies of successful mHealth deployment in Europe (refer to Annex) and will continue to work with policy makers and with all other public and private sector stakeholders to ensure that mobile broadband technologies, devices, services and applications are used to improve the delivery of healthcare. To this end, COCIR is putting forward the following key recommendations.

1. INTEGRATE MHEALTH INTO HEALTHCARE DELIVERY STRUCTURES

mHealth, like eHealth, should not be considered as an addition to traditional healthcare but should be thought of as a natural evolution of healthcare delivery, allowing existing services to be better coordinated along the continuum of care. This requires careful planning, effective procurement processes and ongoing training of medical staff²¹.

COCIR encourages committed and integrated governance structures for the deployment of mHealth solutions that can engage and mobilise all stakeholders in the transformation process.

2. ENABLE CITIZENS' ACCESS TO THEIR DATA

Encouraging a proactive technology pull by users, rather than just a push by suppliers and providers, is required for innovative technologies to have maximum transformational effect in healthcare. However, the ability of citizens to engage with their health remains extremely limited. The market for mHealth apps that provide access to patient data and associated services, most notably, is not as developed in Europe as it is in the US – where EHRs are often accessed via smartphones or, increasingly, tablets by both patients and healthcare professionals – and the percentage of users downloading health-related applications is significantly smaller in Europe vis-à-vis the US²².

COCIR encourages the adoption of interoperable EHRs across Europe so as to enable citizens' full secure access to their medical information and associated services. COCIR also encourages the European Commission to advance on the Transatlantic eHealth/health IT Cooperation Roadmap.

3. DEVELOP APPROPRIATE REIMBURSEMENT STRATEGIES

Although the market for mHealth seems to be bridging the gap between institutional healthcare and the consumer electronics model, whereby people are willing to pay out-of-pocket for some healthcare services, mHealth cannot and will not become part and parcel of the existing healthcare delivery structure if there is no clear understanding of 'who invests and who pays'. A dialogue on how to finance and reimburse the adoption of these technologies has been initiated, but it is still in the starting blocks and needs to be taken forward.

COCIR encourages coherent Member State policies that can integrate mHealth services into ordinary reimbursement mechanisms. This might require the involvement of new, important players such as insurance companies.

²¹ For examples of consistent and systematic planning processes for eHealth investments and successful procurement, see ECHAlliance and empirica (2012), ProeHealth: study on enhancing procurement of ICT solutions for healthcare.

²² Juniper (2010), Mobile healthcare opportunities: monitoring, applications & mHealth strategies 2010-2015.

4. ESTABLISH A HARMONISED DATA PROTECTION REGIME THAT ENABLES INNOVATION

Timely and optimal healthcare depends on the availability of comprehensive health data at the point of care and throughout the healthcare cycle. While the protection of individuals' personal data is paramount, the quality, safety and continuity of healthcare must not be jeopardised by over-restrictive data protection measures.

COCIR supports a revised data protection framework – including Member State legislation – that balances the need for safety and privacy while allowing for agile, accelerated innovation²³.

5. SUPPORT MOBILE BROADBAND POLICIES THAT SUSTAIN INVESTMENT IN CONNECTED DEVICES

Communication and data transfer for businesses, public organisations and citizens alike need reliable, robust and high-capacity networks. Ubiquitous high-speed wireless broadband data networks are at the heart of the mHealth reality; they are crucial for the emergence and delivery of new, advanced applications that can play a key role in health-critical situations – the availability of mobile broadband and investments in next-generation networks, providing a guaranteed quality of service, are therefore key enablers for high-bandwidth mHealth applications.

COCIR supports a harmonised and comprehensive approach to mobile broadband use in the EU that ensures sufficient resources are timely freed up for the provision of next-generation private and public services. Such an approach will be vital to create scale around new, innovative services and business models in the mHealth arena.

6. PROVIDE CLEAR AND SIMPLE REGULATORY GUIDANCE FOR mHEALTH

mHealth is still a relatively new market. The explosion of mHealth apps for both consumer and professional use, moreover, shows that many small businesses are part of this new ecosystem alongside more established market players. It is therefore important that regulation, particularly in the app space, does not inhibit the development of new solutions while also protecting the safety and trust of users. An approach which is too restrictive, for example on medical purpose, would deter innovation while failing to provide benefits to consumers and healthcare professionals. Apps that relate to the general health and wellbeing of the individual and involve non-invasive monitoring, e.g. of monitoring calorie intake, should not require regulation.

COCIR welcomes the European Commission's upcoming initiatives to clarify the regulatory environment for medical apps. The Commission's guidance should be clear and simple in order to facilitate both compliance and take-up.

7. FOSTER THE USE OF WIDELY RECOGNISED INTERNATIONAL STANDARDS

Standards, profiles and specifications allow a common definition of data and data exchange formats that is essential to enable interoperability at the technical, semantic and organisational levels. As widely recognised standards (e.g. HL7 and SNOMED CT) and profiles (e.g. IHE and Continua) continue to grow geographically, a broader network of consistent communications can enable integrated healthcare delivery while the need for regulation is reduced.

COCIR welcomes the implementation of international standards and profiles. Market-driven standards – or the use of existing standards – should be supported while avoiding strict technology mandates.

²³ Joint statement of the Healthcare Coalition on Data Protection, 'Benefits of data processing in healthcare and medical sciences while protecting patients' personal data', 29 January 2013

ANNEX: CASE STUDIES

BUONGIORNO CReG, LOMBARDY (ITALY)

The northern Italian region of Lombardy launched in 2011 a large-scale initiative named Chronic Related Group (CReG) to better coordinate its management of patients with chronic diseases, both inside and outside the hospital, in five local health units in Milan, Bergamo, Como and Lecco. In this context, three GP associations have developed the 'Buongiorno CReG' project to support doctors in implementing new telehealth solutions for monitoring their patients in an accurate, reliable and cost-effective manner.

'Buongiorno CReG' has created a secure, cloud-based remote monitoring solution for over 300 general practitioners and 37 000 patients living with one or more chronic diseases such as diabetes, chronic obstructive pulmonary disease (COPD), hypertension and chronic heart failure.

Each chronic disease requires multiple devices and data points for complete monitoring of factors contributing to a patient's overall health. Prior to the project, these data points were collected via several different streams, all requiring their own back-end connectivity strategies, as well as multiple software solutions in order to capture the data being pulled. Using the Bluetooth, Bluetooth Low Energy, Wi-Fi, and ANT+ WLAN radio protocols, the service now collects biometric data from the various devices via a single gateway and protocol system; the data is then transferred to a single data centre utilising redundant, private connections over the mobile network and transferred back to GPs and patients via a user-friendly Web interface.

Family doctors now have a single touch point for access to all the data captured across multiple devices and are thus able to track the health of patients with chronic diseases – including treatment and medication compliance – in a more consolidated and streamlined way that allows them to consult patients remotely, personalise treatment, ask for specialist advice if necessary and act promptly in case of an emergency. 'Buongiorno CReG' also provides education and empowerment tools and a proactive service centre.

