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# EU US Cooperation on eHealth Issues

## Editorial



## Articles



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# Editorial: EU-US Cooperation on eHealth issues

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We live in a world that is becoming increasingly globalised. As people travel more and more widely, as businesses become more international, as trade barriers are repealed, cooperation between countries and stakeholders becomes ever more important.

The importance of cooperation is also recognised in the eHealth domain. In both the European Union (EU) and the United States (US), eHealth (or "health IT", as it is called in the US) is developing rapidly, fuelled by new technologies and innovation. In their Memorandum of Understanding of 2010 and in the roadmap agreed in March 2013, the EU and US emphasise the need to "enhance inter-governmental cooperation and [...] collaboration between governments and the private sector".

The aim of the cooperation between the EU and US is to develop, deploy and employ innovation and technology in eHealth to empower individuals, support care, improve clinical outcomes, enhance patient safety and improve the health of citizens. This will be achieved by promoting and supporting a community of public- and private-sector entities, including suppliers of eHealth solutions, to work towards these goals.

The implementation of the roadmap raises a number of questions: What policies and strategies of cooperation should be adopted to maximise the effectiveness of eHealth? How should these policies and strategies fit in with existing ones? What standards should there be in eHealth? How should these standards be established and maintained? How should the problem of interoperability of electronic health records (EHRs) be solved? How should healthcare workers be trained to operate ICT-based technology and systems? What proportions of which healthcare professions should acquire these skills?

Since the EU-US collaboration on eHealth is underway, dialogue with stakeholders has been welcomed. This journal issue offers a number of responses to these questions. They follow the overall approach of the cooperation between the EU and US, starting from more policy- and organisational-related matters, and move towards human resource issues while including technological and interoperability challenges. Arising on several occasions are the specific challenges of privacy, security, safety, and consent. Among the institutions represented in this issue are international non-governmental organisations such as the World Health Organization and European-based professional-representative bodies like the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry and the European Federation of Nurses. Some of the articles draw directly on the work of the EU-US eHealth formal arrangements; others use the existing collaboration to suggest related or additional activities and tasks that might be explored together in the future. Examples of what is happening in two specific countries, such as Ireland and Italy, are proposed as opportunities and initiatives that could be explored under the umbrella of the EU-US cooperation on eHealth through further pilot initiatives or standards-setting. They cover EHRs (and patient summaries), which are core components of the EU-US Memorandum of Understanding. A third example examines how web-

based care for patients could also be investigated under the same Memorandum of Understanding and roadmap. Skills-related papers draw attention to implications for the training of two professions in health-related IT/eHealth, one on the technical side of eHealth, and the other with a healthcare orientation: information technology (IT) specialists, and nurses. Last but not least, the final paper of the journal issue places the work of the EU-US collaboration on eHealth within a proposed wider theoretical model that draws on work developed through the 1990s and first decade of the twenty-first century on transnationalism and globalism. It ends with the tantalising possibility of the establishment of an even more concrete translatlantic eHealth-related organisation in the future than that which exists today and, like suggestions made by the very first author in the issue, one which could have implications for the globe overall.

The first paper looks at the big picture of EU-US cooperation from a wider background. **Clayton Hamilton** places the EU-US Memorandum of Understanding and the roadmap in its global context. In particular, he views these issues from the perspective of the World Health Organization and its forum, the World Health Assembly, and especially from a recently adopted World Health Assembly resolution on eHealth standardisation and interoperability. He further discusses the importance and advantages of establishing global eHealth standards and interoperability, what the transatlantic cooperation can and will achieve, and what its impact will be – not only for Europe and the US, but also for the rest of the world.

In the issue's second paper, **Nicole Denjoy** presents the perspective of the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), in the light of the EC-US roadmap. The paper focuses on eHealth policies and large-scale strategies and the future of healthcare. It discusses many of the subject areas which are central to the roadmap, including interoperability and the training of the healthcare workforce, as well as other issues such as mHealth and digital hospitals. The aim is to underline the potential of eHealth to transform healthcare into a seamless integrated care system that encompasses the hospital, the patient's home and elsewhere, and to provide some insight on how this could be achieved. In this way, the paper strives to provide a common vision and implementation strategy which can guide the development of digital hospitals and clinical information systems.

The third paper, by **Barbara Foley**, **Rachel Flynn**, **Tracy O'Carroll** and **Jane Grimson**, turns to standards, and in particular standards relating to the collection of health data. They discuss the importance of the "Guiding Principles for national health and social care data collections" published in 2013 by Ireland's Health Information and Quality Authority (HIQA). Although this publication was geared to setting national standards in data collection, the authors show that its solutions can also be applied to their advantage in other countries in Europe or the US. Moreover, given the central role of data in providing a national overview of a particular health or social care service, the adoption of effective data-collection standards could lead to improved analysis of the healthcare situation. In this way, the standards would help to inform developments in eHealth strategies and policies, including helping to shape the nature of international collaboration in the area.

The fourth paper, by **Claudio Dario**, **Tommaso Piazza**, **Elena Vio**, **Arianna Cocchiglia** and **Sergio D'Angelo**, moves on to the subject of with the interoperability of electronic health records (EHRs). The authors propose a solution for how EHRs can be used for people travelling in foreign countries, for business or for leisure, and in particular for transatlantic travel. They note that there is currently no infrastructure or 'infostructure' which is able to support intercontinental document-sharing in the way they envisage. Thus they propose a framework based on the Patient Summary, a standardised set of basic medical data. If the Patient Summary is digitised and utilises international standards of interoperability, they foresee that it could help to ensure the continuity of care for people who are

travelling, particularly for patients with chronic conditions. In order to demonstrate the feasibility of using the Patient Summary for these purposes, the authors aim to implement a pilot project involving people travelling between Italy and the US.

Another take on interoperability is presented in the fifth paper of this issue by **Ed Conley**. Conley says that EU-US collaborative developments in eHealth should be patient-centred rather than technically driven. Patient-centred 'webs-of-care', which illustrate a patient's relationships with different elements of the health system, could provide the foundation required. He argues that the web-of-care comprises multiple participants who need standards of interoperability to be implemented in order to work together most effectively for the benefit of the patient. Moreover, patients understand non-operability as 'fragmentation' of their web-of-care. The author argues that this patient-centred approach would facilitate many benefits, not just providing a solution to issues of interoperability (such as the 'many-to-many' problem), but also a better general functioning of the health system and better information-sharing to facilitate research.

The sixth paper in the journal shifts the emphasis to the training of the healthcare workforce. **Jean-Pierre Thierry** looks at the numbers of IT specialists employed in the health services of various countries. He notes that there seems to be a notable difference among developed countries regarding the proportion of Health Information Technology (HIT) professionals in health systems, and wonders whether this might provide evidence of a digital divide. With the use of digital technologies set to increase, the author argues that the importance of IT training should not be underestimated. However, the number of studies conducted in this area is still small. More studies are recommended to get a clearer understanding of the situation.

Training related to eHealth is also important for healthcare staff. In the seventh paper, **Paul De Raeve**, **Alessia Clocchiatti** and **Silvia Gomez Recio** focus on the training and role of nurses. They argue that nurses are hugely important in implementing eHealth systems, particularly telehealth services, since they coordinate healthcare from the patient's perspective, and they play a key role in changing traditional healthcare approaches towards integrated care. Nurses are helping to facilitate the evolution of the health services, including the shift from a hospital-centred model to community-based care and integrated services. The authors argue that cooperation and joint activities between the EU and US on investing in the nursing workforce, especially in regard to eSkills development and standards of care, will help to further develop the healthcare sector, so that it becomes a key driver of well-being, productivity and growth. It is essential to facilitate new eHealth strategies through the use of standards and guidelines for effective, sustainable and integrated care which will enable the optimal deployment of these services.

The final paper in the issue employs political theory to put the EU-US cooperation on eHealth into a theoretical context. **Alexandros Stylianou** discusses how globalisation alters the rules of the game by creating transgovernmental networks. This facilitates the emergence of new actors that function above and below the state, which in turn leads to the creation of regimes and what came to be known as institutional transgovernmentalism – a theory valuable to understand some current trends on eHealth transatlantic cooperation. Towards the end of his paper, Dr Stylianou explores various aspects of EU-US collaboration on eHealth and indicates how they fit within the theoretical model he describes.

# The transatlantic cooperation framework for eHealth: Potential benefits to global health

This paper highlights the importance of adoption of health data standards in care delivery and its relevance to health systems in strengthening micro-economic development. Referring to the Memorandum of Understanding established between the United States (US) Department of Health and Human Services and the European Commission on cooperation surrounding health-related Information and Communication Technologies, the paper introduces the recently adopted World Health Assembly resolution (WHA 66.24) on eHealth standardisation and interoperability. It suggests that significant health and economic gains can be realised at a global level through a transatlantic partnership for eHealth and that such benefits will ultimately extend well beyond simply the European Union (EU) and US zones.

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Keywords

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> “The transatlantic cooperation framework for eHealth offers potential benefits and impacts on a large scale, and carries with it the potential to save lives, foster economic growth, and define the future landscape of healthcare.”

# 1. Introduction

*"The use of eHealth and mHealth should be strategic, integrated and support national health goals. In order to capitalise on the potential of ICTs, it will be critical to agree on standards and to ensure interoperability of systems. Health Information Systems must comply with these standards at all levels, including systems used to capture patient data at the point of care. Common terminologies and minimum data sets should be agreed on so that information can be collected consistently, easily and not misrepresented. In addition, national policies on health-data sharing should ensure that data protection, privacy, and consent are managed consistently"* (WHO, 2011: 14).

Global health has been described as the health of populations in a global context, transcending the perspectives and concerns of individual nations. Acknowledging the fact that diseases do not recognise borders, the World Health Assembly (WHA) adopted the International Health Regulations (IHR) as an international legal instrument. It binds all 194 Member States of the World Health Organization (WHO) together with the aim of helping the world to prevent and respond to acute public health risks that carry the potential to cross borders and threaten populations worldwide. The implementation of the IHR as a legal instrument requires that Information and Communication Technology (ICT), together with the implementation of health data standards and health information technology (IT) standards, allow the seamless exchange of data between and within information systems and transmit reportable data in a reliable and timely manner to the authorities concerned. This is where global health meets global eHealth in terms of joint responsibility and global response.

There has been a noticeable and steady increase in the development and use of eHealth systems for health care delivery around the world. While innovations of eHealth systems and services are abundant throughout the health sector, in low-middle income countries they are more noticeable in the area of maternal and child health service delivery. Innovative examples of eHealth services include notification systems for maternal deaths using mobile telephones, facility data and discharge data management of pregnancy and delivery using near-real time information systems, stock management information systems (for management of essential medicines and medical products available for mothers and children at care facilities), human resources for health information systems (for tracking qualified midwives to administer lifesaving interventions), and appointment reminders and counselling and testing services locators (for antenatal and immunisation reminders). These developments have taken place particularly throughout the last decade. Post-2015, the focus on maternal and child health will continue.

Many countries have embarked on eHealth systems and services to provide essential care for both mothers and children. Management of essential medicines and medical products available for mothers and children at care facilities (such as antiretroviral prophylaxis, uterotonic agents, DPT (Diphtheria, Pertussis, Tetanus) vaccine, antibiotic treatment for pneumonia, contraception, rapid diagnostic tests for malaria, vitamin A, and oral rehydration packages) all require adoption of common drug and medical product standards. The adoption of standards for the representation of drugs, unified coding of units of measurements, uniform facility codes and related facility registry elements become relevant in this context. If drug and health product manufacturers, healthcare providers and supply-chain management information systems adopt standards for data exchange, then the serious problem of stock-out of drugs and essential commodities at point-of-care facilities can be averted. Similarly, to manage adequate ratios of qualified midwives who can administer lifesaving interventions and health workers trained and living in communities who can provide essential basic care, and to maintain adequate numbers of live births attended by skilled health personnel, requires the adoption of the Standardized Classification of Occupations.

While these innovations are essential for the continuous improvement of health services delivery, it is equally important that these eHealth systems adopt relevant standards for the interoperability of data between and within national and sub-national health information systems. The lack of adoption of standards in eHealth systems is contrary to the strengthening of health systems, does not yield good return on investments, increases the risk of losing entire financial investments, and creates health systems fragmentation and information silos in countries.

Implementation of standards can be considered as a necessary prerequisite in many countries for the rapid expansion of the health systems delivery environment. However, implementation and maintenance of standards are neither easy nor inexpensive. Since large investments are needed to operationalise timely, reliable and fully functional information systems with the ability to seamlessly exchange data, the adoption of standards must be well planned prior to implementation.

## 2. The Transatlantic cooperation framework for eHealth

The Memorandum of Understanding established between the US Department of Health and Human Services and the European Commission on cooperation surrounding health-related Information and Communication Technologies and the Transatlantic eHealth/Health IT Cooperation Roadmap represent the first two in a series of crucial steps for aligning efforts on both sides of the Atlantic to facilitate and accelerate the development and implementation of ICTs within the respective health sectors of the US and the European Union (EU). The WHO recognises the importance of the agreement to strengthen transatlantic cooperation in eHealth and Health IT between the two geographic regions and its benefit to the global community at large. This agreement compliments resolution WHA66.24 on eHealth Standardisation and Interoperability, passed during the sixty-sixth session of the World Health Assembly. The transatlantic cooperation framework for eHealth offers potential benefits and impacts on a large scale. It carries with it the potential to save lives, foster economic growth and define the future landscape of healthcare. Without a cooperation agreement to promote an open and proactive approach to the development of a common standards framework in the area of eHealth/ Health IT, the global community risks the emergence of parallel and competing standards that the world can no longer afford.

The global community has experienced the impact of the failure to reach common standards in technology numerous times in the past. These examples serve as a reminder of the consequences that follow when parties fail to reach consensus in the derivation and adoption of international standards. It is worth considering, for example, the opportunity cost associated with the regional developments of standards such as PAL (Phase Alternating Line), NTSC (National Television System Committee), and SECAM (Sequential Couleur à Mémoire) for broadcast television systems, or GSM/ TDMA (Global System for Mobile Communications) and CDMA/IS-95 (Code Division Multiple Access) for voice and data communication in mobile devices. These technical divides have silently stifled the global capacity to communicate, grow and innovate. A significant amount of effort has subsequently gone into bridging the functional gaps that emerged. Global health is simply too important to “agree to disagree” on the development and adoption of the relevant standards for implementing ICT into healthcare delivery.

The contribution of a transatlantic cooperation framework for eHealth has the potential to go well beyond the borders of the EU and the US. The adoption of a framework of globally accepted standards for ICT in health applications could provide low-middle income countries with an opportunity to “fast-track” the development of their national health systems. eHealth can provide the catalyst for transformation of clinical and health information flows, introduction of patient safety initiatives, patient-centric treatment approaches, and more.

Global health security is an issue of increasing importance for governments, private businesses and individuals, all of whom have a stake in ensuring the highest level of protection against the impact of large-scale public health threat events, should they occur. The transatlantic cooperation framework for eHealth is inextricably linked to improving socio-economic development and the health and well-being of European and American populations alike. Similarly, it is a key component in the drive for improving health security of the regions – ensuring appropriate and timely action for epidemic alert and response – which several Member States have experienced in recent years.

## 3. Expectations of a Strategic Transatlantic Partnership

The question remains as to what a strategic transatlantic partnership will ideally need to produce and what investments it will take to realise the objectives set forth. The high-level outcomes proposed below are derived from experience gained by the WHO in working directly with Member States at both national and sub-national levels.

- Agreed minimum criteria for designing patient-centric Electronic Health Records (EHRs) based on interoperability standards. The standards must ensure Electronic Health Record (EHR) format design, data synchronisation, system architectures and interfaces with larger eHealth systems and services such as clinical management systems, ePrescription (electronic medication services), decision support systems, chronic disease management services, laboratory information management systems, diagnostic imaging systems, and telemedicine.
- Acceptance and implementation of Identifiers (for uniquely identifying persons, facilities, service providers and diagnostic equipment).
- A common information security, privacy and ethics framework for eHealth.
- Acceptance and implementation of the International Classification of Diseases (ICD) & International Classification of Functioning, Disability and Health (ICF) standards for coding of diseases and treatment causes.
- Acceptance and implementation of data exchange and transport standards, privacy standards as well as security and confidentiality standards.
- eHealth standards adoption through full implementation of National eHealth Strategies that account for all elements of eHealth: policy, infrastructure, services, standards, governance, and protection.
- A standard framework of key performance indicators for eHealth.
- An accreditation mechanism that certifies alliance with an accepted standards framework and version.
- Guidelines for national training curriculum for medical practitioners in the full use of ICT-based clinical and laboratory systems.

## 4. WHA Resolution on eHealth Standardisation and Interoperability

Setting norms and standards and promoting and monitoring their implementation is one of the six core functions of WHO. The adoption of a resolution on eHealth standardisation and interoperability (WHA66.24) by the World Health Assembly in its 66th Session is a translation of this core function in the field of eHealth. The resolution requested the Director General of WHO to:

- Provide support to Member States, as appropriate, in order to integrate the application of eHealth and health data standards and interoperability in their national eHealth strategies through a multi-stakeholder and multi-sectoral approach including national authorities, relevant ministries, relevant private sector parties, and academic institutions;
- Provide support to Member States, as appropriate, in their promotion of the full implementation of eHealth and health data standards in all eHealth initiatives;
- Provide guidance and technical support, as appropriate, to facilitate the coherent and reproducible evaluation of ICTs in health interventions, including a database of measurable impacts and outcome indicators;
- Promote full utilisation of the network of WHO collaborating centres for health and medical informatics and eHealth in order to support Member States in related research, development and innovation in these fields;
- Promote, in collaboration with relevant international standardisation agencies, harmonisation of eHealth standards.