VALCRÒNIC, VALENCIAN COMMUNITY (SPAIN)

The Valencia autonomous region launched in March 2012 a system to monitor chronic patients, reduce expenses caused by readmissions, slow disease progression and enhance self-care and active participation of both patients and their families. The programme, named Valcrònic, was initially piloted in the two health departments of Elche and Sagunto and aimed to improve the quality of care for up to 12 000 individuals with chronic diseases such as diabetes, COPD, heart failure and hypertension.

Valcrònic uses devices in patients' homes to obtain biomedical information that is then transferred to healthcare professionals via tablets or smartphones. Patients included in Valcrònic receive a number of devices such as blood pressure monitors, scales, pulse oximeters and glucometers with which they take daily readings that are transmitted to tablets via Bluetooth and subsequently sent to primary care doctors and nurses. Healthcare professionals have thus access to a total of 18 parameters through which they can act quickly to prevent deteriorations of health status based on the patients' conditions.

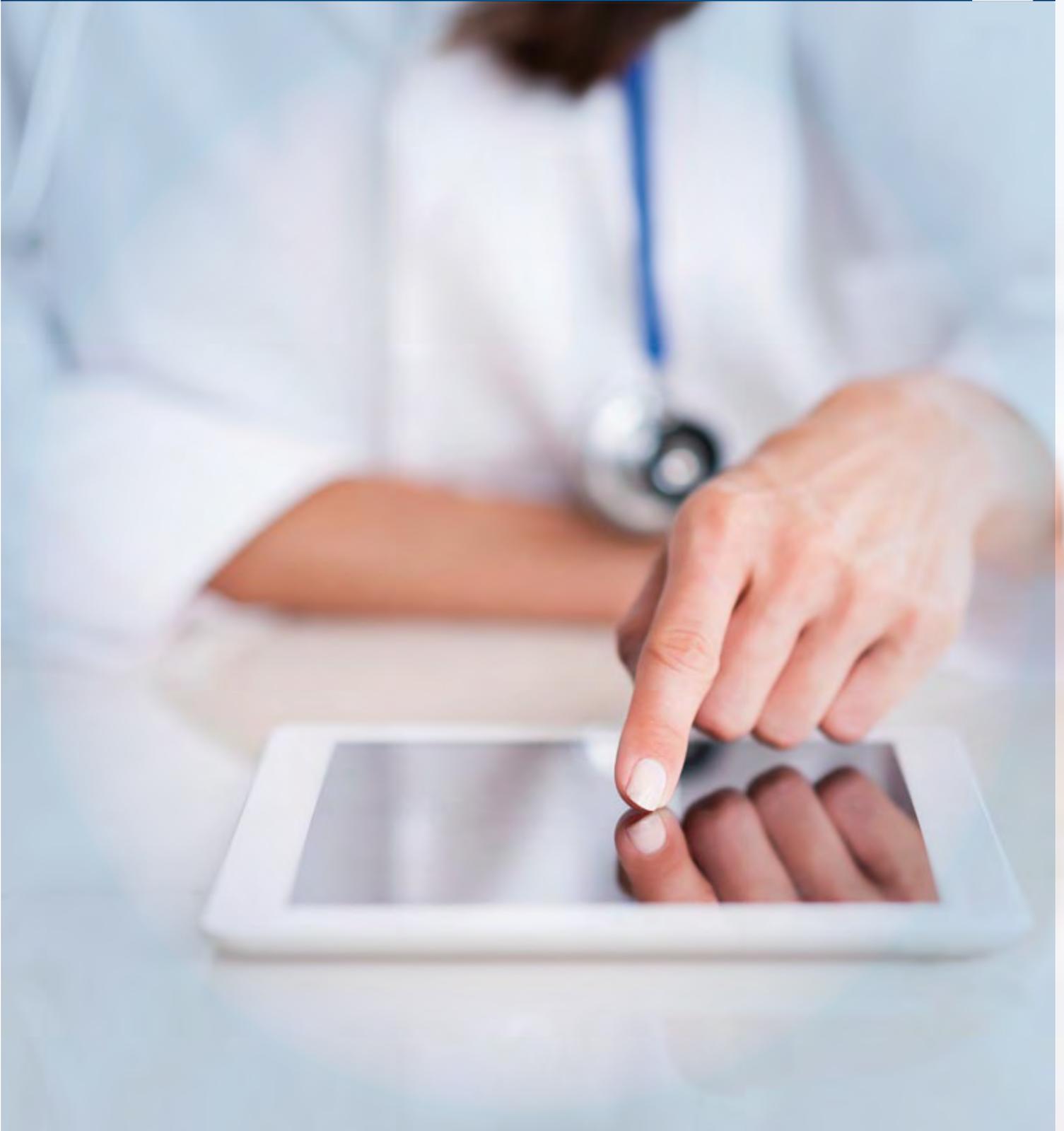
According to data from the Valencian Health Council, implementations in the first health centres have resulted in a significant decrease in hospitalisations and visits to the emergency room from chronic patients, who generated 80% of visits prior to the pilot. Operating data for new health centres will soon be analysed with a view to studying a possible extension of the initiative to other areas in the Community, which is home to more than 148 000 patients who are subject to more than ten different treatments, as well as about 1 700 who receive up to twenty²⁴.

²⁴ Press release, 'El centro de salud de Santa Pola implanta el programa de gestión de enfermos crónicos, VALCRONIC', 18 April 2012



COCIR RECOMMENDATIONS ON INTEROPERABILITY

4



PART 4 COCIR RECOMMENDATIONS ON INTEROPERABILITY²⁵

4

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eHealth 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 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**

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

²⁵ More detailed information also published in COCIR ehealth toolkit edition 2012 (part 3 and 4)

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

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 benefit 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 reflected 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 finds the term that best reflects the information he wants 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 difficult 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.

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 cases²⁶:*

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

Our observations 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 uncertainty²⁷.

3. FOSTER USE OF INTERNATIONAL STANDARDS AND MARKET FOCUSED PROFILES

COCIR welcomes the Digital Agenda objective to foster EU-wide standards²⁸ 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)²⁹*
- *Standards and profiles be available on FRAND (fair, reasonable and non-discriminatory) terms to facilitate adoption*

²⁶ See definitions in annex

²⁷ See COCIR Position paper on the privacy and protection of health data for more information.

²⁸ Digital Agenda: Foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015, through stakeholder dialogue, page 30.

²⁹ In line with HITC <http://www.hitc-project.eu/> and M403 phase I recommendations <http://www.ihe-europe.net/drupal/sites/default/files/final%20report%20eHealth.pdf>.

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 Network³⁰ etc. Unfortunately, local eHealth actors are not well-informed on these initiatives and tend to build local eHealth programmes in isolation.

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 an 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).*

A standard common clinical data structure is also needed to imbed the coded data in a semantically meaningful system (e.g. CDA³¹).