These five components of resolution WHA66.24 underscore the critical nature of the work that needs to be done in reaching consensus on an eHealth framework that provides a roadmap for full implementation of the mandate at national and sub-national levels. WHO will work closely with global partners to facilitate the development and implementation of national eHealth strategies that clearly mandate for the implementation of standards. Within this context, transatlantic cooperation is an important contributor to the emergence of a common standards framework for eHealth.

## 5. Conclusions

There is little doubt that significant health and economic gains can be realised through a transatlantic partnership for eHealth, and that such benefits will ultimately extend well beyond the EU and US zones. WHO recognises the challenges currently faced by many Member States in identifying and adopting existing standards for Health IT implementation and in ensuring that their health professionals are appropriately skilled so as to embrace the use of IT as an integral part of the clinical process. It is hoped that the EU-US cooperation framework will ultimately emerge as an example of consensus and capacity-building within the respective health sectors, and that it will lay the groundwork for the implementation of a collective set of Health IT standards that in time can be propagated to all countries globally.

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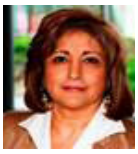
# COCIR perspectives on advancing eHealth in Europe: Need for healthcare transformation towards seamless integrated care

Healthcare systems in both the EU and the US will need to deliver more and more services of higher quality, possibly at more contained costs, to meet the swelling demand for quality services and new patient expectations. In other words, there is a need to build a sustainable future especially in the context of the current economic crisis.

The need to use information and communication technologies (ICTs) to interconnect providers, practitioners and all other stakeholders in the healthcare system – including patients – is stronger than ever. Unfortunately, there is a slow uptake of the eHealth solutions in Europe and the market remains very fragmented. eHealth and its more recent incarnation as mobile technology (mHealth), beginning with the widespread adoption of Electronic Health Records (EHRs), are the necessary tools to transform healthcare delivery both inside and outside the hospital.

The solution will not be a one-size-fits-all approach. Political will, along with clear governance and incentives, will be important success factors. Digital hospitals and clinical information systems (CIS) are directly contributing to improving and modernising healthcare delivery. However, a common vision and implementation strategy is required for their successful development, including ICT skills for health professionals and reimbursement strategies. Integrated care will also need to happen, largely outside the hospital, and will be crucially enabled by the pervasive mobile technology that is already in consumers' hands.

In this regard, interoperability – crucially enabled by international standards – should be recognised as a key ingredient to transform healthcare.



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Keywords

Digital Hospitals, electronic health records, mHealth, interoperability, IT workforce

> "eHealth, and its latest incarnation as mHealth, beginning with widespread adoption of electronic health records, are the necessary tools to radically improve the delivery of healthcare and ensure sustainability in the long term both inside and outside hospitals."

# 1. Introduction

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) is the organisation that represents the medical imaging, health ICT and electromedical industry in Europe. COCIR was established in 1959 and has been based in Brussels since January 2006. In February 2007, COCIR opened a China Desk in Beijing to strengthen its presence and support its members in China. For years, COCIR has built strong competences in eHealth and has pushed this technology as one of the most efficient ways to promote integrated care. There is compelling evidence that healthcare, when combined with ICT, results in better access, reduces health inequalities, and ensures better quality of products and services, while driving cost-efficient ways to achieve more sustainable healthcare systems in Europe and beyond.

COCIR welcomes the EU-US roadmap which expresses an official willingness to cooperate on eHealth. This is an important initiative, which offers the potential to boost the eHealth market for EU companies wishing to expand their business in the US and vice versa.

In this paper, COCIR underlines the potential of eHealth, including mobile technology (mHealth), to transform healthcare into seamless integrated care whether at the hospital, on the move, or at home. Connected hospitals and mobile technology will be key actors in this transformation. Interoperability and a skilled workforce are needed to realise and accompany the benefits offered by eHealth.

# 2. Transforming healthcare through digital hospitals

There is an urgent need to transform healthcare delivery at the patient level and to integrate currently fragmented organisational processes. It is obvious that this transformation will need to start from hospitals. It is here that a first paradigm shift from 'silos' – that is, isolated blocks consisting of single clinics or units within hospitals – towards integrated delivery systems must happen to then involve the full care model.

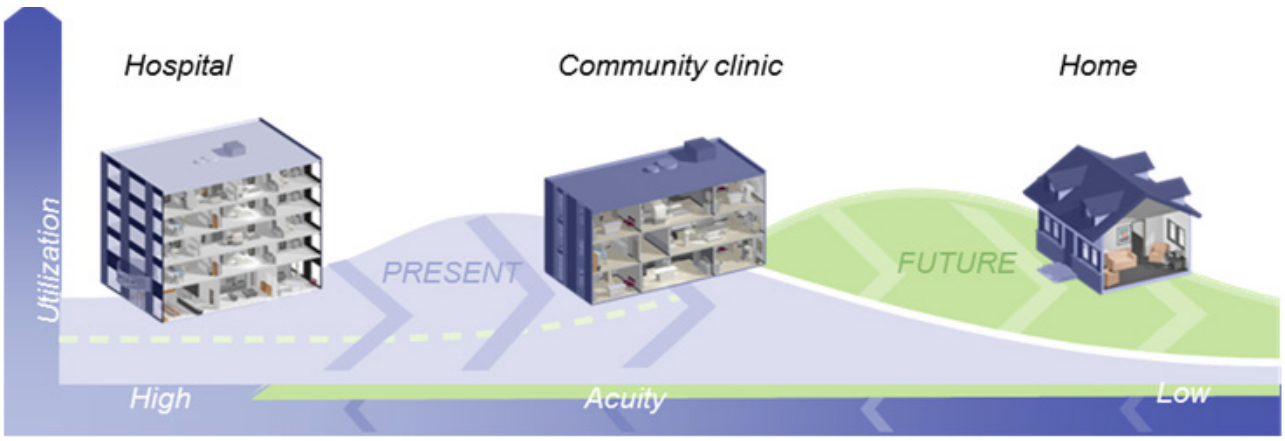


**Figure 1:** Use of ICT in different locations in the present and future

The first basic step comes from advancing the adoption of Electronic Patient Records (EPRs). This is a critical step towards fully integrated EHRs and clinical information systems (CIS). Unlike the EHR, which brings together medical information about a patient across a variety of providers (ideally, all providers interacting with a patient), the EPR (which is also called the Electronic Medical Record (or EMR)) holds electronic information about a patient's health that is generated and maintained in a single healthcare institution such as a hospital or a physician's office.

There is a growing body of evidence on the outcomes of EPRs, EHRs and associated CIS implementation in primary and secondary care (COCIR, 2013). However, despite the role that EPRs, EHRs and CIS can play in improving the quality, safety and efficiency of healthcare delivery, investment across Europe has remained static over the past few years. This proves that there remains a crucial need to build awareness about digital hospitals and their potential to improve the quality of care and connect hospitals to the wider health community for more efficient healthcare systems.

ICT industries can bring the necessary tools and competencies to make the digital hospital become a reality, thus reducing medical errors and enhancing the performance and safety of healthcare systems. However, it is only with the involvement of all stakeholders that the return on this investment can be materialised and proven.

The road to digital hospitals is not an easy one. Although a fully integrated and shared EHR has not yet been achieved, hospitals have made some progress in adopting EPRs over the last two decades. Patient administration systems (PAS), for instance, are very commonly found today in European hospitals, followed by departmental systems such as laboratory information management, pharmacy department management and radiology information management.

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

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

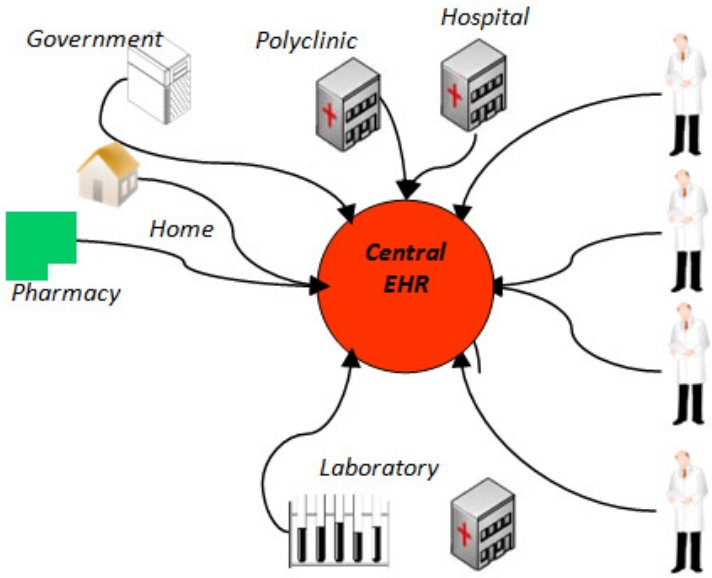


**Figure 2:** Representation of the environment surrounding the central patient EHR

More emphasis should therefore be put on BPR, combined with technology which has clinical and administrative outcomes, health professional convenience and patient experience (and engagement) in the early planning stages.

Since hospitals will remain at the epicentre of new, integrated care delivery structures, equipping hospitals with the necessary eHealth solutions is essential to ensure significant progress in improving healthcare delivery. However, progress towards digital hospitals is restrained by the current low levels of investment. While US hospitals spend on average 2.9 % of their budget on IT (both the internal and external spends), most European countries are far below this amount (HIMSS Analytics Europe, 2012).

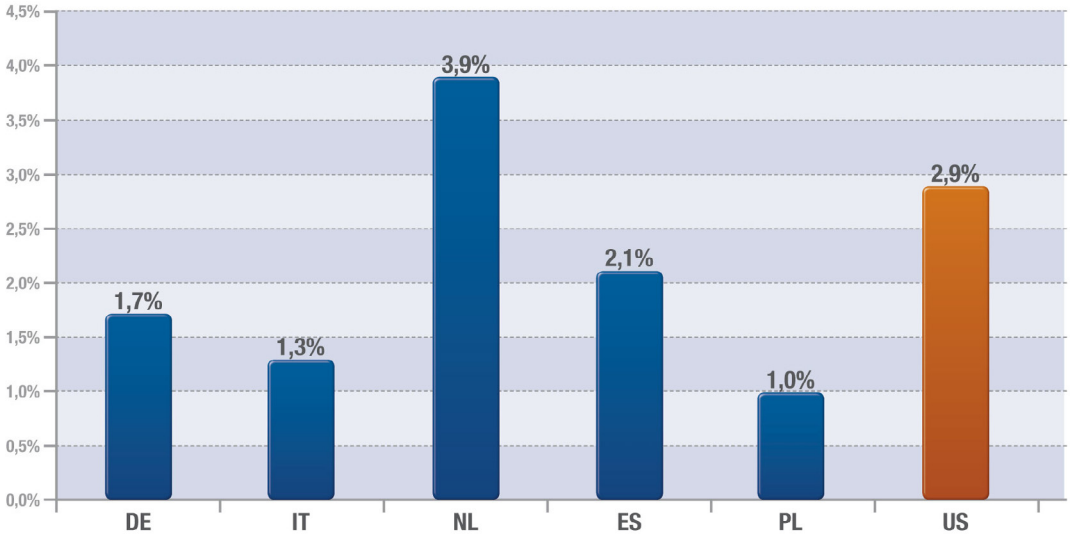


**Figure 3:** IT investment – representation of the annual IT operating expense in % of total hospital operating expense

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

Today, there is a perception that many national and regional eHealth plans or initiatives are not addressing hospitals anymore, as a result of the belief that 'the work is done'. However, 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 provides a response to patient empowerment. While many tools, like EPRs, are now becoming available, clinical adoption, use in daily clinical routine practices and the evolution towards integrated EHRs remain a challenge. Since the vast majority of hospitals have failed to see technology as an enabler of internal transformation, integration in the wider social and health services delivery would remain too distant an objective with just the current level of policies, investment and incentives.

In addition, advanced CIS have still a long way to go and are far from reaching maturity, from the sharing of information, to decision support at the point-of-care through advanced and predictive analytics. 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 bringing evidence-based, patient-centred decision support to the point of care. However, clinical availability remains limited.

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 to them. Where they are convinced, it takes time to generate strong evidence and support outcome thinking.

Consistent evidence shows 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 expectations (Baum & Abadie, 2012).

Many medical professionals, however, are not yet convinced of the benefits of eHealth 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 to support and improve the delivery of quality healthcare.

Public authorities, therefore, need to steer this situation and give a positive impulse to the effective use of ICT in the hospital setting to bring new directions for health system change and redesign.

## 3. Advancing healthcare with mHealth

Major areas of improvement also exist beyond the hospital in enhancing the exchange and sharing of patient information so as to develop care pathways that can continue in the home and outside of healthcare facilities.

mHealth – that is, the provision of eHealth services and information that relies on mobile and wireless technologies – is most likely to bring benefits in this respect, as well as create additional opportunities in the hospital setting, not least because mobile networks are the most pervasive communications platform that exists today (ITU, 2013). Similarly to eHealth, of which it is part, mHealth describes a broad set of technologies (e.g., 3G and Wi-Fi) that can support a variety of health-related services. It is not a separate category of services in itself (as is, for instance, telehealth – which in turn is largely enabled by mobile technology).

In recent years, 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 (Hobbs, 2009). 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 €5.4 billion or 30 % each) leading over the North American market (28 %) (GSMA & PwC, 2012). Previously, in 2008, Frost & Sullivan calculated that the European mobile and wireless healthcare technologies market was worth just over €1 billion (Frost & Sullivan, 2008).

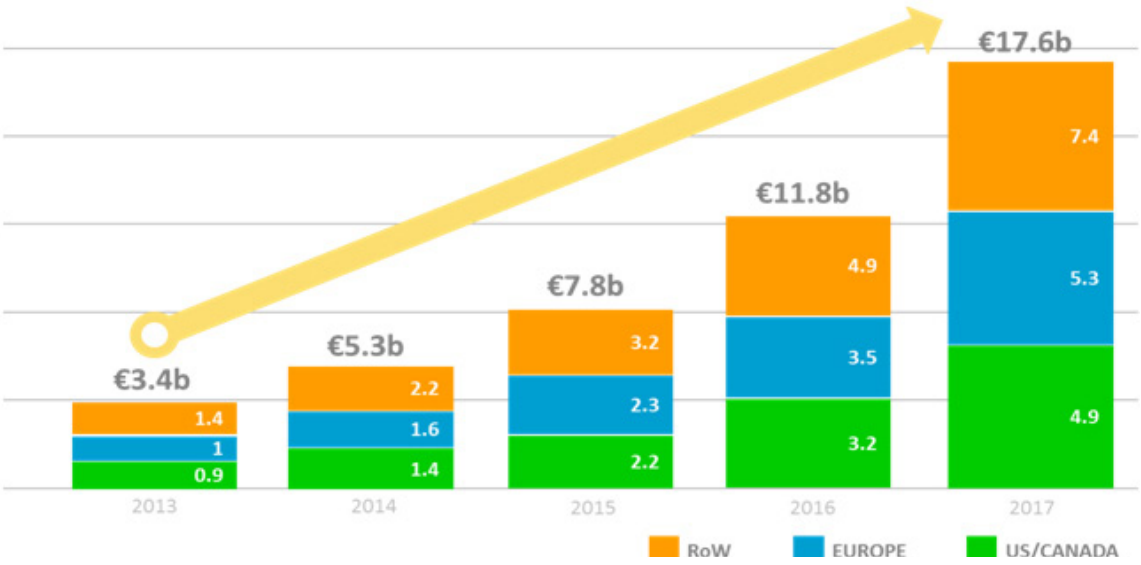


**Figure 4:** Estimated mHealth revenue, 2013-2017

By bridging the gap between institutional healthcare and consumer electronics, the potential of mHealth to enable new models of care that improve access and quality, empower patients, and make healthcare systems more sustainable, is enormous. To fulfil this potential, however, mobile technology – precisely like eHealth more in general – needs to be integrated into delivery structures and considered as a natural evolution of healthcare delivery rather than an addition to it. This requires, among others, appropriate reimbursement strategies that favour the development of cooperation mechanisms between single hospitals and other organisations, such as general practitioners and pharmacies (COCIR, 2013).

## 4. Accelerating eHealth through interoperability

As healthcare is a large ecosystem consisting of complex human organisations, it is a challenge to link the different actors, IT systems and institutions across different medical disciplines, cultures, languages, jurisdictions, and administrative entities. In this highly complex context, consistent and integrated care must be supported by the adoption of widely recognised international standards and profiles: this is a key precondition to enable the necessary economies of scale that are needed to unlock the potential of eHealth and mHealth to revolutionise healthcare.

eHealth interoperability means the ability of two or more eHealth systems to use and exchange both computer interpretable data and human understandable information and knowledge (COCIR, 2013). This includes three levels:

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 information exchanged is interpretable by any other system or application not initially developed for this purpose; and

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 additional operator intervention.

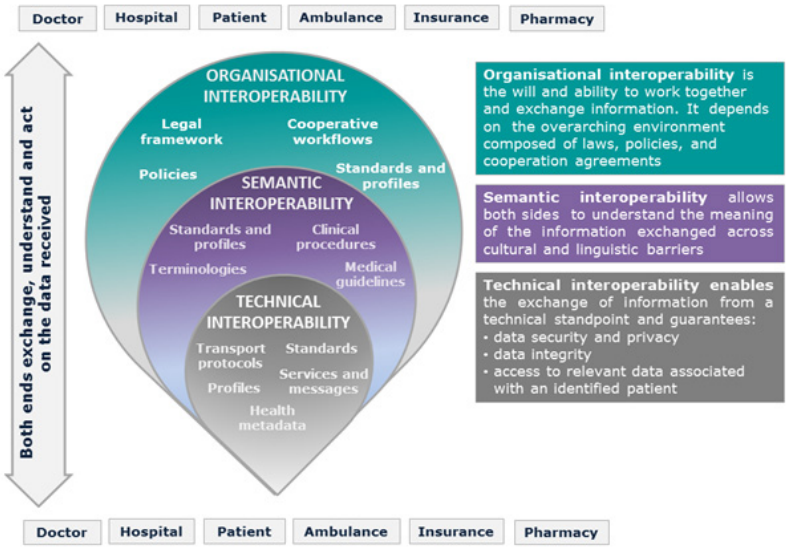


**Figure 5:** Representation of the three levels of interoperability

Interoperable systems lead to the acceleration of communications and the reduction in data capture operations, duplicated efforts, and workload. Giving medical professionals faster access to patients' data that is interoperable across care settings will also enable better diagnosis, quality treatment, and patient safety through avoidance of medication interactions, improved knowledge of the patient health status, family history, personal history and better care coordination between the different healthcare professionals.

Encouraging a proactive technology pull by users, in addition to a push for interoperable solutions by suppliers and providers, is required for innovative technologies to have a 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, for instance, 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. The percentage of users downloading health-related applications is significantly smaller in Europe vis-à-vis the US (Juniper, 2010).

With this in mind, the Transatlantic eHealth/health IT Cooperation Roadmap can offer Europe a useful incentive to advance on the path to achieving the necessary level of interoperability not only for the basic patient summary across the Atlantic but also for full-blown EHRs across the EU, so as to enable citizens' full secure access to their medical information and associated services.

## 5. Investing in the IT workforce

The transformation of healthcare needs to be supported not only by innovative technologies but also by skilled people. Limited but significant studies made in several countries (the US, UK, Canada, and Australia are among the most documented) show that the progression in eHealth triggers additional demand for a trained workforce and other factors, including:

- Hospital leadership;
- eHealth programme managers;
- IT specialists;

- Project managers;
- Organisational issues and change management; and
- Training and education.

There is, however, a serious gap in eSkills among health professionals in Europe. Left unaddressed, this gap will slow down the realisation of the benefits that innovation in eHealth can bring in the coming years.

eHealth uptake will require a greater number of skilled professionals as well as a well-trained workforce to generate a successful and efficient adoption in technologies that can:

- Engage, continue and accelerate national, regional and local ICT programmes (such as EHRs and telemedicine);
- Assure that key factors of success are met (e.g., project and change management, and education of the non-IT healthcare workforce);
- Seek and assure that added-value will emerge at both the public and private levels (such as through skill improvement and adaptation, competitiveness, innovation, healthcare specialisation);
- Increase acceptance and confident use of ICT-based tools; and
- Develop cross-over skills between clinical and IT specialists to build a bridge and a common language between them.

In order to overcome the existing bottlenecks, all key stakeholders (including industry, academia, research organisations, healthcare workforce, and local governments) need to join forces.

The private sector needs to step up its programmes and take corporate responsibility to boost health eSkills. Industry should strengthen its links with academic and research organisations and the various stakeholders that contribute to continuous education. Private Public Partnerships (PPPs) can help achieve the goal of updating the skills of the health workforce that operate telemedicine, remote care and cure, and run health analytics for improved decision making.

Moreover, governments at a local level can play a critical role. They need to engage the health community with incentives to ensure they are adopting and using the appropriate technology efficiently. National governments should learn from existing successful PPPs to increase training and certification capabilities to health workers. There is also a need to build awareness and make better use of the 2014-2020 cohesion policy funds to develop effective educational programmes.

Finally, hospital managers should ensure they are also being advised on the needs of nursing staff to ensure that solutions are customised and can respond to specific needs.

This change will not happen overnight and will require industry and political courage in order to preserve and ensure best possible access to healthcare for citizens via a reformed, sustainable approach.

## 6. Conclusions

Notwithstanding some continued scepticism and slow uptake, eHealth and its latest incarnation as mobile technology (mHealth), beginning with widespread adoption of EHRs, are the tools necessary to radically improve the delivery of healthcare and ensure sustainability in the long term both inside and outside hospitals.

Interoperable technologies, based on international standards, will be key preconditions to achieve the economies of scale that are needed by industry. This will supply truly transformable solutions that can result in the best added-value for healthcare professionals and citizens. This applies to digital hospitals and clinical information systems as well as to the care taking place outside hospitals, which will be crucially enabled by mHealth.

However, because healthcare is a large ecosystem consisting of complex human organisations, political will along with clear governance and incentives represent indispensable success factors. Favourable reimbursement mechanisms and good eSkills among the workforce, among other things, will be key ingredients that allow innovative technologies to enable healthcare transformation.

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# Driving continuous improvement in health information with the development of Guiding Principles for national health data collections

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It is globally accepted that health data is a vital resource and is used for many important purposes such as informing decision-making, monitoring diseases, planning services, policy making, improving population health, international reporting and benchmarking. The importance of having better health information systems has been highlighted by international organisations such as the Organisation for Economic Co-operation and Development (OECD) National health data collections collect a considerable amount of data on a regular basis to provide a wealth of information about health and social care services. While the data collected has many uses, there are challenges faced by national collections.

In order to address some of these challenges, the Health Information and Quality Authority (HIQA) in Ireland has developed some "Guiding Principles for national health and social care data collections". The purpose of these principles is to provide data collections with guidance on important areas such as governance and structural arrangements, data quality, workforce, and information governance, and on the best way to collect and use healthcare-generated data.

The delivery of safe and effective healthcare to patients depends on health information being accurate, valid, reliable, timely, relevant, legible and complete. The principles incorporate international evidence and promote a practice that is up-to-date, effective, and works towards greater consistency across all national data collections. They provide a basis for planning and measuring improvements as well as identifying and addressing gaps and quality issues.

While these principles have been developed for the Irish context, they are sufficiently generic to be applicable to other equivalent contexts and health data collections in the United States (US) or Europe. In this paper, we use examples from the guiding principles to demonstrate the applicability of the principles across different jurisdictions.

> "These guiding principles for national health data collections provide a basis for planning and measuring improvements as well as identifying and addressing gaps and quality issues."

# 1. Introduction

It is globally accepted that health data is a vital resource and is used for many important purposes such as informing decision-making, monitoring diseases, planning services, policy making, improving population health, international reporting, and benchmarking.

At an international level, the importance of having better health information systems was highlighted in 2010 at a meeting attended by Health Ministers from all OECD countries. In their final communiqué, the Ministers called for "more and effective use of health data that has already been collected" (OECD, 2010). Ministers also later noted that expanded use of health information and communication technologies (ICTs), particularly electronic health records, can help to deliver better quality of care, reduce medical errors and streamline administration (OECD, 2013).

On-going collaboration between the European Union (EU) and the US in relation to the Digital Agenda for Europe has also stressed the significance of the role of information and communication technology (ICT) to the health and social care sector. In the agreed roadmap from 2013 (Health IT.gov, 2013) there is a focus on the development of standards to support interoperability of electronic health records and the development of a skilled workforce in the eHealth area. These priority areas are of particular importance in driving improvements in national health information systems and health data collections in order to ultimately improve the delivery of health services, including disease prevention and health promotion. In preparation for the introduction of electronic health records, national collections can support interoperability by adopting a standards-based approach.

## 1.1 National health data collections – history and overview

National health data collections are defined as national repositories of routinely collected health and social care data including administrative sources, censuses, surveys and patient registries (HIQA, 2013).

Some of the earliest examples of national health information systems in Europe and the US are in the area of cancer registration. The oldest example of a modern cancer registry is that of Hamburg, Germany from 1929 (IARC, 1991). Population-based cancer registration with an epidemiological and ecological objective started in the US in 1935, when a division of cancer research was formed in the Connecticut State Department of Health (IARC, 1991). The Danish Cancer Registry was founded in 1943 under the auspices of the Danish Cancer Society and it the oldest functioning registry covering a national population (NORDCAN, 2013). Other examples of early health information systems are in the area of public health surveillance, particularly with a focus on infectious diseases and epidemics (Declich & Carter, 1994).

National health data collections collect a considerable amount of data on a regular basis to provide a wealth of information about health and social care services. Safe reliable health and social care depends on "access to and use of good quality information which is essential to achieve a high quality, value for money, healthcare system" (Thacker et al., 2012). For example, data from cancer registries can be used in a wide variety of areas of cancer control ranging from patient care, healthcare planning, through to primary and secondary prevention and research, so benefiting both the individual and society. National data collections for public health surveillance are used not only for the detection of epidemics but also as the foundation for "decision making in public health and empowering decision makers to lead and manage more effectively by providing timely, useful evidence" (Thacker et al., 2012). Another example is national reporting on adverse clinical incidents and near misses which is an established technique resulting in reduction of accidents and injuries in patients (WHO, 2005).

Based on international best practice, four key overarching objectives relating to health information have been identified that are based on maximising health gain for the individual and the population:

- Health information is used to deliver and monitor safe and high quality care for everyone;
- Health information should be of the highest quality and where appropriate collected as close as possible to the point of care;
- Health information should be "collected once and used many times"; and
- Data collection should be "fit for purpose" and cost-effective.

The Guiding Principles for national data collections developed by HIQA in Ireland (HIQA, 2013) incorporate international evidence and provide a framework of best practice to enable data collections to collect quality data and work towards driving improvements in health information.

## 1.2 Challenges faced by national health data collections

While the health data collected by nations has many uses, there are challenges faced by national collections. A survey was conducted by HIQA of a representative sample of ten national collections in Ireland, where significant challenges were identified (HIQA, 2011b). These are similar to the challenges faced by national data collections in other countries, for example in a survey conducted by the Centers for Disease Control and Prevention (CDC) in the US, it was found only one in five reported that CDC surveillance systems are flexible and readily able to adopt new methods in a rapidly changing environment. Six major areas of concern were identified, namely "a common lexicon; global surveillance needs; informatics, including information technology; a skilled workforce; data access and use; and data management, storage and analysis" (Thacker et al., 2012).

In addition to the challenges faced by individual national data collections, there are others that fall outside the scope of the national collections themselves. The situation in most countries is that national collections have evolved over time in a largely uncoordinated fashion, with each collection addressing a specific administrative purpose or clinical area. This has led to the development of isolated 'silos' that show significant variation in quality, fragmentation, duplication, access, and costs. There is a growing international consensus that insofar as possible, data should be collected only once and then used for multiple purposes (Cimino, 2007). Thus, for example, data captured during the course of healthcare delivery can be used directly in patient care including the production of discharge summaries. However, this data can also be used for other purposes such as clinical audit, provision of data to a national registry, case mix, reimbursement, planning, and so on.

Another major deficiency in terms of health information is that not all countries have a unique patient/health identifier for all the healthcare encounters that are in place. In the US, for example, the Social Security Number (SSN) is a unique identifying number that can distinguish patients in public healthcare programmes such as Medicare and Medicaid. However, the SSN is not used for all healthcare encounters. This is in contrast to countries such as Poland and the United Kingdom where the identifying numbers are exclusive to the provision of health services and are not used for tax or social security purposes (OECD, 2013). In Ireland, the absence of a unique identifier for individuals across the health and social care systems, and for healthcare practitioners and organisations, leads to further duplication, fragmentation, increased costs and undermines the quality and safety of services making it very difficult to follow the care pathway of an individual (HIQA, 2011b).

A number of reviews have been published in recent years highlighting the variance in the national health information infrastructure in different countries. The OECD has conducted a survey (OECD, 2013) of members of the OECD Health Care Quality Indicators Expert Group, which included countries

from Europe, the US and Australia. While the infrastructure for health information varies across the countries surveyed, the overall finding was that improvements are taking place across all countries. Many of the countries examined by HIQA in 2011 while conducting an international review, in particular Canada and New Zealand, have begun harmonising their data collections using a variety of roadmaps, strategies and legislative means to bring the diverse range of data collected together (HIQA, 2011c). The World Health Organization has also published a review of 'Country Health Information Systems' (WHO, 2011), examining the infrastructure in place for health information across a very broad range of countries, in particular low- or middle-income countries. Not surprisingly, it was found that the very countries that face the greatest health challenges, in general, have the weakest systems for gathering, managing, analysing and using information.

## 2. Methodology

The first step in the development of the Guiding Principles were the preparation of a detailed catalogue of all national health and social care data collections in Ireland (HIQA, 2010a). A survey was then conducted by HIQA of a representative sample of ten of these national collections in order to understand in more detail the availability of data, uses of data, access to data, and the high level information flows (HIQA, 2011b). The overall aim was to identify and extract specific themes to inform the development of these principles. An international review of the approaches taken by other countries was conducted, which covered six countries in detail (HIQA, 2011c). A multidisciplinary advisory group was convened which worked with HIQA in the development of these Guiding Principles, and a public consultation was also conducted (HIQA, 2011a).

## 3. Guiding Principles for national data collections

There are eight guiding principles for national health and social care data collections which are of equal importance (Table 1). These principles incorporate international evidence and promote a practice that is up-to-date, effective and works towards greater consistency across all national data collections. They provide a basis for planning and measuring improvements as well as identifying and addressing gaps and quality issues. The guiding principles cover the themes of governance, statement of purpose, legislation and standards, use of resources, data quality, information governance, use of information, and workforce.

**Table 1:** Guiding Principles for national health and social care data collections

| No. | Guiding Principle |
|---|---|
| 1 | **Governance arrangements**<br><br>Formalised governance arrangements are in place to ensure that the objectives of the national health and social care data collection are met. |
| 2 | **Statement of purpose**<br><br>The managing organisation of the national health and social care data collection maintains a publicly available statement of purpose, setting out how it will achieve its stated objectives. |
| 3 | **Legislation and standards**<br><br>The managing organisation of the national health and social care data collection is compliant with relevant legislation and standards. |

| | |
|---|---|
| 4 | **Use of resources**<br><br>The managing organisation of the national health and social care data collection plans and manages the allocation and use of resources to ensure the objectives of the national collection are met. |
| 5 | **Use of information**<br><br>The information produced by the national health and social care data collection is accessible to data users in line with legislation and disseminated to optimise its benefit. |
| 6 | **Data quality**<br><br>The effectiveness of the national health and social care data collection in meeting its objectives is systematically monitored, evaluated, and continuously improved to ensure data quality. |
| 7 | **Information governance**<br><br>The managing organisation of the national health and social care data collection has effective arrangements in place for information governance which protect the rights of people about whom it holds information. |
| 8 | **Workforce**<br><br>The managing organisation of the national health and social care data collection plans, organises and manages its workforce to deliver its objectives. |

The purpose of these guiding principles is to provide current and future data collections with guidance on these eight important areas of activity. While the principles have been developed for the Irish context, they are sufficiently generic to be applicable to other equivalent contexts and data collections in the US or Europe. In the following sections, three specific examples from the guiding principles (the use of information, data quality, and governance) are used to demonstrate the applicability of the principles across different jurisdictions. Further detail is provided in the full version of the Guiding Principles (HIQA, 2013).

## 3.1 Use of information

Guiding Principle 5 deals with the area of use of information from national health data collections. Most national data collections are regarded as secondary sources of information. This means the national data collection uses the information generated as a result of providing care for purposes other than direct service-user care, such as planning, managing, auditing or research.

Considerable time, effort and resources are invested into producing a high quality health data collection. In order to maximise the potential of these data collections to support improvement in quality and safety of health and social care as well as health gain generally, it is essential to promote, encourage and facilitate the use of the data. Depending on the nature and resources available to the managing organisation, data can be made available through a variety of different mechanisms.

It has been internationally recognised that health data is not being used to its full potential, and steps are being taken to address this weakness. The US has developed a framework to improve the use of secondary data "Toward a National Framework of the Secondary Use of Health Data" (Safran et al., 2007). The following six components for this framework were outlined:

- Transparent policies and practices for the secondary use of health data;
- Focus on data control, rather than data ownership per se;
- Consensus on privacy, policy and security;

- Public awareness;
- Comprehensive scope; and
- National leadership.

The EU has already key initiatives underway that are helping provide additional insights on how to address the issues around the re-use of health data. At an EU Summit on "Trustworthy Reuse of Health Data" held in 2012, a white paper was developed to help inform governments, private sector data source owners, clinicians, and anyone else interested in the management of this data, with regard to the appropriate steps needed for good data stewardship (IMIA, 2012).

Information is a valuable resource. Wherever possible, it should be 'collected once and used many times' provided the appropriate protections and safeguards are in place. There is a need to strike a balance between an individual's right to privacy and the desirability to make information available to improve the quality and effectiveness of care through audit and research for the public good. In both Europe and the US, there is a growing recognition that healthcare can be transformed through the secondary use of health data. There is a strong consensus on the need for standards and guidance in secondary data use. A PWC review of secondary health data use identified a number of key issues that organisations need to consider in terms of assessing their readiness for secondary data use (PWC, 2009). The issues were as follows: cooperation and connectivity, privacy and security, technology, governance, standards and compliance, quality and value, and patient-centric information network. Table 2 outlines some examples of how to maximise use of information from national collections.

**Table 2:** Examples of how to maximise the use of information from national data collections (Source: HIQA, 2013)

| |
|---|
| • Make the data available and report on the data within a reasonable time frame. |
| • Publish the use of data policy, which includes information about how to access the data and terms and conditions for using the data. |
| • Have clear procedures on the process to access data from the initial request for data through data generation and final dissemination. |
| • Encourage use of data by data providers, for example the use of clinical statistics by hospitals to monitor their own performance. |
| • Specialist training is provided for certain data users if required. |
| • Provide a data dictionary to enable data users to accurately use and interpret data. |

## 3.2 Data quality

Guiding Principle 6 concerns the important area of data quality. Data quality can be defined as "the totality of features and characteristics of a data set that bear on its ability to satisfy the needs that result from the intended use of the data" (Arts et al., 2002). Data quality refers to data that is "fit for purpose" or "fit for use". Therefore, a realistic target for health and social care services is to produce data that is sufficiently accurate, timely and consistent to make appropriate and reliable decisions rather than aiming to produce completely perfect data (Wang & Strong, 1996).