³⁰ 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.

³¹ CDA: Clinical Document Architecture

LEGAL AND REGULATORY TRENDS

5



PART 5 LEGAL AND REGULATORY TRENDS

5

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DATA PROTECTION REGULATION



COCIR supports an effective, clear and reliable data protection framework and welcomes the intent to harmonise the legal framework at European level through the adoption of an EU regulation. COCIR also recognises considerable improvements in the provisions for data concerning health. However COCIR recalls that quality healthcare depends on the availability of comprehensive health data at the point of care and throughout the healthcare cycle. COCIR feels some provisions of such EU regulation could restrict the availability of health data, delay innovation, create legal uncertainty and increase compliance costs. COCIR therefore recommends that the following aspects of the regulation be considered.

COCIR'S MAIN RECOMMENDATIONS TO IMPROVE THE GENERAL DATA PROTECTION REGULATION:

- 1. CLARIFY DEFINITIONS** (Art. 4): The use of anonymised and pseudonymised data by the healthcare and research sectors should be facilitated by the Regulation. Article 4 should define these terms and explicitly clarify that anonymised data are not personal data and are not subject to the Regulation. The provisions on pseudonymised data should take context and the likelihood of re-identifying a data subject into account, and provide incentives to data controllers to pseudonymise data.
- 2. MAINTAIN CLEAR AND SEPARATE RESPONSIBILITIES BETWEEN THE HEALTHCARE PROVIDER AND THE MEDICAL TECHNOLOGY PROVIDER**, as per the current regime (Art. 28- 33- 34- 77). The relationship between the healthcare provider and the medical technology provider should be managed by contract, not by law.
- 3. REDUCE ADMINISTRATIVE BURDEN** (Art. 26): In an environment where outsourcing is part of the business model and care delivery, seeking approval of the healthcare provider before enlisting other medical technology providers generates administrative burden on both sides, without bringing benefits to privacy.
- 4. ALLOW PROCESSING OF DATA CONCERNING HEALTH BY MEDICAL TECHNOLOGY MANUFACTURERS FOR MAINTENANCE AND EQUIPMENT PERFORMANCE EVALUATION PURPOSES** (Art. 81 - 83): Professionals employed by medical technology manufacturers (technicians, engineers, medical professionals), should be able to access data concerning health for technical maintenance and equipment performance evaluation.

DETAILED BRIEFING

COCIR believes the following provisions could be improved to add legal clarity, legal certainty and ensure feasibility in a healthcare environment.

The following detailed briefing includes additional information substantiating the four main recommendations (Part A) articulated above as well as ten secondary recommendations (part B).

A COCIR MAIN RECOMMENDATIONS

1. CLARIFY DEFINITIONS (ART. 4)

The proposed definitions for 'Personal Data' and 'Data Concerning Health' are too broad. For instance the serial number of a medical device may be considered 'data concerning health' although it is associated with a medical equipment and not with a data subject.

The Regulation should provide a definition for anonymised and pseudonymised data.

COCIR PROPOSES THE FOLLOWING DEFINITIONS:

- **'Anonymised data'** means personal data that have been modified in a way that the information can no longer be attributed to an identifiable, natural person. Accordingly, anonymised data are not personal data and should be explicitly excluded from the scope of the Regulation in article 4, as recognised in recital 23.
- **'Pseudonymised data'** means any personal data that have been altered so that it cannot be attributed to a data subject without the use of additional data which is subject to separate and distinct technical and organisational controls to ensure such non-attribution. The use of pseudonymised data is very important in healthcare. Below are a few concrete examples where pseudonymised data are used to improve the quality of care, with no risk to patients' privacy:
 - > **In radiology:** A radiologist collects images from a patient in a longitudinal study and sends the data to a medical device manufacturer for analysis and development of algorithms (e.g. tumor detection). The manufacturer runs the new enhanced algorithms and asks the radiologist to compare the new algorithms performance with the old on a patient-by-patient basis (e.g. not on an aggregated basis). The manufacturer reports the new algorithms results using the pseudonyms supplied by the radiologist.
 - > **In hospital care:** The pseudonym (e.g. a bed number) is used to collect and collate data from different sources: patient monitors, laboratory data, nurses notes, and data collected from a centralised patient data collection and analysis workstation in an intensive care unit, etc. in the development of CDS algorithms for predicting patient outcomes.
 - > **In homecare:** Data collected at a person's home in a longitudinal study is used to predict readmission (e.g. in COPD patients). The pseudonym is used to collect and analyse a single person's data over time.

Under the proposed regulation, data controllers have no incentive to pseudonymise data since the pseudonymised data, would be subject to obligations under the Regulation. Data pseudonymisation provides clear safeguards to significantly diminish the likelihood of re-identifying a data subject. The regulation should alleviate some of the obligations imposed on data controllers with respect to pseudonymised data, in order to create an incentive to implement this type of protection.

2. MAINTAIN CLEAR AND SEPARATE RESPONSIBILITIES BETWEEN THE HEALTHCARE PROVIDER (DATA CONTROLLER) AND THE MEDICAL TECHNOLOGY PROVIDER (DATA PROCESSOR) (ART. 24-26-77)

The new obligations on processors create confusion around responsibility between healthcare provider (data controllers) and medical technology provider (data processors).

Responsibilities and liabilities between the controller and the processor need to be handled through contractual arrangements, not through law.

COCIR recommends keeping the approach of the existing legal framework in Directive 95/46/EC. This would promote clarity as well as better enforcement from the point of view of the relationship with supervisory authorities.

3. REDUCE ADMINISTRATIVE BURDEN WHEN ENLISTING A SUB-PROCESSOR (ART. 26)

Requiring each Data Controller (e.g. a hospital) to agree to each sub-processor enlisted by a Data Processor (e.g. eHealth service provider) introduces an excessive administrative burden and increases costs for both the Data Controller and Data Processor. COCIR recommends keeping the existing legal framework in Directive 95/46/EC. Responsibilities and liabilities between the controller and the processor should be handled through contractual arrangements, not through law.

4. ALLOW PROCESSING OF DATA CONCERNING HEALTH BY TECHNICIANS FOR TECHNICAL MAINTENANCE AND EQUIPMENT PERFORMANCE EVALUATION (ART. 81-83)

Article 81 provides that data concerning health may be processed by a healthcare professional or a professional with an equivalent obligation of professional secrecy.

It is not clear whether this provision covers technicians and engineers employed by manufacturers, who may have access to Data Concerning Health when maintaining medical systems, either onsite or remotely. The regulation should clarify that professionals who have signed a commitment of secrecy by contract with their employer qualify as '*professionals with an equivalent obligation of professional secrecy*'.

The proposed exemption for processing data concerning health in article 83 does not seem to take into account registry studies for the improvement of medical devices or medical services effectively making it impossible for companies to meet regulatory requirements under the medical devices Regulation. The regulation should clarify that the processing "for historical, statistical or scientific research purposes" in the meaning of Article 83 includes processing for the purposes of the manufacturer's regulatory pre- and post-market obligations with respect to clinical evaluation of a medical device, by clear guidance³².

³² This concern falls if anonymised data are not subject to the Regulation

B COCIR SECONDARY RECOMMENDATIONS

1. EXTEND THE EXEMPTION TO THE RIGHT TO BE FORGOTTEN TO HEALTHCARE (ART. 17)

Implementing the right to be forgotten in healthcare requires careful consideration of the consequences. Deleting data from an electronic health record can run counter to patient safety, public interest, healthcare research and eHealth deployment. Medical records, patient registries and other clinical databases should be exempted from the right to be forgotten.

2. ALLOW THE SECONDARY USE OF ANONYMISED AND PSEUDONYMISED DATA FOR HEALTH PURPOSES (ART. 20)

The text of Article 20 might render legitimate use of data for health research impossible or extremely difficult, with great consequences for the social benefits in this area. COCIR recommends deleting Article 20 or reverting to the language currently used in Article 15 of Directive 95/46/EC³³.

3. DELETE 'PRIVACY BY DESIGN' AND 'PRIVACY BY DEFAULT' OBLIGATIONS (ART. 23)

Although COCIR supports imbedding privacy and data protection features in products and services from the onset, we are concerned that 'Privacy by Design' and 'Privacy by Default' mean different things for different people. The intent of both is already reflected in the Regulation through new requirements: data protection impact assessment, data minimisation, etc. COCIR feels these concepts are superfluous and should be deleted.

4. CONSIDER CONTEXT AND FEASIBILITY FOR DATA BREACH NOTIFICATIONS (ART. 31 - 32)

The definition of 'breach' and associated notification requirements, especially the concepts of 'reasonable timeframe' and 'mitigating effects of safeguards' and 'potential for harm/adverse impact' pose issues of practicability in a real world environment. Industry would greatly benefit from a more pragmatic and proportional approach. A two-step approach could be considered for the notification of the breach, and the submission of the requested documentation within a longer time frame. This would allow more time for a qualitative impact assessment, and efficient corrective and mitigation actions.

5. ENSURE DATA PROTECTION IMPACT ASSESSMENTS AND PRE-AUTHORISATION OBLIGATIONS TAKE ACCOUNT OF THE CONTEXT AND ARE NOT 'ONE SIZE FITS ALL' (ART. 33- 34)

Data Protection Impact Assessment should not be mandatory, and should be relative to the scope and types of processing activities, and based on a well-defined category of "high-risk" activity. Organisations should be able to construct their own assessment, based on their specific type of organisation, legal requirements, contractual obligations, and, where appropriate, internal policies.

Prior consultation should not be needed when processing is based on consent or contract. Where approval is required (Article 34), a clear time line for the approval should be clarified prior to effective dates.

6. KEEP CERTIFICATION INDUSTRY LED AND VOLUNTARY FOR MORE EFFICIENCY (ART. 39)

Certification mechanisms and data protection seals and marks developed and managed by industry should be favoured. They should remain voluntary rather than mandatory and COCIR recommends the adoption of existing internationally recognised standards (e.g. ISO/IEC 27001) rather than developing new certification mechanisms. COCIR also recommends removing paragraphs 2 and 3 on delegated and implementing acts in Article 39.

³³ This concern falls if anonymised data are not subject to the Regulation.

7. RECOGNISE COMPLIANCE WITH NON-EU FRAMEWORKS, E.G. HIPAA PRIVACY AND SECURITY RULES IN THE U.S., AS ADEQUATE SAFEGUARD FOR TRANSFERRING DATA BEYOND EU BORDERS (ART. 42)

Many COCIR members have a strong presence outside of Europe (e.g. in the USA), and have invested in processing capabilities there. Transfer of health data to the USA should be allowed under the HIPAA rules which provide safeguards for privacy. The transfer of anonymised and pseudonymised data should not require further authorisation or consultation where the recipient does not reasonably have access to the key, and contractual or legal restrictions prohibit re-identification of the data subjects.

8. ALLOW THE TRANSFER OF ANONYMISED, PSEUDONYMISED AND ENCRYPTED DATA TO A THIRD COUNTRY, WITHOUT FURTHER REGULATORY AUTHORISATION, WHERE RE-IDENTIFICATION IS NOT POSSIBLE (CHAPTER V)

Anonymised data which are not personal data and pseudonymised data which do not reasonably permit re-identification of a data subject, and encrypted data³⁴ which do not permit understanding of the information, are central to many data processing operations. Responsible data controllers and processors have invested heavily in a raft of data processing techniques to prevent the identification of data subjects and protect user/patient privacy. For example, reasonable controls are implemented by data controllers to prevent the recipient from obtaining access to encryption keys, and/or, contractual restrictions are implemented to prohibit re-identification of the data subjects. These efforts should be recognised and encouraged. The transfer of data that are subject to the above protective measures and techniques should therefore not require additional or further authorisation or consultation.

9. TO INTRODUCE PROPORTIONALITY TO ADMINISTRATIVE SANCTIONS (ART. 79)

COCIR recognises the need for credible enforcement mechanisms, specifically sanctions and fines, but notes that the current proposal lacks proportionality. This may result in making the EU less competitive in attracting investment in facilities or services. Furthermore some terms would need a clear definition to be implementable, e.g. 'incomplete information', 'insufficiently transparent', etc.

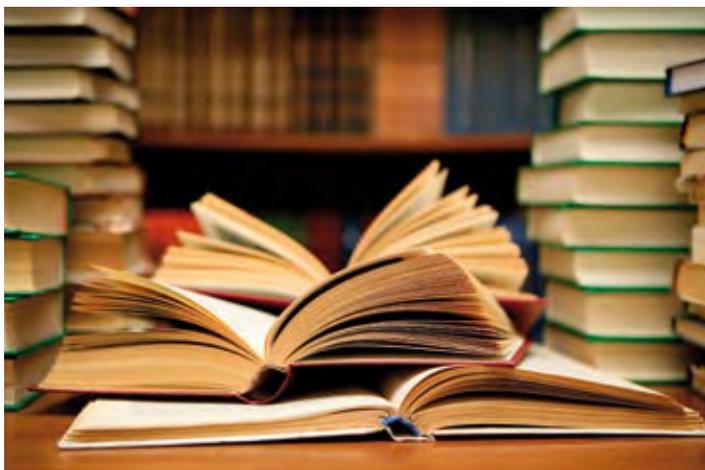
10. LIMIT THE NUMBER AND SCOPE OF DELEGATED ACTS FOR MORE LEGAL CERTAINTY

The number and scope of delegated acts undermines the legal certainty of the Regulation. The number should be reduced and clear timelines introduced for those remaining.