The primary objective of any national health data collection is to inform the population it serves and its data users in order to improve the quality of care and service provided. In order to achieve this objective there must be full confidence and trust in the quality of data collected. Data can be said

to be of good quality when it does what it is needed to do. For example, laboratory test results for urgent cases are communicated as quickly as possible and are detailed enough to help the treating doctor decide on the appropriate treatment.

The quality of data can be assessed against a number of "dimensions". There are many of these dimensions identified in international literature (Wang & Strong, 1996). These include accuracy, validity, reliability, timeliness, relevance, legibility and completeness, as described in Table 3.

**Table 3:** Dimensions of Data Quality

| Dimension | Description |
|---|---|
| Accuracy | Accurate data refers to how closely the data correctly captures what it was designed to capture. |
| Completeness | Complete data is data that has all those items required to measure the intended activity or event. |
| Legibility | Legible data is data that the intended users will find easy to read and understand. |
| Relevance | Relevant data meets the needs of the information users. |
| Reliability | Reliable data is collected consistently over time and reflects the true facts. |
| Timeliness | Timely data is collected within a reasonable agreed time period after the activity that it measures and is available when, and as often, as it is required |
| Validity | Valid data is collected in accordance with any rules or definitions applicable for that type of information. These rules check for correctness and meaningfulness before data is used. |

The challenges around data quality are universal. In a report published by the Health and Social Care Information Centre in the United Kingdom (HSCIC, 2012), a number of consistent factors were identified across the entire national health service (NHS) that lead to poor quality of nationally submitted data across all activities, sectors and datasets:

- Lack of standards and guidance;
- Poor training and awareness of the impact of poor data quality;
- Local system updates and changes;
- Reorganisation and reconfiguration of services; and
- Knowledge and use of data and its quality.

Health information standards support data quality by facilitating interoperability between information systems and through the meaningful and appropriate sharing of data. The use of international data standards ensures that there is consistency and comparability, and promotes responsibility and accountability for the quality of data collected and reported on by national data collections. Data dictionaries, international classifications (such as the WHO International Classification of Diseases) and clinical terminologies (such as SNOMED-CT) are the standards that help data collections work towards ensuring that there is a common, consistent understanding of each data variable, and also help with sharing data and supporting interoperability. Table 4 outlines some steps that national collections can take to achieve data quality.

**Table 4:** Examples of steps that data collections can take to achieve quality data (Source: HIQA, 2013)

- Assign a named person responsible for data quality.
- Uniquely identify all data subjects, where possible.
- Have policies and procedures in place ensuring best practice on all aspects of data quality including data collection, validation, storage and processing.
- Regular data quality training is provided to the workforce.
- Validation and other data quality spot-checks are regularly carried out to support the collection of complete and valid data.
- Key performance indicators are in place to provide objective measures of data quality.
- Records retention and disposal policies are based on legislation and best practice.

### 3.2.1 Workforce and data quality

Despite the increasing efficiencies in information technology, human input will remain large and consequential to the success of national data collections. The workforce is the core of each data collection and is integral to the provision of quality data. A national data collection operates most effectively when the right people with the right knowledge, skills and competencies are deployed appropriately to deliver quality data. While the value of the national data collection depends on the quality of the data contained in it, the literature points out that incorrect patients can be registered or data items can be inaccurately recorded or not recorded at all (Arts et al., 2002). This type of error can be partly due to insufficient training or a lack of structured training for participants in using the data definitions and guidelines, as has been noted over the past 20 or so years (Arts et al., 2002; Declich & Carter, 1994; Needham et al., 2009). The individual members of a workforce must be skilled and competent. A programme of repeated training has been shown to improve data quality (Porcheret et al., 2004).

The issue of eHealth workforce development has been prioritised in the Transatlantic eHealth/health IT Cooperation Roadmap with plans to work together to address "competency and knowledge deficiencies" and develop common goals to achieve a "robust supply of highly proficient professionals" (Health IT.gov, 2013).

## 3.3 Information governance

Guiding Principle 7 deals with the area of information governance. The principles of good information governance allow national health and social care data collections to ensure that personal information, such as that contained in a health or social care record, is handled legally, securely, efficiently and effectively in order to deliver the best possible care to people who use health and social care services (HIQA, 2012). Robust information governance practices facilitate:

- The collection of high quality data;
- The maintenance of privacy and confidentiality of individuals;
- Information that is held securely; and
- The appropriate safeguards for secondary use of information that are in place to protect an individual's rights to privacy and confidentiality.

There are many challenges with regard to the areas of information governance and personal health information. Concerns around the privacy of healthcare information are very real and have been highlighted in studies in a number of countries. One study in particular reviewed privacy concerns of patients and nurse practitioners in primary care in the US (Olsen et al., 2005). It was found that significant concerns regarding privacy were identified by both groups, particularly in relation to disclosures of patient information for research purposes without patient permission.

The legislative environment varies greatly within jurisdictions. In the US and individual EU Member States there are various pieces of legislation relating to the protection of personal information in general and, for some countries, additional legislation specific to health data protection. Recent legislation and privacy policies have been influenced by the 1980 OECD privacy guidelines, which were updated in 2009 (OECD, 2009). These guidelines emphasise that data collections are respectful of personal privacy when they follow the following principles:

- Collection limitation;
- Data quality;
- Purpose specification;
- Use limitation;
- Security safeguards;
- Openness;
- Individual participation; and
- Accountability.

These principles have also been reflected in the 1995 Data Protection Directive of the EU (EUR-lex, 1995) that regulates the processing of personal information. The proposed EU Data Protection Regulation (a draft of which was unveiled in January 2012) extends the scope of the EU data protection law to all foreign companies processing data of EU residents (European Commission, Justice Division). In the US, there is a federal Privacy Act (1974) with data protection requirements for federally held personal data and the Health Insurance Portability and Accountability Act 1996 (HIPAA), which specifies data protection requirements for personal health data (OECD, 2013).

In relation to information governance, the HIQA Guiding principles also cover the important area of consent. The basic principle for using personal health and social care information is that the data subject is aware of how the data is being used. In many countries, including Ireland, there are situations where the need for informed consent has been removed within legislation, for example for the protection and control of cases and outbreaks of infectious diseases (HPSC.ie). The preparation of a Statement of Information Practice (HIQA, 2013) is another important step that a service provider can take to describe how information is used for both primary and secondary purposes. It sets out, at a high level, what information the service collects, how it is used, with whom it is shared and for what purpose, the safeguards that are in place to protect it, and how service users can access information held about them.

With so much health and social care information being collected, used and shared by national data collections, it is important that initiatives are undertaken to protect the privacy of each individual and ensure that sensitive personal health information is handled legally, securely, efficiently and effectively in order to deliver the best possible care.

Privacy impact assessments (PIAs) are a common tool employed in many countries to protect and enhance individuals' privacy. PIAs are used across all sectors but are particularly useful for healthcare providers in assisting with the identification of potential risks in the collection and use of personal

health information as this information is categorised as being sensitive. The primary purpose of a privacy impact assessment (PIA) is to protect the rights of individuals (HIQA, 2010b). Table 5 outlines some examples of good information governance practices.

**Table 5:** Examples of good information governance practices
(Source: HIQA, 2013)

| |
|---|
| • A named person responsible for information governance. |
| • Policies and procedures are based on best practice for all aspects of information governance. |
| • Regular training for the workforce on relevant information governance policies and procedures. |
| • A statement of information practice or similar tool to communicate with data subjects. |
| • Formalised agreements to set out the strict procedures with third parties regarding access to data subjects' data. |
| • Ability to audit all access to data subjects' information. |
| • Paper and electronic files containing data subjects' information are stored securely when not in use and have a specified retention period. |
| • Individual login details and passwords are assigned to those in the workforce who have access to data subjects' information. |

## 4. Conclusions

Safe, reliable health and social care depends on access to and use of good quality information. The OECD states that "information is essential to achieve a high quality value for money, healthcare system" (OECD, 2010). Accurate, quality information has a key role to play in planning and managing services. It is of significant importance to help determine the most beneficial location for a new service, whether or not to introduce a new national screening programme, and to evaluate performance.

International experience has shown that introducing an EHR is complex and presents many challenges.

Some of the key enablers to deliver an EHR include:

- A set of standards including communication, coding and terminology, based on widely available and implemented international standards;
- A system of unique identification for individuals, organisations and professionals, a robust, reliable, secure network which connects all healthcare professionals and organisations;
- Appropriate governance arrangements to ensure the privacy and confidentiality of patient data; and
- Appropriate workforce skills and resources.

For countries, such as Ireland, that are in the early stages of development of the eHealth sector, and have yet to introduce a national electronic health record, there are steps that can be taken to improve national data collections and the data they collect. The guiding principles use a standards-based approach to do this, which will facilitate an easier migration to an EHR, and further enhance the concept of "collect once use many times".

National health and social care data collections are crucial in terms of providing a national overview of a particular health or social care service. It is hoped that the adoption of these guiding principles will in time lead to the rationalisation and harmonisation of the development and governance of new and existing national data collections. This will in time enable improved analyses of secondary data to inform decision-making, monitor diseases, plan services, inform public health policy making, conduct high quality research, and plan for future health and social care needs. Furthermore, by reducing fragmentation and duplication not only can the quality and utility of the data be increased but costs can also be reduced through the pooling of resources, and sharing of infrastructure, skills and expertise.

Secondary use of health information, such as that collected by national health data collections, has the potential to transform healthcare. With healthcare reform on the national agenda in the US, led by the Obama administration, and the on-going collaborations between the EU and the US in relation to health IT/ eHealth, there is a huge potential for the advancement in this area in the coming years.

While the guiding principles do not address the challenges around harmonisation at a national level, they provide a basis for planning and measuring improvements in addition to identifying and addressing gaps and quality issues. The principles incorporate findings from national and international evidence and promote practice that is up-to-date, effective and works towards greater consistency across all national data collections to improve how these collections achieve their objectives. They also address some of the challenges faced by national collections through the use of standards, for example, by driving data quality through the use of standards such as data dictionaries, and classification and clinical terminologies.

Overall, the guiding principles presented in this paper provide a framework of best practice that could be adopted by national health and social care data collections in EU Member States and the US to collect quality data, work towards driving improvements in health information, and ultimately lead to safer and better care for all.

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# Cross-Border Interoperability for Travelling Patients: A Proposal for Italian and American Patients

This paper describes how information and communication technology (ICT) can facilitate continuity of care for people travelling in foreign countries or on foreign continents. A possible solution is to share the Patient Summary, a clinical document containing information on the health status of the patient. Intercontinental sharing of this document would be easier if the Patient Summary were digitised and based on international standards of interoperability. A number of projects have been developed to create the Patient Summary as a digitally-structured document, and to share it on regional, national, European Union (EU) or American levels. However, there is no current infrastructure or infostructure capable of supporting intercontinental document sharing and implementation in the short term that will give immediate results.

An initial experiment with the sharing of the Patient Summary, based on interoperability between physicians in distant countries with a high volume of reciprocal tourism, can be undertaken in Italy and the United States of America (USA), two countries that are currently experiencing an increase in tourism.

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eHealth for travellers, semantic interoperability, technical interoperability, XDM IHE profile

> "If digitised and based on international standards of interoperability, the Patient Summary can help ensure continuity of care for people travelling for purposes of either business or leisure."

# 1. Introduction

In recent years there has been an increase in long distance travel, whether for business or leisure. The deregulation of the traditional airline industry has created competitiveness that has reduced travel costs, and made cross-border and transcontinental travel possible even for those on limited budgets. Traveller demographics are varied and reflect the general population: they include elderly people, and people with disabilities or chronic illnesses. Even apparently healthy people may have known susceptibilities (e.g., allergies) that are of medical concern in an emergency situation. It is important, from a medical point of view, to guarantee as much clinical support as possible for such travellers. Patient care depends on information available to the physician. As a result, patient care in a host country (where the patient is travelling) can be more effective if a local doctor can access available summary information on the patient's health status, and on known allergies and medical history. These data are stored in a clinical document called the Patient Summary. However, the information in the original language cannot be used if it is not related to a common language based on coded terms.

A number of projects have been developed for realising the Patient Summary as a digitally structured document, and sharing it on a regional, national, or EU level (for details, see later in this paper). These projects have defined the structure and contents of the Patient Summary. However, there is no current infrastructure or infostructure that can support document sharing on an intercontinental level. Implementation in the short term, with immediate results, would only be possible through an available and supporting interoperability standard.

This paper proposes a solution that helps guarantee quality of care for cross-border patients by sharing a summary of health care information between the traveller's physician in the home country and the physician who examines the patient in the host country. With the appropriate economic resources, a pilot project could be designed and implemented in both Italy and the USA, two countries experiencing an increase in tourism.

# 2. Facts and Figures on Italy-USA Travel and Tourism

Italy ranks high in the top 10 for international tourism. In the 1990s and at the beginning of this millennium, Italy was the fourth most visited country after France, Spain and the USA. In 2004, China climbed to third position, overtaking Italy, whose position remains stable in terms of revenue. Today Italy is the fifth destination in the world for international tourist arrivals and the sixth nation for tourism receipts (UNWTO, 2013).

Furthermore, tourism is an important sector of Italy's national economy. According to the World Travel and Tourism Council (WTTC, 2013) tourism in Italy accounts for approximately 8.6 % of gross domestic product (GDP), and is expected to grow by 2 % annually through 2021.

According to the 2011 Flash Eurobarometer survey on the attitudes of Europeans towards tourism (European Commission, 2012a), Italy was the second holiday destination of EU citizens, with 7 % of the total. Italy overtook France in this regard and is second only to Spain as a destination. Examining data from a range of years (2005-2010 and 2009-2011), Italy was also first among the EU Member States for accommodation capacity, second for arrivals, fourth in the world rankings for currency earnings, and fifth in the world rankings for arrivals (Table 1).

**Table 1:** Key Statistics on Tourism in Italy

| Key Statistics - Italy | |
|---|---|
| Travel & Tourism Revenue (€ billion, 2011) | 136.1 (8.6 % of GDP) |
| Inbound Tourist Arrivals (million people, 2011) | 46.1 |
| Inbound Tourism Receipts (€ billion, 2011) | 33.2 |
| Hospitality Industry - Hotels and Other Accommodation (units, 2011) | 153 728 |
| Hotel Industry - Number of Bed-Places (units, 2011) | 2,252,636 |
| Hotel Industry (Hotels and Restaurants) - Number of Employees (2010) | 1,540,000 |

Sources: WTTC 2012 Italy Country Report, UNWTO 2012 Highlights, Italian Institute of Statistics, Confcommercio, Invitalia

In 2012, about 6.2 % of travellers to Italy came from the Americas (Figure 1), and almost 65 % of these were United States (US) citizens. In 2013, the Italian National Observatory on Tourism (ONTIT) predicted that approximately 10 % of visitors to Italy would be North or South Americans, making the USA the country outside of the EU with the highest number of tourists travelling to Italy.

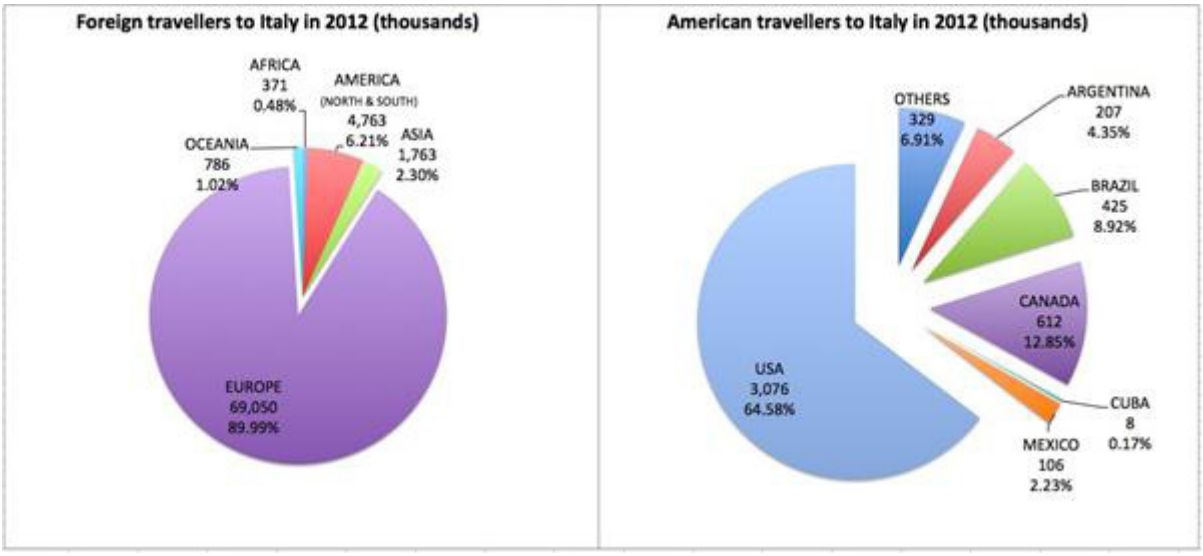


**Figure 1:** Origin of Travellers to Italy in 2012
Source: ONTIT

ONTIT also reported that America (with North and South America considered as a single continent) is the second most preferred continent, after Europe, for Italian travellers (Figure 2), and with the USA as the most visited country.