- The categories of recipients of health data should not be determined by delegated acts, but by healthcare organisations (Art. 14.7).
- The legal framework should be fully harmonised to avoid conflicting provisions between the Regulation, delegated acts and national law (Art. 81.1).
- Measures, criteria, requirements, etc., provided for by delegated acts (Art.81.3) should be technology, service and business model neutral and industry-based.

³⁴ Encrypted data are information that has been transformed and made unreadable by the use of algorithms. Only those with the key can decrypt the data

REGULATORY TRENDS ON MEDICAL SOFTWARE



Considering technology is evolving so fast, this requires a regulatory framework commensurate with the high level of innovation and complexity in products and services. The current regulatory system must evolve fast to avoid unhealthy friction with the healthcare needs.

Solutions provided become more complex, more integrated and increasingly medical equipment is being controlled by software, almost to the extent that medical devices are software. This requires more specific attention from regulators to software, its development and validation in order to bring more safety, highest quality while increasing access to healthcare in a cost efficient way.

The explosion of mHealth apps for both consumer and professional use, moreover, shows that many small businesses are part of this new ecosystem alongside more established market players. It is therefore important that regulation does not inhibit the development of new solutions while also protecting the safety and trust of users.

COCIR calls for a supportive regulatory system, predictable and cost-efficient to consolidate the EU leadership position in medical device innovation and give patients rapid access to healthcare

CURRENT REGULATORY FRAMEWORK FOR MEDICAL SOFTWARE IN EUROPE

The medical devices are regulated through a number of New Approach Directives such as:

- 93/42/EEC, Medical Devices Directive
- 90/385/EEC, Active Implantable Medical Devices Directive
- 98/79/EC, In Vitro Diagnostic Medical Devices Directive

which were transposed under National Laws in European countries after their adoption at European level.

Through the EU Directive 2007/47/EEC enforced in March 2010 at national level in all EU Member States, the definition of medical devices was amended to include also stand-alone software.

Because of the unclear situation for several stand-alone software and because of the non uniform interpretation on why certain software is a medical devices in some, but not in other European Member States, the European Commission created a sub-group in December 2009 with the objective to establish a EU guideline on medical software to determine how and whether a software is a medical device or not.

This guidance document is aimed at bringing some clarity for manufacturers, organizations and public authorities in Europe. This guidance started on the basis of a Swedish draft guideline. This European guidance MEDDEV 2.1/6³⁵ published in January 2012 is titled "Guidelines on the qualification and classification of standalone software used in healthcare". The purpose of this non-binding European guidance document is:

- To clarify the relevant criteria for qualification of standalone software that is a medical device, and the application of classification criteria for such software,
- To help manufacturers, health care providers and other interested parties to better understand what determines a standalone software as a medical device
- To harmonise the interpretation of the regulatory requirements for standalone software.

Such guidance document is being further discussed since 17 April 2013, as there is a need for additional updates based on fast evolving technologies.

³⁵ http://ec.europa.eu/health/medical-devices/files/meddev2_1_6_of_en.pdf

On 26 September 2012, the European Commission adopted a Proposal for a Regulation on medical devices and a Proposal for a Regulation on in vitro diagnostic medical devices which will, once adopted by the European Parliament and by the Council, replace the existing three medical devices directives listed above. This new regulation is planned to be adopted by 2015-2016. So far, no new specific requirements are foreseen for medical software, besides the existing European guidance document. A lot more can be done. The classification rules for example were made with hardware in mind and don't apply well to software. This leads to disparate product classifications and creates difficulties at tender level.

Despite the existence of the European Guidance document mentioned above, **some European countries** have decided to develop specific documents/regulations in order to clarify some aspects of medical software.

FOR EXAMPLE:

IN SWEDEN: the Medical Products Agency published in April 2013 a guideline reflecting many of the questions that they received over the last couple of years. And which is intended to clarify the status of some products that are available on the Swedish market.

Refer to <http://www.lakemedelsverket.se/english/product/Medical-devices/>

IN BELGIUM: a royal decree was published on 24 December 2012 to reduce the amount of severe consequences due to dangerous practices involving individualized medication preparation. Part of the decree discusses automated individualized medication preparation involving computer systems. It contains among others requirements on minimum information the pharmacist should provide to the patient, and on how to deal with changes of medication.

See page 59890: http://www.ejustice.just.fgov.be/mopdf/2012/09/28_3.pdf#Page28

IN FRANCE: Article L.151-38, II of the French Code of Social Security (29 December 2011, aka HAS law) was published. It applies to medication prescription software. Not in scope, but envisaged for the future: administration and dispensation software. ANAP is planning to develop standards focusing on:

- Interoperability with other modules of HIS and electronic health record. Aim is to improve safety, performance, usability, cost of prescription. It takes into account diversity of medical practices (pills, injections, sub-cutaneous administration, dosages in terms of drops, spoons, milligrams, ...)
- Traceability

COCIR welcomes the European Commission's upcoming initiatives, including further consultation expected soon with the GREEN PAPER to clarify the regulatory environment for medical software and in particular Medical Apps. The Commission's guidance should be clear and simple in order to facilitate both compliance, fair competition and take-up.

UPDATES ON REGULATORY STATUS FOR MEDICAL SOFTWARE OUTSIDE EUROPE

Several other geographies have started some regulatory initiatives such as in **Japan**, in **Canada**, in **China** and in the **USA**.

IN CANADA:

Canada explicitly recognizes that software can be a medical device (refer to http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logiciels-eng.php).

Canada has released and is enforcing their new guidance document. It clearly indicates that they consider it possible for software to be a medical device.

It classifies these devices based on their classification rules:

- Class II Software required a license by September 2011 and Class I software by February 2011
- Any patient management software used only for storing, acquiring, transferring or viewing data, or images is considered a Class I medical device

- Any patient management software with capabilities beyond basic data visualization, acquisition, transfer and storage is considered a Class II medical device:
- includes any patient management software involved in data manipulation, data analysis, data editing, image generation, determination of measurements, graphing, flagging of results, identifying a region of interest or performing calculations (if the software performing calculations directly impacts diagnosis and/or treatment of a patient)
- Free and Open-Source Software (FOSS) that is used for patient management is subject to the same regulatory requirements

IN THE USA:

1. US FDA is intending to regulate Mobile Medical Applications.

For more click here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm>

'Standalone' software can be:

- not a medical device (not within the FDA's jurisdiction)
- a device for which FDA exercises 'enforcement discretion'
- classified as class I (general controls), i.e. typically no 510(k)
- classified as class II (special controls in addition to general controls), i.e. typically 510(k)
- classified as class III (premarket approval), i.e. PMA

Examples include: central stations, PACS, clinical information, electronic health record, decision support, various 'protocol converters' e.g. HL7 translators.

FDA CDRH publishes a number of software guidances that provide a lot of general information regarding FDA concerns as they related to both 'standalone' and embedded software. Those guidances are produced to assist the applicant in guiding their product through the regulatory process. The new draft 'apps' guidance further clarifies FDA thinking as it relates to standalone software intended to run on commercial, off-the-shelf mobile platforms, e.g. smartphones and tablet computers. It clearly indicates that mobile medical applications can be classified Class I, II or III and explicitly excludes (they will be subject to their own guidances later):

- clinical decision support, personal health record, electronic health record, apps that analyze, process or interpret electronic health data
- or those things not considered medical devices: office automation (e.g. collecting patient history, billing, coding, scheduling, training)

It also clarifies that calculating an index or score (e.g. APGAR) from data is a medical device.

Existing list of software guidances are listed hereafter:

- 0938 (2005) - General Principles of Software Validation; Final Guidance for Industry and FDA Staff : Replacement is expected soon. US FDA recently recognized the IEC 62304 lifecycle process standard.
- 0585 (1999) - Off-The-Shelf Software Use in Medical Devices. Replacement is expected soon.
- 1741 (2011) - draft Mobile Medical Applications
- 0337 (2005) - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

2. The Office of the National Coordinator for Health Information Technology (ONC) proposed a draft on certification for EHR modules

Those modules are containing:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only - electronic medication administration record
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

As of 2014 such software requires certification before it can be put on the market.

INITIATIVE RECENTLY TAKEN AT INTERNATIONAL LEVEL

The International Medical Device Regulators Forum (IMDRF) validated at their Management Committee of March 2013 a New Work item on Medical Software, proposal initially submitted by DITTA (The Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association) in 2012.

COCIR considers this is an important step forward in order to achieve a global regulatory convergence on medical software and determine common key criteria to qualify whether software is a medical device or not.

INTERNATIONAL STANDARDS DEVELOPMENT FOR MEDICAL SOFTWARE TO SUPPORT REGULATORY FRAMEWORK

International Standardisation organisations such as ISO and IEC have generated international standards which are currently being revised in order to bring some support to the regulatory framework. We have seen an intensification of cooperation between ISO TC 210, ISO TC 215 and IEC TC 62 in order to bring some consistency in international standards covering medical software.

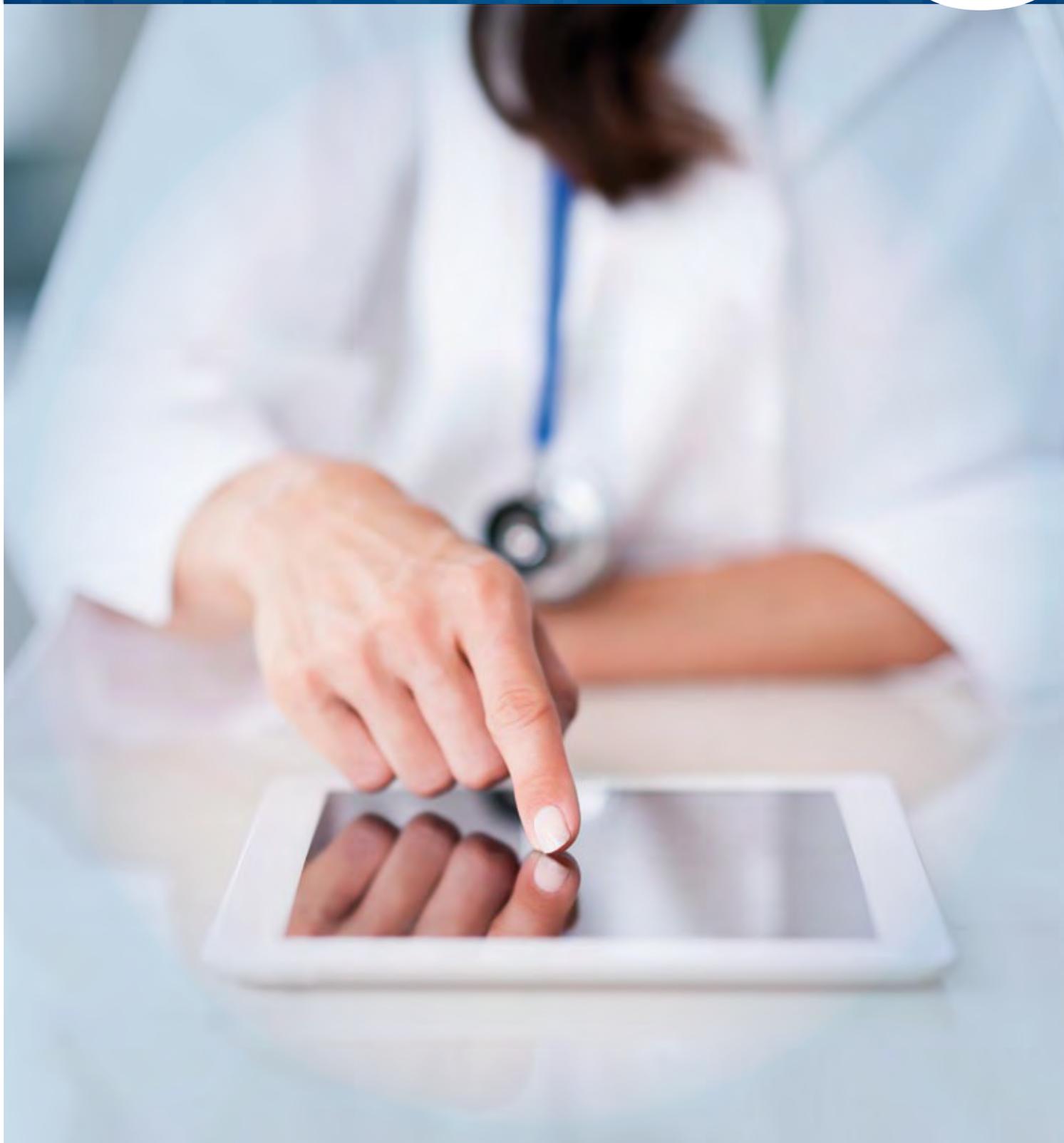
Currently, the IEC 82304-1 and IEC 62304 standards are being revised. In addition, IEC 80001-series covering hospital networks are also progressing.

In addition, standards, profiles and specifications allow a common definition of data and data exchange formats that is essential to enable interoperability at the technical, semantic and organisational levels. As widely recognised standards (e.g. HL7 and SNOMED CT) and profiles (e.g. IHE and Continua) continue to grow geographically, a broader network of consistent communications can enable integrated healthcare delivery while the need for regulation is reduced or where standards can play an important complementary role to the existing regulatory framework.

COCIR welcomes the implementation of international standards and profiles. Market-driven standards – or the use of existing standards – should be supported while avoiding strict technology mandates.

COCIR GLOSSARY OF TERMS

6



PART 6 COCIR GLOSSARY OF TERMS

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COCIR is constantly keeping updated the Glossary of Terms which was initially created in May 2011. This is in order to make sure that any key term used is clearly defined.

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.