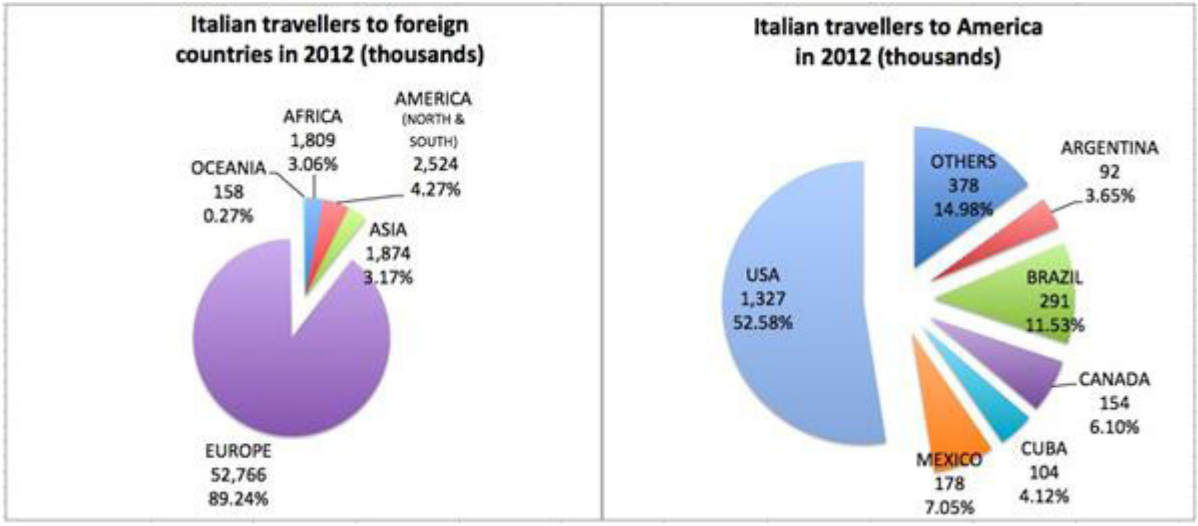


**Figure 2:** Destination of travellers from Italy in 2012
Source: ONTIT

## 3. Patient Summary for Travellers

A number of EU countries have developed Electronic Medical Record (EMR) management systems to improve quality and continuity of care. The Patient Summary, the EMR, and the Electronic Prescription support safe and appropriate medical services, allowing clinicians to access data and information, and offer effective care.

While there has been shared interest in developing these three systems, recent focus has been on system interoperability among the countries offering these services. Today, EU countries are working on a series of initiatives to identify solutions for interoperability of the digital health systems currently in use, allowing citizens easy access to these services.

One of these initiatives is European Patients - Smart Open Services (epSOS). This is a large-scale, electronic health interoperability pilot that started in 2008, and focused on building and evaluating a European service infrastructure for cross-border exchange of electronic health record information among its partner countries.

Given the number of tourists visiting the USA and/or EU countries every year, and bearing in mind that there is already a project dealing with interoperability among European hospitals, it would be beneficial to try extending local or EU experiences to the USA, and implement the main service – the Patient Summary – for patients with chronic conditions.

The main benefits of electronic health system interoperability between the US and Europe would include:

- Improved quality and safety of health care for non-resident patients;
- Improved confidence in travelling, including for patients with medical conditions;
- Guaranteed continuity of care, specially chronic patients;
- Reduction of cost to a host country's health system to treat non-resident patients; and
- Reduction of travel insurance costs.

The Patient Summary is a standardised set of basic medical data, containing:

- General information on the patient (e.g., name, date of birth, place of residence);
- A medical summary consisting of the most relevant clinical patient data (e.g., allergies, current medical problems, medical implants, vaccinations or major surgical procedures during the last six months);
- A list the patient's current treatments; and
- Information on the Patient Summary (i.e., when and by whom the summary was generated or updated).

In the event of emergencies, the Patient Summary allows clinicians to access useful information in order to provide appropriate medical care and avoid, for example, administering unnecessary or harmful medications. If digitised and based on international standards of interoperability, the Patient Summary can help ensure continuity of care for people who are travelling for either business or leisure or other reasons.

The sharing of the Patient Summary between health professionals located in different continents can be guaranteed only if certain obstacles are overcome. The information in the Patient Summary must be supplied to clinicians in the language of the travelling patient's destination. It is also important to identify enhanced solutions to overcome language barriers, by translating prescriptions and/or information in the appropriate language, and translating and converting measurement units into those used in the host country. For this reason, the information in the original language cannot be used if it is not related to a "common language" based on coded terms. It is necessary to use standard encodings (examples include HL7, LOINC, SNOMED CT). This guarantees the semantic interoperability that allows local information systems to read the content of the document. Another issue is the lack of an infrastructure that can support document sharing on an intercontinental level. Short-term implementation with immediate results would be possible only through an available and supporting standard, for example, the Integrating the Healthcare Enterprise (IHE) profile.

In order to develop an interoperable service, it is necessary to provide recommendations, functional and technical specifications, organisational models and technical tools for improving the interoperability of the national systems.

Building a pilot project between different European nations and the US will add complexity to that tackled in the epSOS large-scale pilot. In order to keep it simple, a small pilot project, involving a few states in Europe, and the US, may be more feasible. For example, in Italy, a transplant centre has been operating since 1998 as an international branch of the University of Pittsburgh Medical Center (UPMC). UPMC is one of the largest health care providers in the US, and, given its growing international interests, could be involved in such an interoperability pilot.

Moreover, this pilot could find political and economic support in the current activities connected with the Memorandum of Understanding (MoU) between the US Department of Health and Human Services (DHHS) and the European Commission on Cooperation Surrounding Health Related Information and Communication Technologies, signed in December 2010. In fact, alongside the MoU, the European Commission's Directorate General for Communications Networks, Content and Technology (DG CONNECT) and the DHHS have agreed on a roadmap to strengthen transatlantic cooperation in eHealth and health information technology (IT). The collaboration is focused on developing and using internationally recognised standards that support transnational interoperability of electronic health ICT.

With these facts in mind, and given the volume of tourist travel between Italy and the US, the authors propose a pilot to be undertaken between Italy and the US. This pilot project would involve travellers who volunteer to participate.

## 4. Impact on Cross-National Health Care Policies

In this section, two examples of eConsultations in Pula will be discussed. Primarily though, the paper will briefly discuss the Croatian context and the reason why the city of Pula has been selected as a case study.

Even if there are basic differences in the provisions, and the economic, organisational and ethical models of the Italian and the American health systems, there is a similar political ambition in both countries to improve these systems.

Implementation of key actions to provide care to non-EU or travelling citizens/patients in the EU, and experimentation with these applications on a small scale, may assist in the development of a systematic approach that could be introduced, in these two countries, both of which have areas endowed with high levels of tourism.

The EU has recently been moving towards improvement in health care delivery to patients outside their country of origin (though little has been done to improve delivery between EU Member States and non-EU States). In fact, several EU guidelines and recommendations related to this challenge have been issued (European Commission, 2008a; 2009; 2011). Italy, as an EU Member State, is required to offer a high level of care to both its citizens and citizens of other EU Member States.

It is also important to remember that, beyond tourism, Italy hosts a number of US military bases, and international business interests are leading many Italian and US citizens to travel for limited periods to each other's countries.

In terms of the sustainability of health care procedures in a cross-border context, the service could conceivably be supported by insurance policies that are already provided to travellers. In addition, providing information on a patient's health status could improve the patient care in the event of an acute episode, and help avoid unnecessary diagnostic tests if the diagnosis is already included in the Patient Summary. Having detailed information on the patient health status could also help avoid medical errors, which – among others – are an additional cost for a health care system.

This application would also have a considerable and positive economic impact. In fact, providing support to international travellers will make them feel more secure. As a result, this added sense of security will likely increase the number of travellers in the two travel directions, and produce economic benefits for both countries.

## 5. Interoperability

The importance of cross-border interoperability of eHealth solutions has been recognised in Europe by:

- The eHealth Action Plan 2004-2012 (European Commission, 2004) and 2012-2020 (European Commission, 2012b);
- The Recommendation on Cross-Border Interoperability of Electronic Health Record (EHR) Systems (European Commission, 2008a);

- The Communication on Telemedicine for the Benefit of Patients, Healthcare Systems and Society (European Commission, 2008b);
- The Communication on "Towards Interoperability for European Public Services" (European Commission, 2010);
- The Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border health care (European Commission 2011); and
- All the relevant EU documents validated by the eHealth Resolution of the World Health Assembly (WHO, 2005).

In the USA, cross-border interoperability of the Patient Summary is recognised by the Department of Health and Human Services' Assistant Secretary for Planning and Evaluation Office of Disability, Aging and Long-Term Care Policy (US HHS, 2011).

The concept of interoperability arises from the need to enable communication among national eHealth infrastructures – in this case, in Europe – instead of devising a new and centralised EU health service network. This approach requires technical, semantic, organisational and legal interoperability among EU eHealth infrastructures, including identity and security matters, as well as information management issues (European Commission, 2013). Certain aspects of interoperability among EU and American eHealth infrastructures related to Patient Summary have not been studied in detail.

It is important to develop national and international standards for EHR interoperability in order to:

- Share patient health information among clinicians in a multidisciplinary, shared care environment;
- Share patient health information among organisations within an enterprise, a regional or national health system, or across national borders; and
- Support interoperability among software applications supplied by different manufacturers.
- The two principal aspects of interoperability in an intercontinental project that help guarantee an appropriate sharing of a Patient Summary among EU and US systems are:
- Semantic interoperability, which has to do with the exchange of information between systems in a format that can be processed by the receiving system; and
- Technical interoperability, which has to do with the exchange of information that can be shared by all actors. The exchange of information, in a first phase, will be realised through the use of data storage media (for example, a USB stick or a CD, or other types of media). This is because the epSOS experience has revealed that now is not the time to create a large common platform for data sharing. Indeed, implementation of the epSOS platform required considerable time and resources. The realisation and implementation of a worldwide infrastructure to exchange health data and documents will most likely be possible only in the future through infrastructure interoperability.

Each of these two forms of interoperability is explored in more detail in the sections that follow.

## 5.1 Semantic interoperability

Semantic interoperability helps guarantee the exchange of the Patient Summary between different systems in different EHRs. It is based on the use of such specific semantic standards as HL7, LOINC, and SNOMED CT.

- LOINC (Logical Observation Identifiers Names and Codes) is a set of universal names and identity (ID) codes for identifying laboratory and clinical test results in order to facilitate the exchange and pooling of results, such as blood haemoglobin, serum potassium, or vital signs, for clinical care, outcome management, and research (LOINC, 2013). The purpose is to assist in the electronic exchange and gathering of clinical results. Several standards, such as IHE (Integrating the Healthcare Enterprise) or HL7 (Health Level Seven), use LOINC to transfer results electronically from different reporting systems to the appropriate health care networks.
- SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms), owned and administered by International Health Terminology Standards Development Organisation (IHTSDO), is a systematically organized collection of medical terms that can be processed by a computer. It provides codes, terms, synonyms and definitions of diseases, findings, procedures, microorganisms, and substances. The primary purpose of SNOMED CT is to support the effective clinical data recording with the aim of improving patient care (IHTSDO, 2013). It is a structured collection of medical terms used internationally to record clinical information and coded to be processed by a computer. It covers areas such as diseases, symptoms, operations, treatments, devices and drugs. Its purpose is to index, store, retrieve, and aggregate clinical data consistently across specialties and sites of care. It helps organise the content of EHR systems, reducing the variability in the way data are captured, encoded and used for patient care and research. It provides a consistent exchange of information, and is fundamental for an interoperable EHR. It can be used to record the clinical details of individuals in electronic patient records, and support application functionality, such as informed decision-making, links to clinical care pathways and knowledge resources, and shared care plans. It can thus support long-term patient care. The availability of free automatic coding tools and services, which can return a ranked list of SNOMED CT descriptors to encode any clinical report, could help health care professionals navigate the terminology.
- HL7 CDA™ is an XML mark-up standard that specifies the structure and semantics of clinical documents for the purpose of exchange (HL7 International, 2013). Features of the HL7 CDA™ standard are listed below:
    - Context: A clinical document establishes the default context for its contents.
    - Human readability: A clinical document is readable by humans, and guarantees that a receiver of a CDA™ document can readily display the clinical content of the note on a standard Web browser.
    - Persistence: A clinical document continues to exist, in an unaltered state, for a period defined by local and regulatory requirements.
    - Potential for authentication: A clinical document is an assemblage of information intended to be legally authenticated.
    - Stewardship: A clinical document is maintained by a person or organisation entrusted with its care.
    - Wholeness: Authentication of a clinical document applies to the whole, and does not apply to portions of the document without the full context of the document.

The advantages of using the HL7 CDA™ standard are that it:

- Minimises technical barriers to implementation;
- Promotes the longevity of clinical records;
- Is designed for exchange, independent of transfer or storage; and
- Enables policymakers to control information requirements.

The HL7 CDA™ standard was developed with the HL7 Development Framework (HDF), and is based on the HL7 Reference Information Model (RIM) and the HL7 Version 3 Data Types. The CDA specifies that the content of the document consists of a mandatory textual part (which ensures human interpretation of the document's contents) and optional structured parts (for software processing). The structured part relies on coding systems, such as those from SNOMED CT and LOINC, to represent concepts.

## 5.2 Technical interoperability

Data exchange is achieved through the use of data storage media. With this aim in mind, the supporting standard is a specific IHE Integration profile: Cross-Enterprise Media Interchange (XDM) (IHE, 2012).

IHE is an initiative by health care professionals and industries to improve the way health care computer systems share information. Systems that support IHE Integration Profiles work together better, are easier to implement, and help care providers to use information more effectively. The goal is efficient delivery of optimal patient care. Several hundred products support one or more IHE Profiles.

Integration profiles describe clinical-information-management use cases and specify how to use existing standards (e.g., HL7, DICOM) to address them. Systems that implement integration profiles solve interoperability problems.

The XDM profile provides document exchange by using a common file and directory structure over several standard media. This also permits person-to-person e-mail to convey medical documents. The benefits of this profile are that it facilitates person-to-person exchange of the clinical information (in the absence of a secure infrastructure for clinical information exchange) via physical media such as a USB or CD.

This integration profile facilitates the exchange of electronic patient-related medical documents across health enterprises, using media or email. In our pilot project, we plan to use data storage media for the exchange of the Patient Summary.

XDM complements the existing Cross-Enterprise Document Sharing Integration Profile (XDS) (IHE, 2012) by providing XDS-defined formats and metadata in a simpler environment: document and metadata transfer through CD and USB memory devices (Figure 3).


**Figure 3:** Health Document Exchange Options - Flexible Infrastructure

This provides a standard-based specification for managing the exchange of documents that health care enterprises of any sort – from a private physician to a clinic to an acute care in-patient facility, and even between different regions or countries – decide to make. This can be between the patient and the patient's care providers or between care providers through the use of media (Figure 4). This enables better interoperability among EHRs and Personal Health Records (PHRs) as a natural complement to the IHE XDS Integration Profile (for cross-enterprise document sharing).

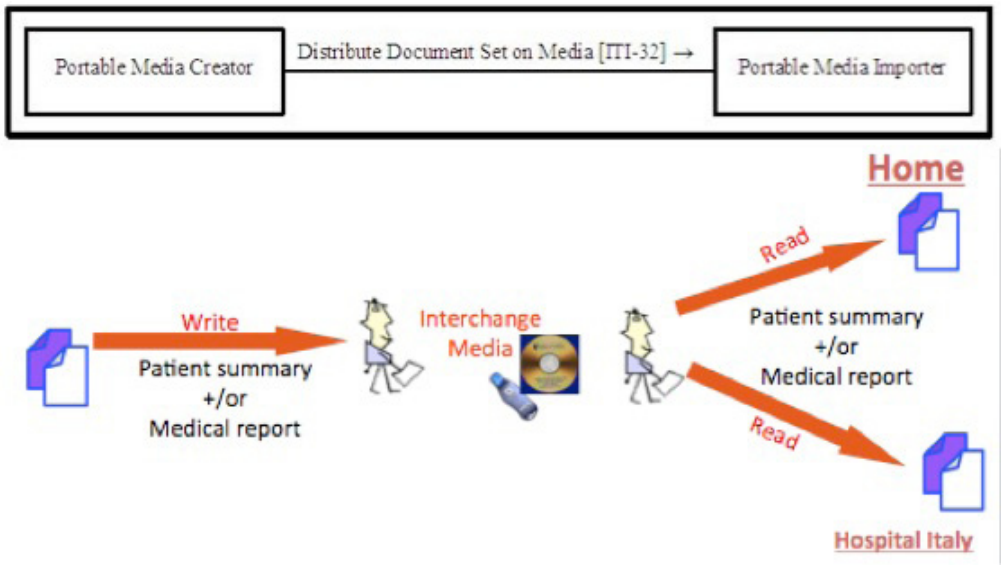


**Figure 4:** XDM Exchange of Health Information

The XDM solution is intended to be easy to implement in conjunction with pre-existing e-mail clients, CD burners and USB ports. XDM does not include any additional reliability enhancements. XDM requires that the recipient device can support human intervention. This is required to manage data importing manually (such as patient ID reconciliation, and selecting data of specific patients from multiple patient documents on the media).

XDM is an agnostic document format, supporting the same document content as XDS and XDR. Document content is described in XDS Document Content Profiles. Examples are XDS-MS, XPHR, XDS-SD, and XD*-LAB.

XDM defines no new metadata: it leverages XDS metadata with an emphasis on patient identification, document identification, description and relationships. A directory and file structure is documented for populating the media. This structure maintains separate areas for each patient listed, and is supported on all referenced media types. Media and structure are selected based on experience with media interoperability in the specific field of radiology, e.g., a PDI profile. The media selected are the widespread CD and USB removable media.

Systems involved in this profile are: EHR, EMR, HIE (Health Information Exchange), and HIO (Health Information Organisation).

## 6. Conclusions

There has been a recent increase in long distance travel, whether for business or leisure. In some cases travellers may need support in a foreign country. Since patient care largely depends on the information available to the physician, patient care in the country of destination can be improved if the local doctor has access to summary information on the patient's health status, allergies and medical history. This data can be stored in the Patient Summary. However, information in the original language may be misleading if it is not translated into the physician's language.