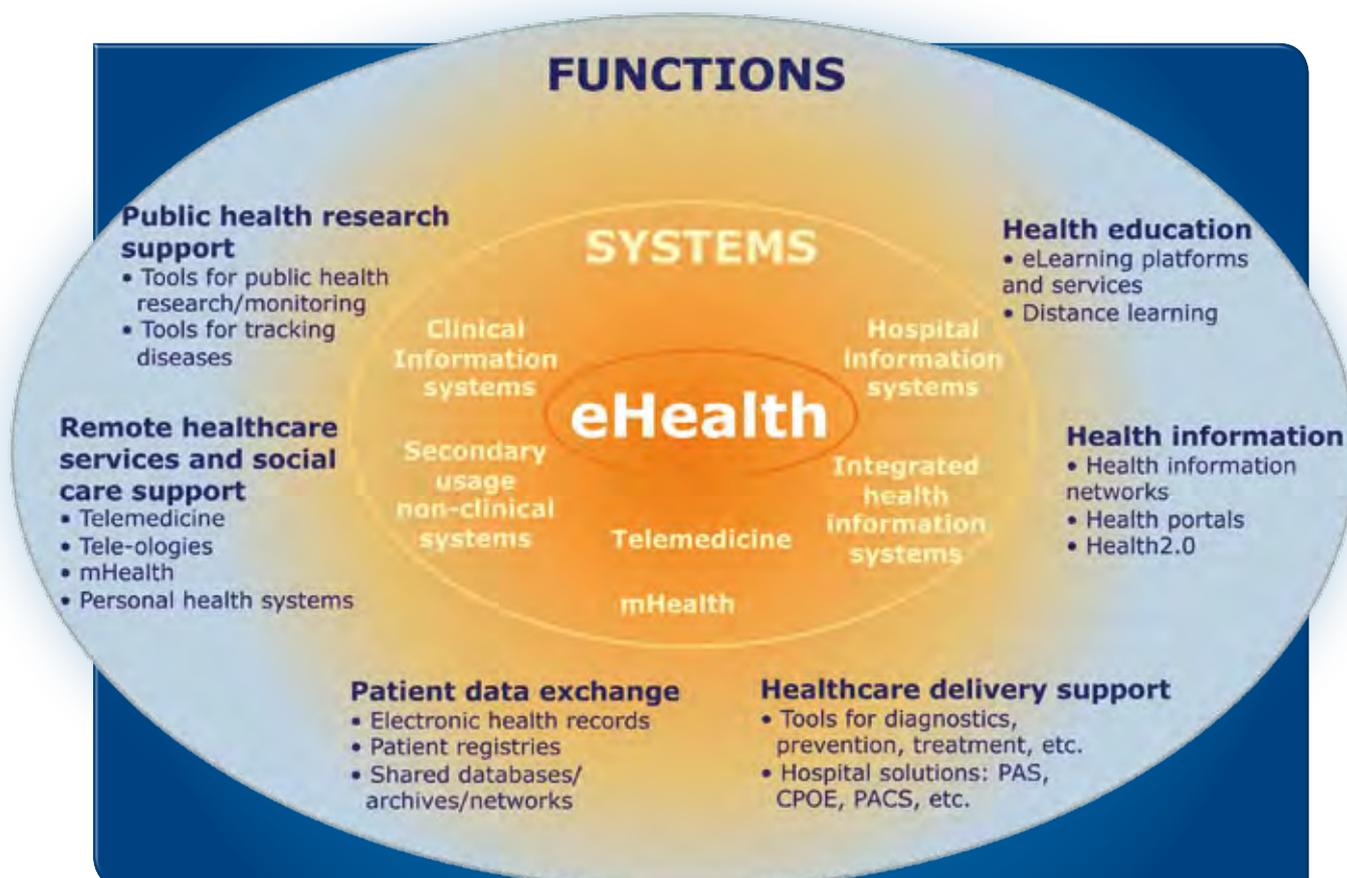
eHEALTH COMPRISES SIX TYPES OF SYSTEMS:

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 home³¹.

AUTHENTICATION

Authentication, in the context of eHealth information security, refers to the confirmation of the identity of a user requesting access to eHealth services and/or patient data. Its purpose is to verify whether or not the user really is who they claim to be. Authentication is not to be confused with Authorisation, which deals with rights particular users or user groups may or may not have.

While Authentication deals with questions like: "Is this person really Dr. X?", Authorisation might ask "Does Dr. X have the right to access this specific kind of data?".

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 care³².

CLINICAL PATHWAYS

Clinical pathways, also known as care pathways, critical pathways, integrated care pathways, or care maps, are one of the main tools used to manage the quality in healthcare concerning the standardisation of care processes. It has been proven that their implementation reduces the variability in clinical practice and improves outcomes. Clinical pathways promote organised and efficient patient care based on the evidence-based practice. Clinical pathways optimise outcomes in the acute care and homecare settings.

Generally clinical pathways refer to medical guidelines. However a single pathway may refer to guidelines on several topics in a well specified context.

CLOUD COMPUTING

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

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.

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.

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 4 of this glossary.

EMPOWERMENT

A process through which people gain or are afforded greater control over decisions and actions affecting their lives³³.

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 electronically²¹.

HOSPITAL DIAGNOSIS IMAGING WORKFLOW

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

HOSPITAL IT

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

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

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

HOSPITAL LABORATORY WORKFLOW

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

eID

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

IDENTIFICATION

Performance of tests to enable a data processing system to 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 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 and fitness;
- they are produced as a result of integration of different institutional and information systems.

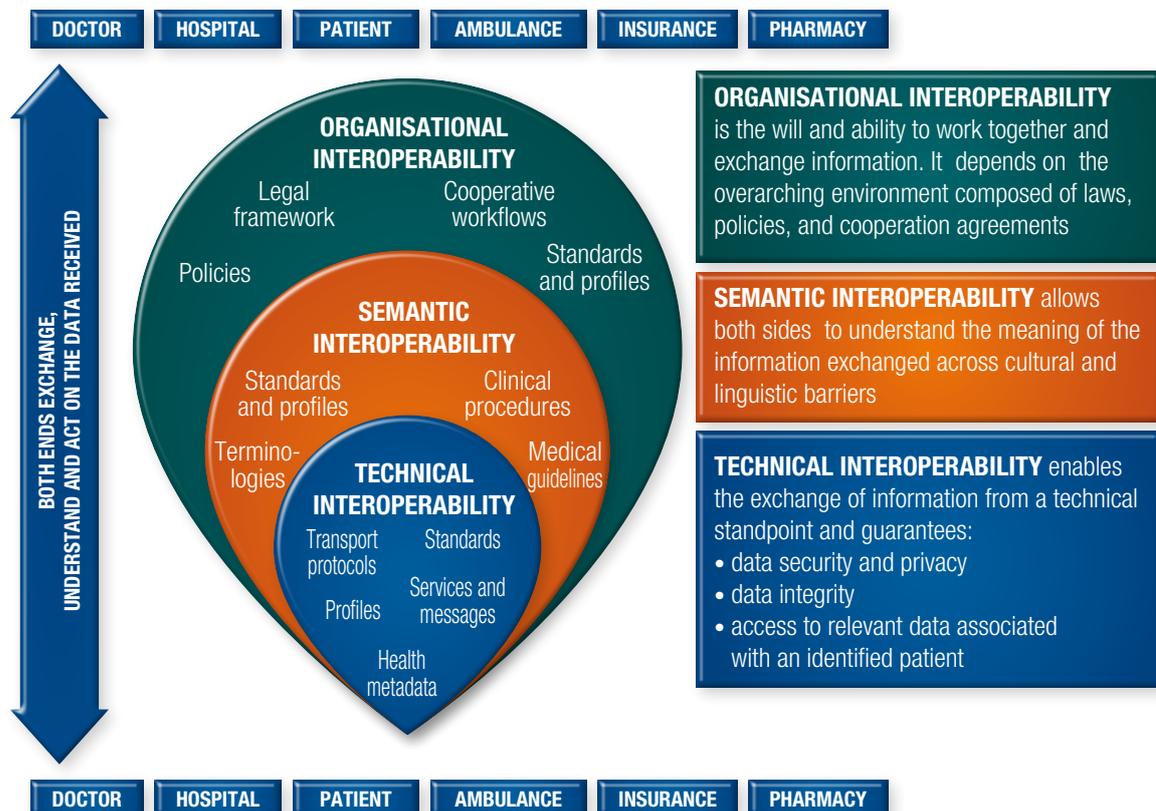
They are personal and possibly personalised in the way they gather, process and communicate data (for feed-back/action)³⁴.

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 knowledge³⁶.

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

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.



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

LABORATORY INFORMATION SHARING

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

LEGACY SYSTEM

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

MEDICAL IMAGING INFORMATION SHARING

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

mHEALTH – MOBILE HEALTH

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

PATIENT CENTERED CARE

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

PATIENT REGISTRY

Patient registries are collections of secondary data related to patients with a specific diagnosis, condition, or procedure. In its most simple form, a disease registry could consist of a collection of paper cards kept inside a box by an individual doctor. Most frequently, registries vary in sophistication from simple Excel spreadsheets which can only be accessed by a small group of doctors to very complex databases which are accessed online across multiple institutions. They can give healthcare providers (or even patients) 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.

PATIENT SELF-MANAGEMENT

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

PATIENT SUMMARY

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.

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.

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.

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.

STANDARD³⁷

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

STRUCTURED DATA

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

UNIQUE IDENTIFIER

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

USE CASE

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

- **CLINICAL USE CASE:** A clinical use case refers to scenarios and terms of the clinical world rather than mentioning computer-related terms.
- **TECHNICAL USE CASE:** A technical use case is a use case that refers to application scenarios, but already assumes some technical measures or components. Technical use cases typically help in the selection of existing specifications and design of solution components.

³⁷ BSI, <http://www.bsigroup.com/en/Standards-and-Publications/About-standards/What-is-a-standard/>

PART 3: HOSPITAL INFORMATION SYSTEMS (HIS)

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

3.1. BUSINESS PROCESS SUPPORT

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

BUSINESS INTELLIGENCE SYSTEMS (BI)

Business Intelligence (BI) systems refer to technologies, applications and practices for the collection, integration, analysis, and presentation of business information to improve business decision-making by using fact-based/data-driven decision support systems. BI systems provide historical, current and predictive views of business operations using data from a (clinical) data warehouse and operational data.

The emerging integrated clinical/financial BI systems approach therefore combines traditional sources (such as human resources, cost accounting and financial reporting) with rich clinical data from computer-based patient record/medical records (EPR/EMR). However, a BI system is much more than a data warehouse. Its purpose is to provide insights that affect and improve business/clinical processes and all the associated outcomes (clinical, financial, etc.). BI also has a real-time, immediate dimension. Results can be either predictive or correlative in nature.

CLINICAL DATA WAREHOUSING SYSTEMS (CDW)

Data Warehousing Systems (CDW) are integrated systems of patient related clinical data allowing the collection and normalisation of data from disparate clinical sources into a database designed to support management clinical decision-making, performance analysis purposes or research. CDW can be 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.

3.2. FINANCE & ACCOUNTING SYSTEMS

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

CODING INFORMATION SYSTEMS

Coding Information Systems are used to collect and code clinical service information for patient billing, insurance claims, activity analysis and cost accounting. They may include DRG-Management features. They enable 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).

3.3. LOGISTICS AND RESOURCE SYSTEMS

Logistics and resource systems are information systems designed to manage the logistics and resources of a hospital. They include – 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.).

3.4. PATIENT ADMINISTRATION SYSTEMS

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

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

ADMISSION, DISCHARGE & TRANSFER SYSTEMS (ADT)

Also called registration systems, ADT systems include pre-registration, patient history (administrative), patient admission and discharge transfer functions. They are rarely 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 4: CLINICAL INFORMATION SYSTEMS (CIS)

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

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

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

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

4.1. CLINICAL KNOWLEDGE, DECISION & PROCESS SUPPORT INFORMATION SYSTEMS

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

CLINICAL KNOWLEDGE MANAGEMENT & CLINICAL DECISION SUPPORT SYSTEMS (CDSS)

Clinical Decision Support Systems are an interactive computer 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.

4.2. CLINICAL ORDER COMMUNICATION MANAGEMENT INFORMATION SYSTEMS

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

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

Clinical Order Entry/Results Reporting information systems allow for the placement of clinical service orders for patient services or medications, including medications, procedures, examinations, nursing care, diets, laboratory tests, etc. - with subsequent automated distribution of the clinical documentation processed as a result of this order. Order entry & 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.

4.3. MEDICAL RECORDS / ELECTRONIC PATIENT RECORD INFORMATION SYSTEMS

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

DIGITAL DICTATION & TRANSCRIPTION INFORMATION SYSTEM

A Digital Dictation Information System facilitates the management of voice-recorded notes and reports. It converts voice-recorded notes and reports as dictated by physicians and/or other healthcare professionals into 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).

4.4. MEDICO-TECHNICAL SERVICE DEPARTMENT SYSTEMS

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

ADVANCED VISUALISATION INFORMATION SYSTEM

Advanced Visualisation Information Systems (IS) or advanced image processing tools, e.g. 3D MPR/MPI, CT/MR matching, Computer Aided Decision (CAD) support the decision making processes and visualisation of the areas of interest for 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).

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.

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 5: TELEMEDICINE

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

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

5.1. GENERAL TELEMEDICINE RELATED DEFINITIONS

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.

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).

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.

5.2. TELEDISCIPLINES

The term «teledisciplines» 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 ophthalmologist. Ophthalmology not only diagnoses typical diseases of the eye but can also generate useful information on other diseases, e.g. diabetes and cardiac conditions and related secondary symptoms. Data typically 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.

COCIR COMPANY MEMBERS:



NATIONAL TRADE ASSOCIATIONS MEMBERS:



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