The framework presented in this paper is aimed at a solution that could improve medical assistance to US or Italian citizens during their travels abroad in either country. It takes place through the sharing of the most relevant medical information, contained in the Patient Summary, between the home physician and the medical team that, in the event of need, is called on to assist the patient in the host country.

The main benefit of Patient Summary interoperability between the US and Europe would include the possibility of maintaining quality and safety of health care outside the patient's own country, and guaranteeing continuity of care, particularly for patients with chronic conditions.

The authors are proposing a pilot project between Italy and the US to demonstrate the feasibility of a shared Patient Summary across continents. Thanks to a mature infrastructure and a consolidated standard of interoperability, the pilot could be implemented in a matter of months. The pilot is in line with the current EU and USA activities aimed at developing internationally recognised interoperability standards and interoperability implementation specifications for electronic health information systems.

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# Realising the Interoperable 'Web-of-Care'

This article examines collaborative challenges for producing systematic health care improvements in the context of the EU-US Health IT Cooperation initiative. Its focus comes as a result of patient criticisms regarding poor information flow across different 'webs-of-care'. The criticism captures real world complexities when patients try to navigate various isolated or fragmented parts of health care systems. This evidence suggests information system fragmentation through non-interoperability directly leads to frustration, delay, and a waste of time and resources.

Patients often express this effect of non-interoperability as lack of 'join-up' in their webs-of-care. An EU-US plan for robust and simplified interoperability to enable routine functioning of webs-of-care is thus proposed as a valid collaborative/convergence target. Seamless operation of future multi-system webs-of-care is also a clear 'acid test' for the effectiveness and patient-beneficial impacts of the EU-US interoperability initiative.

Seamless information flows within secure webs-of-care require an efficient solution to the 'many-to-many interoperability' problem. This solution should encourage the emergence of multi-vendor supply chains that can work to unify the entire 'patient path'. Progress towards full international realm interoperability can occur in the shorter term by adaptive software solutions that will offer some initial benefits.

'Many-to-many interoperability' in the form of secure health care information exchange is also valuable for systematic health care improvement studies. In particular, document standards are required for consistent aggregation of high quality data to accelerate distributed translational research through electronic health records (EHRs). These advances need to be coupled to eHealth workforce developments supporting distributed research collaborations formed around the 'knowledge cycle', which is discussed as a harmonising mechanism for spreading evidence-based best practices.

Standardising interoperable information exchange in networks also gives new opportunities for patient-controlled information sharing. With the patient at the centre of the network, improved mechanisms for consent management means that patients can share information with anyone they trust. The use of interoperable consent directives also promises greater patient involvement in research and the capacity to pre-consent for new recruiting research studies.

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Sintero.org

Keywords

Analytics, document standards, electronic health records for research, information governance, interfaces, interoperability, knowledge, single source, web-of-care

> "A focus on seamless interoperation of webs-of-care resulting from EU-US eHealth co-operation will be meaningful to the patient."

# 1. Introduction

The EU-US Health IT Cooperation Assembly held in Dublin in May 2013 was a landmark event in the development of global eHealth. It was founded on a Memorandum of Understanding (MoU) and a roadmap to be implemented between the European Commission and US Department of Health and Human Services under the auspices of the Transatlantic Economic Council (TEC). This initiative signalled a major political will for collaborative improvement of health using IT, with potential impacts for over a billion people.

In Dublin, the European Commission Directorate General (DG Connect), The Office of the National Coordinator (ONC) for Health Information Technology, and other Assembly members articulated the first parts of the roadmap with a focus on (i) the international interoperability of health records and (ii) the need to improve the eHealth skills of the current workforce. The demands for increased access by patients and clinicians were highlighted, as were some formidable barriers towards realisation. Beyond the financial constraints that many countries will continue to experience, barriers included multiple non-interoperable record systems (with different codings, classifications and messaging standards), significant variations in professional practice, workforce skill/capacity shortfalls (such as lack of consensus on skills, expertise or credentials that qualify someone as a health informatics professional), and poor 'join-up' (that is, fragmentation) in care processes and the information systems that serve them.

However, the Assembly also heard examples of scalable eHealth frameworks with the potential to both lower cost and raise quality of health care. In these cases, both collaboration and innovation were at the forefront, circumventing many of the barriers. Yet everyone involved acknowledged that "these are early days". Much effort lies ahead in order to make the initiative work. For instance, with the international interoperability of health records so high on the agenda, selecting and establishing single standards of choice is a priority. However, there are fiercely held views on which choices need to prevail in the EU-US context, and which should not. Perhaps this is the critical point characterising this initiative – there are difficult decisions needed in order to find a 'stack of single standards' that are sufficiently acceptable to the eHealth field to justify implementation at scale. The outcome must be a step-change in the way complex interoperability problems can be solved so as to ensure practical use at much lower price points – as amplified later in this paper.

# 2. Interoperability requirements in complex patient-centred 'webs of care'

It is generally accepted that EU-US collaborative eHealth developments should not be technically driven. The ideal would be for them to be developed from real-world requirements that are both meaningful and empowering for patients. The EU-US initiative will need to focus and promote the patients' points of view as it goes forward. However, continuity of care represents a complex 'many-to-many interoperability' problem.

Patients may need to interact with many organisations and professionals spanning the primary (family health), secondary (hospital/specialist units), and community health services. In some patterns of care this will extend to social services and it will increasingly involve the voluntary sector, family and friends. Moreover, since each health professional interacts with many different patients, there is also a challenge to develop interoperability to support intuitive access to patient records. This needs to be implemented in ways that support (or do not hinder) good clinical practice. It is clear that innovations in information processing (thereby exploiting interoperability) are needed to help clinicians make sense of potentially large amounts of information at the point of care.

An important contribution to understanding the real-world challenge for interoperability initiatives came when patients and carers contributed to a United Kingdom (UK)-based *National Voices* (2011) study on fragmented health care systems. One contributory factor to this fragmentation could be that traditional information infrastructures have been weighted towards serving organisations and not patients. To express patient and carer views on this subject, *National Voices* developed a diagrammatic representational method called the 'web-of-care' that detailed where seamless communications were required from the patient's perspective (see the example in Figure 1). This translates to a common patient requirement that all points in their individual web-of-care need to 'join up'. This study stated that many patients feel a sense of frustration when they have to repeat information for the many systems that they encounter. It also expressed patient's lack of power in the absence of a systematic method to enable continuity of communications under their control.

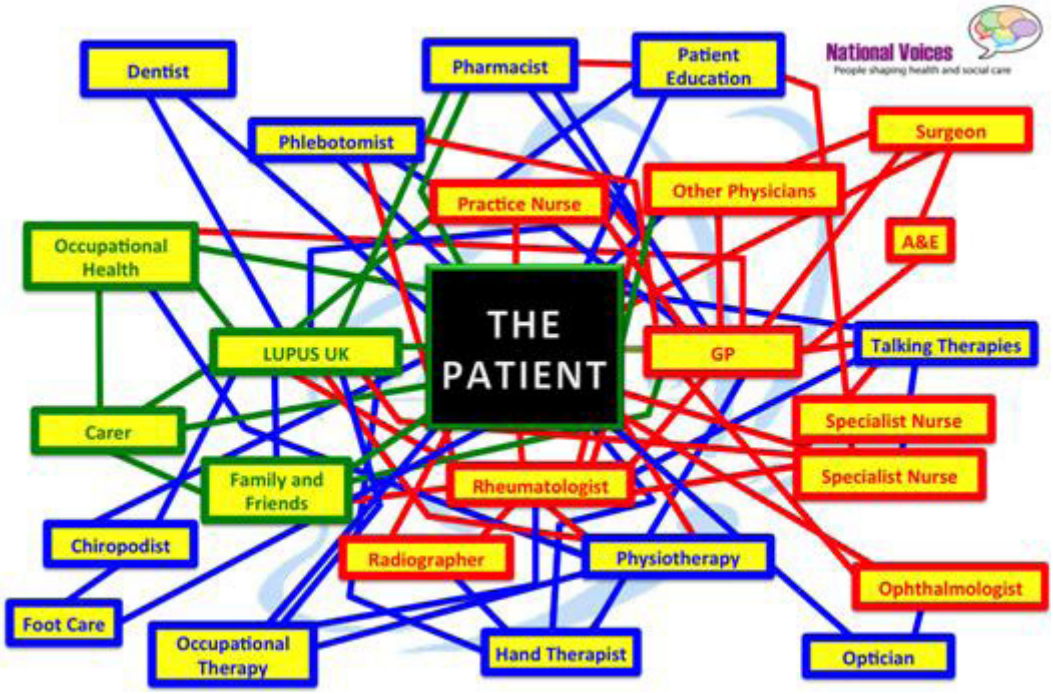


**Figure 1:** A real 'web-of-care' from a patient with a complex illness (Lupus)

With reference to this figure, the web-of-care is a diagrammatic representation of inter-person communications needed for a specific patient's integrated care. It is assumed that, when supporting the people in each unique web-of-care, there will be numerous information system suppliers, multiple care sectors and professional, organisational and individual contributors. The inherent complexity and rapidly changing dynamics in real webs-of-care – particularly in those where the patient has either a complex condition or experiences multiple conditions– suggest why a large-scale collaborative health IT interoperability framework design must be simple enough to permit instant adaptation to a changing network. Improvements of current system capabilities need to start with the recognition that a person's quality of care often depends on seamless communications between the people involved in his or her support network. This requires a stable, functional interoperability of information flow across care settings. This is therefore partly an issue of completeness of coverage: if any of the participant systems cannot securely exchange information when the need arises, the patient's full requirements cannot be met. Some parts of these networks may be well supplied with health IT solutions, but other parts not; it is thus a key challenge to render all systems capable of information exchange.

As in the above figure, although webs-of-care can appear chaotic, complex and non-standardised, detailed study of several webs-of-care reveals different individuals can express similar real-world requirements. The diagrams thus provide useful information for scalability on the part of different eHealth system designers, implementers, and professional providers of care. As a real-world representation of interoperable information flow, design of a common means for secure, safe and efficient coupling will lead to major benefits that improve the current state of fragmented systems.

In summary, webs-of-care are not geo-centric, organisation-centric or vendor-centric but rather patient-centric. It is important that a focus on seamless interoperation of webs-of-care resulting from EU-US eHealth co-operation will be meaningful to the patient.

This section of the article continues by exploring four forms of interoperability requirement for patients in terms of webs-of-care. They include overcoming the 'many-to-many' interoperability problem, the encouragement of interoperability in supply chains, planning for convergence, and the reduction of fragmentation. The implications of each of these are then outlined in section 3 of the paper.

## 2.1 Simplifying the 'many-to-many interoperability' problem at EU-US scale

As a direct challenge for the EU-US health IT cooperation initiative, the interoperable web-of-care model described in this article requires multiple information systems (both sources and recipients) to select and adopt common interoperability interfaces and electronic document standards. These can be considered from an information exchange perspective (i.e. to permit routine exchange between the outputs of one system to the input of another). Strategic decisions to simplify exchange by minimising the number of required interfaces and document formats (to support their exchange between all systems serving the patient's web-of-care) is a must for achieving low-cost scalability of interoperability. For wide-area use, a single distributed interface between one common international format/standard and all participating national system formats/standards is a preferred option (Benson, 2012 outline the reasons why). Distributing a single interface for common exchange avoids the impossible task of having to provide and maintain multiple mappings between many information models.

In the short term, adaptor (interface) work is needed between the national information system level and the international realm. This work could be shared across health record system vendors that supply webs-of-care. Limits to adaptor approaches exist; they share an analogy with language translation. While high quality translation may well be feasible between a local language and a common language (given that semantic equivalences can be met), it is not economically feasible to offer translations between all existing languages. Similarly, real-world webs-of-care cannot be supported sustainably by a multiplicity of translations through the above interfaces/formats. In order to reduce costs radically while raising quality, one must also reduce the complexity of interoperability in a radical manner. In seeking how to do this, the EU-US taskforce addressing interoperability could consider reviewing how to:

- Set one document/exchange standard for webs-of-care (candidates are already on the table);
- Eliminate interface optionality for local interface to the international realm;
- Loosely couple all 'source and recipient' information systems in webs-of-care;
- Place information sharing under patient control (see the section of this article on consent);
- Simplify the use of validated electronic IDs (i.e. trusted eIDs) in webs-of-care;
- Develop international data aggregation specifications for secondary use of EHR data in a range of research use cases.

The last point is vital for realising subsequent MoU/roadmap aspects such as 'universal provision of clinical decision support' and 'more cost-effective clinical research' goals. The current roadmap activities (reported at the May 2013 Dublin Assembly) have some clear actions on simplification through the selection of single 'cross-community acceptable' standards (e.g. push transactions of medical records based on secure email with mutual X509 certificates). There is currently less visible momentum on standard approaches to trusted eID services and patient-controlled information sharing (e.g. via vendor-neutral consent documents).

## 2.2 Encouraging interoperability in eHealth and research market supply chains

The TEC has expressed its hope that the EU-US Cooperation on eHealth can "boost economic growth at a time when we both need it" (De Gucht, 2013). The trade barrier effects of different regulations and standards are well appreciated. It is also well understood that changes to regulations are increasingly difficult once in place and established. However transatlantic participants in eHealth – as a comparatively young industry – have an opportunity to work together and lower barriers for reciprocal trade. It is also a fact that regulations, standards and specifications exist for a reason, and that the field is not starting from scratch. There are some legitimate technical and regulatory barriers in the supply of health IT systems to markets. These often have a technical accreditation (testing) component – perhaps as part of admission to a national procurement catalogue. This type of testing is likely to include capabilities relevant to interoperability at a national level.

National accreditations (certifications) for interoperability are a starting point for the development of transnational interoperability specifications at a particular level of granularity (such as document-level exchange). National certification 'test bench' technologies can act as a point of reference validating capabilities like transactional messaging content, inter-system acknowledgements, security (certifications) and transport standards which all need to be rigorous. In the long term, semantic interoperability (where the data does not require transformation due to a common language being used across all points in webs-of-care) is a goal. In the short term, however, it is unlikely that all national realms for interoperability specifications could easily converge to the same specifications, which raises a role for adaptive transformations between national and international realms (or between systems serving different parts webs-of-care). While one can consider this for now, it is also true that this type of 'interoperability on the fly' has its limits.

## 2.3 Planning for convergent interoperability

How can cross-market (multi-vendor, multi-sector) health IT systems that have been developed in different parts of the patient path interoperate seamlessly in the context of the web-of-care? If the patient path is a linear expression of the web-of-care (Figure 2), one can focus on the types of information systems that need to interoperate for the complete coverage described earlier. Figure 2 illustrates how a patient information system may couple consistent trusted electronic identities (eIDs) that are bound to recorded data across the timeline by multiple types of solutions/systems on the market. The method of exchange across this timeline needs to be one that can be supported by all systems. This is likely to have a standardised electronic document format (various options are under consideration by the EU-US collaboration). The systems themselves may or may not be accredited for interoperability at a given national level. To supply webs-of-care, systems need to have long-term capability to support common formats/metadata directed by international realm interoperability specifications.

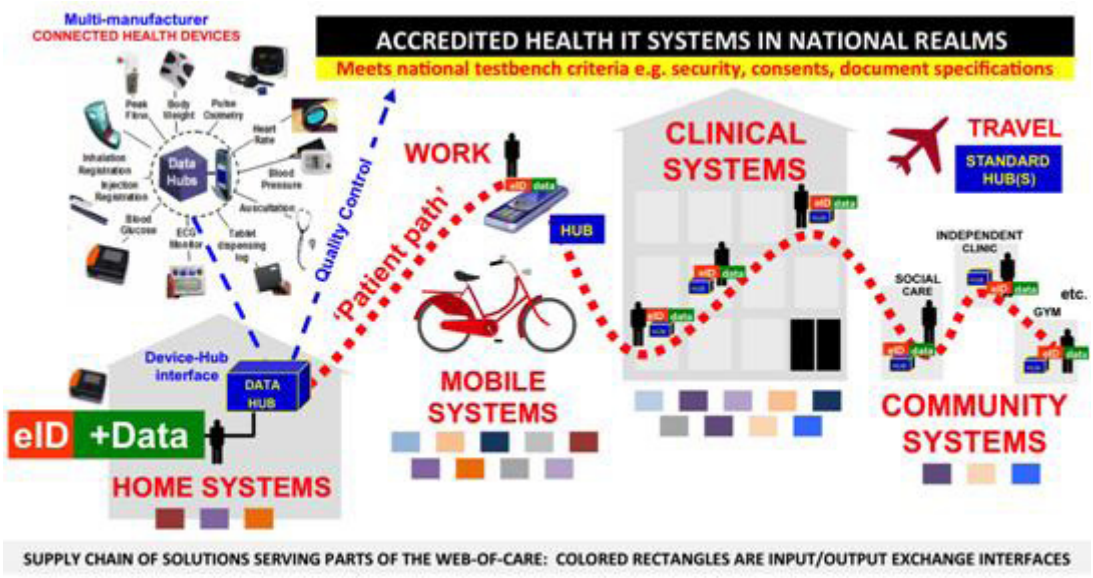


**Figure 2:** Multi-IT system interfacing across the patient path

What is evident from Figure 2 is that diverse IT products, originating from different sectors of the market, may well have evolved various interfaces for input and output of information. While there have been some major initiatives to standardise interfaces in specific supply sectors (notably personal health devices that are shown in the top left of the above figure), there is still radical fragmentation tat exists in the mature market. In areas like telehealth and telecare, this has undoubtedly been a barrier to mass adoption as many extant solutions use proprietary interfaces, and companies see no benefit or incentive to change. As a result, the degree of consumer choice may be lower than it could be, and confusion about cross-compatibility is a reality. Some parts of the supply chain will be subject to types of national accreditation testing. While these tests can help defragment technical specifications (raising the quality and consistency of the supply chain), the testing may follow geographic boundaries: accreditation in one country may not apply to other countries. From a vendors' perspective, a single stack of standards that can be used everywhere is of obvious benefit.

The significance of documents in cross-system information transfer and their role in regulating human activities is not about to change. Record systems populated and exchanged as documents (e.g. form-based reports) can represent real world tokens of work done and can trigger further work. Document standards also provide a means to educate professionals with regard to good clinical practice (Royal College of Physicians Health Informatics Unit, 2013). Standardised documents can provide a robust technical means to store, retrieve and extract information along a patient's path. They can also record standardised patient's consents integrated to a standardised audit trail.

## 2.4 Reducing fragmentation by interim adaptive solutions

Fragmentation of standards hinders progress in resolving the 'many-to-many interoperability' problem presented by real-world webs-of-care. Fragmentation may thus exist between legacy supply chains in national IT realms and a common international standards stack (a prioritised collection of single standards for specific functions). In these cases, adaptive interfacing methodologies using interface engines and mapping code can – within limits – provide 'interoperability-on-the-fly'. This principle is illustrated in Figure 3 with reference to the types of systems and interfaces described in Figure 2.


**Figure 3:** Adaptive interoperability to an international standards stack

## 3. The journey to international standards convergence

All the propositions presented above set out only an interim solution; the most efficient, scalable, solution would be the common implementation of the international realm specifications. However, this may be unrealistic for a number of reasons.

Solutions may not pass current 'national realm' accreditation tests (unless the national standard is harmonised with an international standard) while local system redevelopments attract significant costs, especially for smaller companies. As shown in Figure 3, the outer, coloured rectangles are used to represent heterogeneous system interfaces. National IT accreditation can make these less heterogeneous for adaptor technologies on the journey to standards convergence. The inner red rectangles in the same figure indicate a common stack of single standards (a 'consistent interface') in the international realm. If stable mappings were possible, bidirectional data transformations (as shown by green double-headed arrows) would be preferred. A bidirectional transformation could work sufficiently well for local information to be consumed internationally (e.g. if the patient was visiting another country) and vice versa for any records generated abroad. This type of scheme can certainly operate at whole document exchange granularity for human readability, but more challengingly it can use structured data granularities. It is vital to consider which data elements actually need to be internationally interoperable.

Some eHealth data use applications (Figure 5) will require higher granularities i.e., following collaborative agreements on data element usage. Irrespective of these considerations, if adaptive 'interoperability-on-the-fly' is chosen it must work 'error-free' without modifying the semantics from source to recipient systems.

The topic of maintaining semantic interoperability at scale is one of the most often explored in the field of health informatics. Its challenges are great, particularly with regards to the fiercely held views on which paths should prevail. An optimist would see value in the EU-US collaboration evolving a common language, i.e. an information strategy that does not require translations across the web-of-care. It could even be seen as common sense to state that there could be one set of data, metadata, transports, terminologies for all to use without translation across source, and recipient systems serving the web-of-care will generate fewer errors at less cost.

An increasing use of a common language is also a prerequisite for the consistent derivation of analytical insights and computation of re-applicable knowledge on best practice.

## 4. Dealing with single points of failure in the web-of-care

Common (routine) exchange mechanisms across the web-of-care have potential to improve care by allowing easier introduction of innovative 'pluggable' informatics solutions that benefit the patient. They can also assist safe and rapid 're-hosting' of records if one supplier system fails, under-performs or withdraws from the market (or a consumer chooses to change a hosting package). By analogy to changing a USB plug-in device, one can imagine many benefits of patient records being exchanged into a replacement system without error or delay. However this capability requires so-called 'loose coupling' of information systems that supply webs-of-care. This is not straightforward where no common language exists (the source data stays the same without need of data transformations). However, while loose coupling at data level remains difficult in practice, other industries have achieved it at a more granular level (consider multi-source bankcard interoperability in ATMs). In so doing collective industry cooperation has raised purchaser-provider choices significantly and prevented potentially deleterious single-supplier lock-ins in terms of supply chain choices. While loose coupling can act as a powerful cost reducing and quality enhancing mechanism supporting greater market access for smaller innovative companies it is not automatic. Realising interoperable web-of-care supply chains will be needed to cope with rapid change and communication network resilience. In summary, ensuring 'replace-ability' or 'substitutability' in the web-of-care supply chain solves some problems, but raises others. However, the benefits of these features are profound - as such their achievement needs to be considered as part the EU-US initiative roadmap.

## 5. Interoperability promoting systematic health care improvements

Patient-centred networks such as the webs-of-care are also an opportunity to reassess and optimise models of care so that they are much more cost-effective. Patient experience and outcomes evidence can be measured in the context of the web-of-care and develop insights on what works and what does not work from the patient perspective. The patient may need to 'navigate' among different providers along his/her unique patient path (which is also called the patient journey).

These concepts of 'navigation' and 'journey' can also be used in health care workflow planning and optimisations through system cost-effectiveness modelling. If such research determines that a particular configuration of a network is optimal, there must be a path to implement the evidence-based recommendation.

The possibility of eHealth interoperability principles assisting the implementation of an optimised pattern constitutes a major advantage. In this way, network reconfiguration can have a purpose of continuous improvement of outcomes and patient experience. This would be similar to companies operating continuous improvement and enhancement of customer experiences. It is one way in which eHealth can drive service remodelling (to generate value for the patient through improved outcomes at lower cost). It can also encourage a much more efficient workforce that responds to webs-of-care.

This section explores a further four forms of health care improvements: the so-called triple aim objectives, driving innovation cycles, universal decision support, and pursuing best practice.

### 5.1 Applying the 'Triple Aim' quality improvement

This approach is also in keeping with the 'triple aim' objectives (Stiefel and Nolan, 2012; IHI, 2013) on which US healthcare agencies are recommended to base their objectives:

- Improving patient experience of care (including quality and satisfaction);

- Improving the health of populations; and
- Reducing the per capita cost of health care.

The triple aim has EU counterparts: the objectives of improved individual and population-level health at lower costs and with more coordinated care. There are similar aims in reducing risks through prevention and health promotion programmes that struggle with the types of multi-systems integration discussed in this paper. Meeting the triple aim type of objectives requires systematic integration for improvement and collaboration within a patient-centred and family-friendly governance framework. In the UK, investments have also been made in eHealth records (Medical Research Council, 2011) and translational research (AHSNs, 2012) that seek major improvements in health outcomes.

## 5.2 Using interoperability to drive 'knowledge cycles'

It is clear that collective insight from data analysis has radical health care improvement potential, although the systematic methodologies (in particular mechanisms for spreading evidence-based good practice) have yet to be fully realised. In finding ways to implement a systematic approach, it is instructive to study a typical eHealth record-based improvement cycle (Figure 4) also from the point of view of scalable interoperability and interface minimisation. The cycle represents a generic form of geographically distributed multi-disciplinary collaboration. The 'join up' required involves several currently disconnected communities, the collaboration of which is essential to the systematic (transformational) improvement of eHealth. These include:

- Frontline clinical practitioners who generate / consume eHealth records and make decisions on the basis of evidence-based guidelines;
- eHealth researchers who create and conduct studies using analytic tools;
- Computer scientists who develop new tools and methodologies for gaining insights and performing knowledge assembly;
- Agencies that review the outputs of researchers (e.g. the weight of evidence to refine guidelines on best practice) for use at the point of care; and
- eHealth system implementers who need to devise and link up the information system interfaces to permit the cycle to work.

This collection of professionals has specific types of information needs, though these are poorly defined along with little provision of dedicated collaborative research infrastructure tuned to knowledge production.

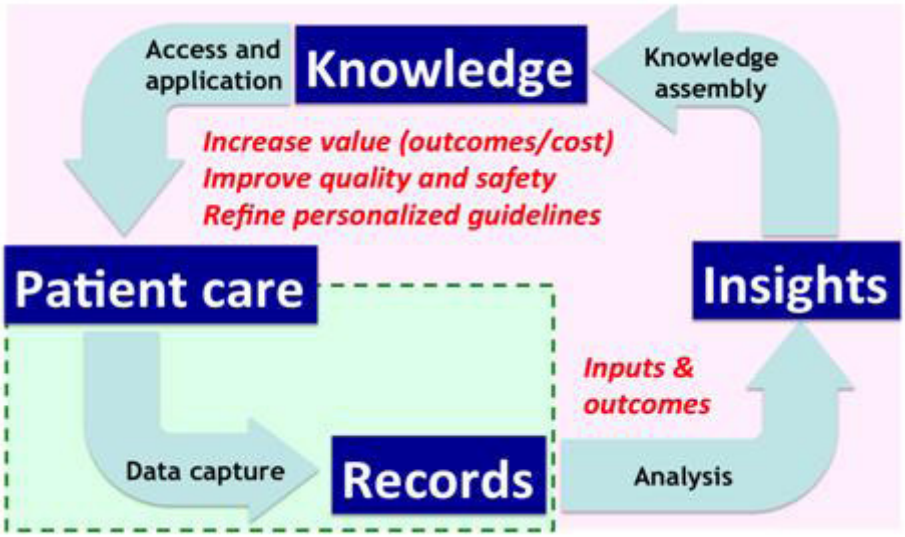


**Figure 4:** A systematic patient care improvement or 'knowledge cycle'

## 5.3 Delivering universal decision support as part of the 'knowledge cycle'

Knowledge creating roles, their interactions, workflows and interoperability requirements across different applications are all legitimate foci for work, in the context of the EU-US collaboration's aims. Work is required to develop the productive 'knowledge cycle' (Figure 4) as a consistent cross-curricular collaborative development activity that unifies.

Fragmentation of purpose is a major issue in research effectiveness as well as in health interoperability. New mechanisms need to be invented that introduce research community outputs directly into the patient path. This involves examining why research conclusions are often hard to implement in order to affect beneficial change. As with frontline care, productive collaboration can only work well if the "right interfaces can be made between the right people at the right time" (Office of Standards & Interoperability, 2013). Interoperability for continuous improvement cycles is thus related to interoperability in the web-of-care. The most compelling reason for this is the improvement mechanism itself, which, in order to be effective (implementable), has to begin and end in point-of-care settings, using health care information standards.

Relatively new fields like genomic medicine offer a good use case for the consistent international development of the knowledge cycle. Trial international document standards such as the Genetic Test Report (HL7, 2013) are now available (subject to information governance and consent) to be used at the point-of-care to gather data, process it according to standards, aggregate pattern analysis or outcomes modelling and present useful analytic results to guideline developers. On receiving this information as a community, guideline developers are well placed to compile outcomes evidence-based decision support for use on the front line. In the case of the Genetic Test Report, guideline refinements from international eHealth records research can be assimilated into local points-of-care using the most recent evidence (as part of a continuous improvement or knowledge cycle). Thus, the Genetic Test Report document not only collects the data from the point-of-care in an internationally consistent manner, but also delivers refined decision support guidelines back to the point-of-care (along with genetic test results).

Knowledge cycles are by definition 'translational' and may thus contribute to the EU-US roadmap the declared goals of both 'more cost-effective clinical research' and 'universal provision of clinical decision support'. These represent areas where the lifecycle of information and its re-use beyond its origination point are essential considerations.

### 5.4 Developing and spreading best practice

Collaborative development of 'knowledge cycles' may be a powerful reason for adopting eHealth approaches in their own right as they can bring beneficial insights validated elsewhere into local systems. They are a pragmatic mechanism for spreading best practice. eHealth researchers from many different specialties and geographical locations would gain collaborative potential to use data to improve healthcare for both individuals and populations according to the notion of the triple aim. Knowledge generation may of course have widely differing scope according to the context and data used. In combination with distributed data modelling approaches, it could be focused on collaborative investigations for causes of specific diseases (as in the Genetic Test Report case), assessing new clinical tests, validating new treatments and interventions or testing the safety / effectiveness of drugs or medical devices. In development terms, these different applications can be described as a spectrum of uses (Figure 4). They offer a good perspective to start thinking through the potentially beneficial common approaches for continuous improvement cycles.

## 6. Support for patient involvement with 'fair tests' of treatments

Research often becomes 'siloed' as a separate activity away from the subject of testing to which it relates. Many thoroughly researched findings never make it back to the front line despite heavy investment in the original studies. This systematic lack of translation of research to practice is another barrier to the relevance to the improvement objectives of the EU-US initiative. Some types of research studies will have a nationally bounded scope, but other types absolutely require an internationally distributed perspective. One can consider a range of potential eHealth research uses (Figure 5) in parallel with health care information sharing.

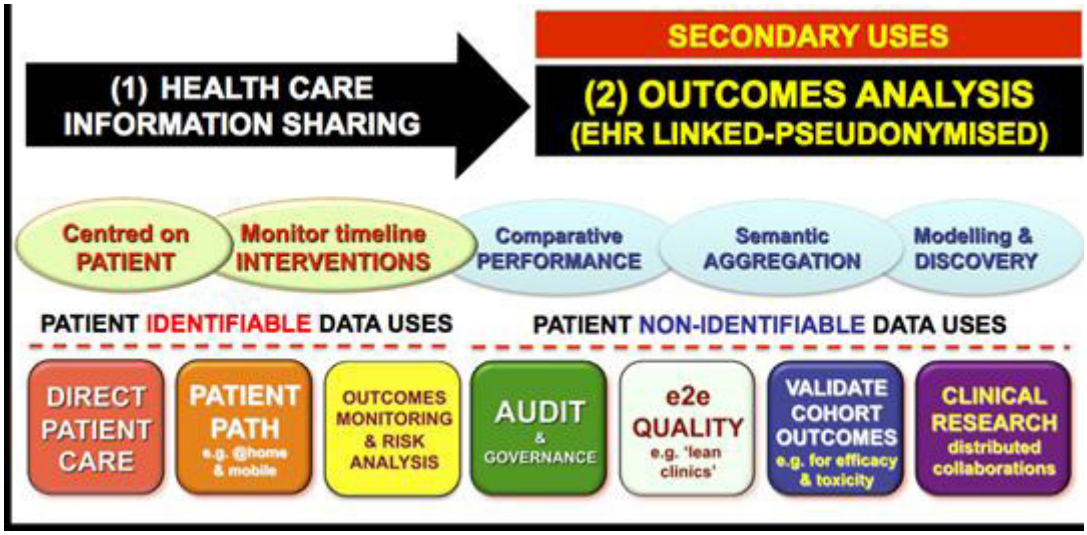


**Figure 5:** Non-exhaustive spectrum of eHealth data use scenarios

Standards-based consistency is needed to help to collate more efficiently the raw data in each study, and distribute the analytical insights and knowledge at scale. In doing this, there is an important role for standard aggregations of data (e.g., data marts) for comparative validation of competing analytic tools or markers. The field is not short of analytic tools, but it is probably short of methods that can validate the best practice for any particular task. Analytic tool proliferation is perhaps another case of fragmentation defeating the purpose of straightforward analysis. In the context of distributed collaboration, there is a need for better community-coherent approaches to the use of technologies like outcomes explanatory modelling and the development of tools like infographics,

classifiers and longitudinal trend analytics. A principle of high cost-effectiveness is 'do once and share', albeit it is perhaps better to say 'do once with excellence and share'. One body of work that the EU-US collaboration could benefit from would be the one from the James Lind Foundation that promotes the use of 'fair tests' in improvement cycles. They promote greater patient involvement in research by, for example:

- Educating patients about why it is important to test treatments carefully;
- Recognising reliable research; and
- Ensuring research is more likely to do more good than harm.

One of the most important messages for the conduction of fair tests of treatments is that the quality of evidence is paramount and data must be free of bias. Another message of the Foundation is that patients must become aware of the background knowledge surrounding research. The Foundation's book 'Testing Treatments' (Evans et al, 2011) and the host site called Testing Treatments Interactive contain a great deal of information on the key points of fair tests that fit well with the concepts of the knowledge cycle.

## 7. Mechanisms for interoperable patient-controlled information sharing

It is important to emphasise that any information flow in the scenarios discussed in this paper, from health care (information sharing) and research (information re-use) is a consideration for local information governance. Patterns of permitted data use, sharing and re-use across localities is generally the concern of information governance boards that interpret local information governance rules.

Working groups such as the European eHealth Governance Initiative (eHGI) add a further international perspective. In addition, specialised in-depth consultations such as the one that recently took place in the UK (Caldicott, 2013) present many recommendations relevant to the development of eHealth as a discipline. It is now acknowledged that appropriate and timely information flow (e.g. sharing across organisational and professional boundaries) can be highly beneficial to the patient under the condition that information governance criteria are met and the patient is empowered in the process. The Caldicott2 review established the principle of the health care professionals' duty to share information when it is in the interest of the patient to do so.

In the context of wider interoperability in communication, a patient's consent to share information in the web-of-care and/or re-use of data for specific research purposes, some basic principles and other classes of information inevitably make their appearance.

Certainly, the existence of common metadata to describe consent can convey the patient's wishes (interoperability) across systems. In practice, it means electronic statements (consent directives) can be created to share information with anyone whom the patient trusts. It gives the patient control for 'who sees what'. By definition, this will include most if not all the people in their web-of-care. The consent directive acts as a gateway between different IT systems but does not itself use personal data.

## 8. Eight essential principles for interoperable consent directives

Interoperable patient consent directives should have a central place in the EU-US cooperation agenda because they are critical for empowering the patient with respect to information sharing (they can put the patient in control). This includes the dynamic ability to give and revoke consents in the web-of-care and in the domain of research. The patient's wishes can be kept up-to-date as a single point of control. As part of an information governance expert consultation within a UK Technology Strategy Board project (miConsent, 2012), focusing on scalable mechanisms for patient controlled information sharing, a series of eight essential requirements for patient-controlled consent management was established:

- Citizen Control: patients can decide with whom to share records in their web-of-care. This may include persons outside the information governance perimeter of the care provider organisations that created the original records. Citizen control means that everything is up to the patient.
- Person-to-Person: sharing with trusted individuals or a validated organisational representative(s). This simplifies sharing away from (complex) role-based access control to simpler record access based on a defined number of people who can be validated with electronic identities.
- Identity Services: the consent directive service needs to be loosely coupled with an electronic identity (eID) service. Loose coupling provides a principle of 'substitutability' which allows different eID providers to work with various consent providers.
- Information Governance Boundaries: consent directives need to cover patients' full webs-of-care, beyond single organisational boundaries.
- Vendor-Neutrality: the consent directive needs to be independent of any provider; it is patient-centric and independent of individual IT system suppliers.
- Compliance Testing: there is a need to prove the interoperability of consent directives across systems through compliance testing.
- Common Metadata: when consent metadata is standardised across all systems, any participant can specify time limits e.g. to the age of the data, standardised information categories for sharing (examples include medication, lab tests, correspondence, hospital admissions and appointments) and data sources (patient apps, blood pressure devices or specific locations such as a hospital).
- Internationalisation of Standards: this is necessary due to consent solution users (information source and recipient systems) needing to operate across wide geographic boundaries and potentially, internationally.

Greater patient involvement in research can be gained by giving control of data use as recorded in their consent directive alongside their web-of-care consents (Figure 6) and by using the same metadata.


**Figure 6:** Common metadata used in both the web-of-care and research consents

## 9. Streamlining consent interoperability for ethical research

Use of data in research for specific purpose(s) to which the patient has consented is central to ethical research processes. The legal requirements for consenting to different forms of research can be complex (Sprung & Winick, 1989; Gill, et al, 2003; Pope, 2012). Special conditions may also exist for re-use of routinely collected EHR data in different types of research study (Figure 5).

The patient may need assurance that data anonymity and security policies are enforced and that their data will only be used for the purpose defined in the consented protocol. Consent management can consume significant study resources especially if re-consenting is required. This can happen where a study protocol has been modified.

Further complexities can arise when new data items (e.g. outcomes follow-up or novel test results) may need to be collected in one system to complement data already located in a separate record system. In research scenarios like these, patient consent directives can clarify and certify patients permissions and wishes about the re-use of their data. As with consent for primary use (health care), a patient-centred approach has advantages for consistent 'referencing' of consent across systems. The wishes of the patient would be considered as priority before any re-use.

Patient-controlled access to information through interoperable consent directives has the potential to simplify involvement in research and allow the donation of data to trusted research networks (Figure 6). In study recruitment, patient consent directives also intervene in the standardisation of pre-consent; i.e., where willingness to participate in a future study can be indicated. Poor recruitment is a major obstacle to progress of clinical research. Efficiency of research would improve for subjects where both eligibility and willingness to participate had been specifically indicated. The impact on researcher communities would be enhanced if consent directive interoperability were standardised in order to permit more systematic discovery of matches between study requirements and pre-consented subjects.

Cross-system interoperability of research consent is a worthwhile goal for a number of reasons. First, correct interpretation and enforcement of the patient's wishes are part of the assurance process (as with the web-of-care examples discussed above). Assurance that data is only used for the consented purposes has a number of dimensions is essential. This is often summarised as the 'three Ts' which stand for Trust, Transparency and Traceability. A systematic approach to the research cycle (Figure 4) means patients gain a clearer understanding of the relationship between their consent and potential benefits/risks.

## 10. Conclusions

This article has argued that the patient-centred web-of-care constitutes a legitimate focus for steering the interoperability effort of the EU-US IT Cooperation initiative. This argument is based principally on an analysis of shortfalls in current systems, the need for patient empowerment, and the portability of benefits to millions of webs-of-care. The argument carries the logic that the web-of-care is a relevant unit of collaborative eHealth, involving multiple participants who need interoperability standards to work together efficiently for the benefit of the patient who is at the centre of the web. The value of solving the 'many to many interoperability' problem at the heart of the web-of-care also has other benefits. For example, network resilience through common implementation standards gives a new capability to mitigate single points of failure. There is also a number of data re-uses that might be positively impacted by a common approach to source interoperability that includes knowledge production/assimilation from collaborative analytic approaches. These developments are extremely important for achieving objectives such as the 'triple aim'. When combined with knowledge capture technologies such as algorithmic outcomes modelling, mechanisms for spreading best practice become feasible. Finally, putting patients in control of information sharing is a theme that requires a clear strategy on common metadata as it applies to interoperable consent directives. These directives are empowering for patients insofar as they allow a 'who, what, when' control of the sharing of health care data and its reuse in research. Internationally scalable pre-consent for the recruitment of patients into specific cohort studies would be of major benefit to EU/US translational research. Overall, these innovations will help this international initiative to have impacts that are meaningful for the patient.

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# A potential 'eHealth Digital Divide' among Developed Countries

The issue of changing needs for specialised human resources in Health Information Technology (HIT) has only been recently recognised due to on studies of a limited number of countries. Based on recently available data from eight European Union (EU) countries, the observed countries could be divided into two groups. A first group gathers together the Australia, Canada, England, the Netherlands and United States of America (USA). They share a staffing ratio around one HIT professional for 50 healthcare workers (2 %). The second group, identified from the data supplied by HIMSS Analytics Europe, gathers together France, Germany, Italy, Poland Portugal and Spain with a staffing ratio of between 0.8 % and 0.4 %. In the European Union (EU), a good correlation between the HIT staffing ratio and the connection of hospitals to a broadband connection above 100Mbps was found. These findings could reveal the existence of a potential eHealth Digital Divide among some of the most advanced countries globally and in Europe. This article encourages further studies at the national, regional and international levels in order to address the specific needs of an HIT workforce. The use of a common framework for HIT resources as well as for the assessment of the maturity of HIT should be encouraged.

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Keywords

Electronic medical records, healthcare information technology, human resources, international comparative studies, public health

> "The use of a common framework for HIT resources and the assessment of the maturity of HIT should be encouraged."

# 1. Introduction

The question of the adaptation of a specialised workforce to the continuing and accelerating computerisation of health care has only been recently raised. As a result, the available data are still partial and are limited to a small number of countries. However, there are sufficient data to make a first preliminary analysis based on published material and from data recently made available for eight Member States of the European Union. Following the work of Hersh in the USA (2008; 2010), who compared the situation among a few English speaking countries with rather similar contexts, the estimation of a staffing ratio derived from the database of HIMSS Analytics Europe reveals strong discrepancies.

# 2. First international comparison

In the United States (US), the impact of the Health Information Technology for Economic and Clinical Health (HITECH) Act on employment is already considered crucial. HITECH, launched in 2009, has funded nearly 85 % of US hospitals and 44 % of outpatient clinics. In February 2013, they had received a total of $US 12.6 billion in subsidies while 50,000 jobs were created during the four-year period between 2009 and 2013. The educational component of HITECH was probably decisive: 17,000 professionals have been trained in health informatics, while universities have issued more than 800 degrees at masters and PhD levels.

It was before the launch of this ambitious programme, in 2006, that the issue of the changing needs for specialised human resources in health informatics was addressed. This is a dimension that has been often surprisingly neglected. Dr. William Hersh, chief of the Department of Medical Informatics and Clinical Epidemiology, Faculty of Medicine, University of Oregon, has published the results of several studies (Hersh, 2002-2013), including several international comparisons made mostly between English-speaking countries such as Great Britain, Australia and Canada. Hersh found out that those three countries have a fairly close ratio between IT specialist/healthcare staff – around 1/50. He also stated that the workforce should increase significantly and that the question of skills building and workforce adaptation should be considered more thoroughly. Those three countries have documented a qualitative and quantitative assessment of human resource needs: they all point out that a clinical information system is a major factor to be accounted for.

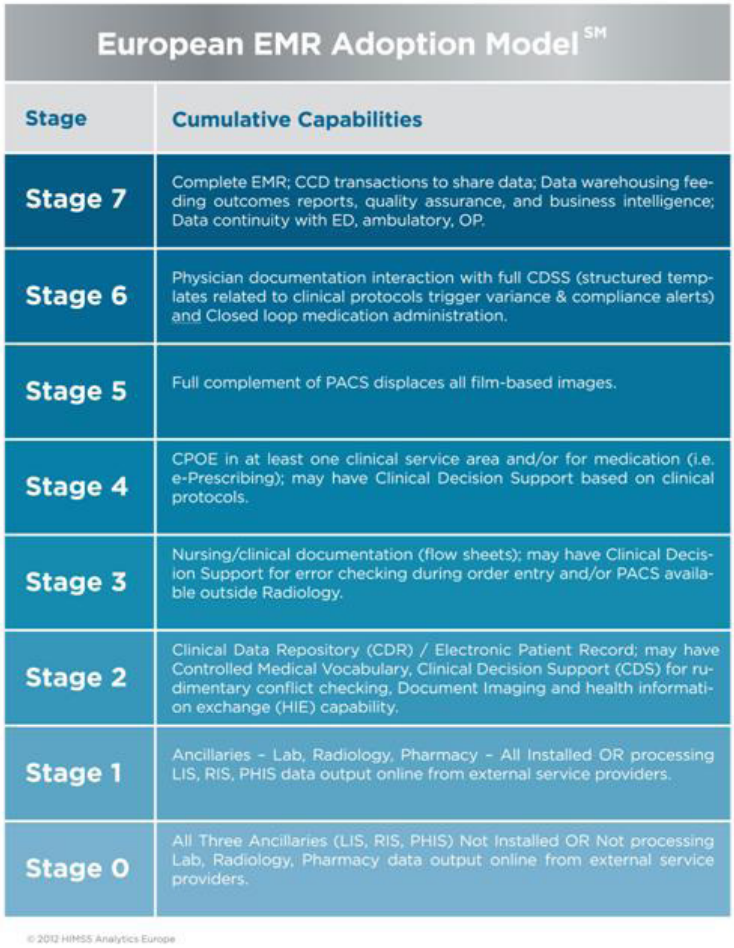
England employs 25,000 people in health informatics out of a total of 1.3 million employees in its National Health Service (Eardley, 2006). In the US, Gartner and Hersh agree on an estimate of the total employment of about 110,000 people, i.e., a ratio of one skilled job for each 60.7 non-IT employees (Hersh, 2010). Similar ratios of around one health information technology (HIT) professional per 50 healthcare professionals are found in Australia and Canada (the staffing ratio in Canada, with 32,450 HIT professionals could not be determined with precision but should surpass 1/50 if the overall number of healthcare professionals is estimated at one million).

Hersh based his approach on data collected by HIMSS Analytics US for more than 5,000 institutions (Hersh, 2008). The incremental need of most of the hospitals in implementing more and more complex functionalities of an electronic medical record was assessed by using the model designed by HIMSS. Hersh's extrapolation concluded that an additional 40,000 IT professionals will be required in addition to the existing 110,000 HIT professionals in the US healthcare system. The HIMSS EMRAM adoption model is an eight-step process (with levels between 0 and 7) that enables the analysis of any organisation's level of EMR adoption, charting its accomplishments, and tracking progress against other healthcare organisations across a country or at the international level. It outlines various

cumulative stages. The survey questionnaire includes questions about the number of IT professionals involved. The relationship between the ratio and EMRAM shows an increasing level between levels 0 and 4 and a plateau between 4 and 6. This underscores what is already known when the complexity at level 4 and above is accompanied by the introduction of multimodal connected prescription (Computerized Physician Order Entry (CPOE)) and embarking on decision support tools. CPOE is one of the most demanding functionalities of an electronic medical record. It should nevertheless allow for a Return of Investment while improving patient safety and quality of care.

## 3. First estimation in some EU countries based on the HIMSS Analytics Europe database

In the EU, as well as in other countries not documented by Hersh, data are more difficult to gather or access. There is also a lack of common definition of skills, jobs and well-defined positions that could allow for the proper collection of data. Some countries only take account of technical competences and would not include jobs assigned to non-technical activities (such as coding or document management). Doctors and nurses or other staff dedicated to HIT cannot be accounted for either. One of the only sources of information available in Europe today is the database of HIMSS Analytics Europe (HIMSS Analytics Europe, 2013). The database includes data on several thousand facilities. Since its introduction in Europe in 2010, more than 1 800 European hospitals have used the EMRAM EU Adoption Model and completed the questionnaire that documents their HIT staff capacity. The EU EMRAM Adoption Model has been adapted from the US model to reflect the current state of play in EU hospitals (Figure 1).



European EMR Adoption Model℠

| Stage | Cumulative Capabilities |
|---|---|
| Stage 7 | 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 | Physician documentation interaction with full CDSS (structured templates related to clinical protocols trigger variance & compliance alerts) and Closed loop medication administration. |
| Stage 5 | Full complement of PACS displaces all film-based images. |
| Stage 4 | CPOE in at least one clinical service area and/or for medication (i.e. e-Prescribing); may have Clinical Decision Support based on clinical protocols. |
| Stage 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 | 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 | Ancillaries – Lab, Radiology, Pharmacy – All Installed OR processing LIS, RIS, PHIS data output online from external service providers. |
| Stage 0 | All Three Ancillaries (LIS, RIS, PHIS) Not Installed OR Not processing Lab, Radiology, Pharmacy data output online from external service providers. |



**Figure 1:** HIMSS Analytics Europe: Electronic Medical Record Adoption Model or EMRAM

Major differences are found between patient identification techniques as well as drug prescription and dispensation organisation. However, in 2013, data are available for only eight of the EU28 Member States and the IT staffing ratio and the EMRAM level reached by hospitals documented in the database may be used for the approximation of the HIT staff for each country (Table 1 and Figure 2 provide a tabular and bar chart representation of precisely the same data).

**Table 1:** HIT staff ratio (IT staff working in the hospital sector or Health sector)

| | IT Staff per 100 staff | Number of hospitals (from data extracted from HIMMS AE database*) |
|---|---|---|
| Netherlands* | 2,04 | 47 |
| Australia | 2,00 | |
| England | 1,92 | |
| USA | 1,64 | |
| Germany* | 0,74 | 140 |
| Portugal* | 0,66 | 29 |
| Italy* | 0,52 | 236 |
| Spain* | 0,50 | 125 |
| France* | 0,49 | 19 |
| Poland* | 0,38 | 141 |

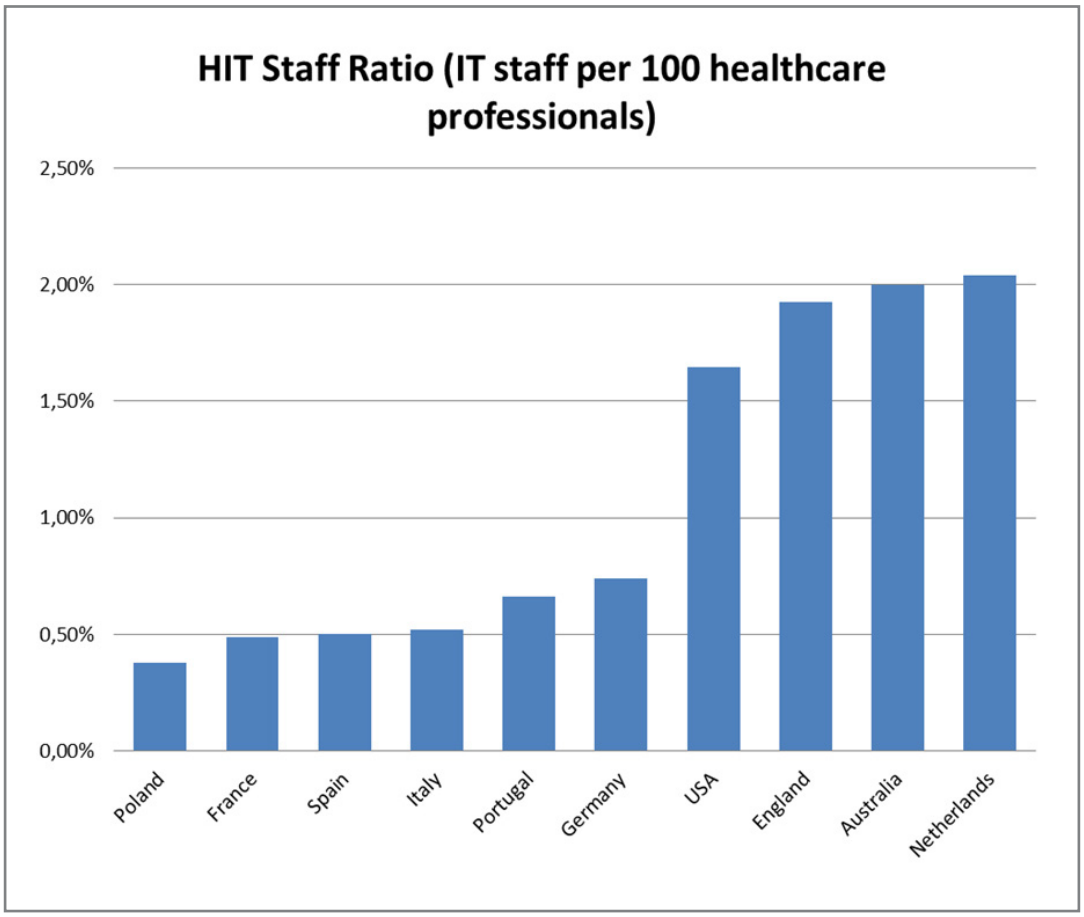



**Figure 2:** HIT staffing ratio (IT staff working in the hospital sector or Health sector)

## 4. A potential Digital Divide?

Based on these preliminary findings, the observed countries could be divided in two groups:

A first group includes the countries studied by Hersh, which have a ratio of HIT staff of between 1.6 % and 2.1 % of the total health employment. The Netherlands is the highest level European country with an assessment derived from the HIMSS Analytics Europe database that belongs to this group. With an estimated HIT staffing ratio of 2.04, Netherlands is fairly close to England, with its level of 1.92. They are the two EU Member States in this group alongside with the US, Canada and Australia.

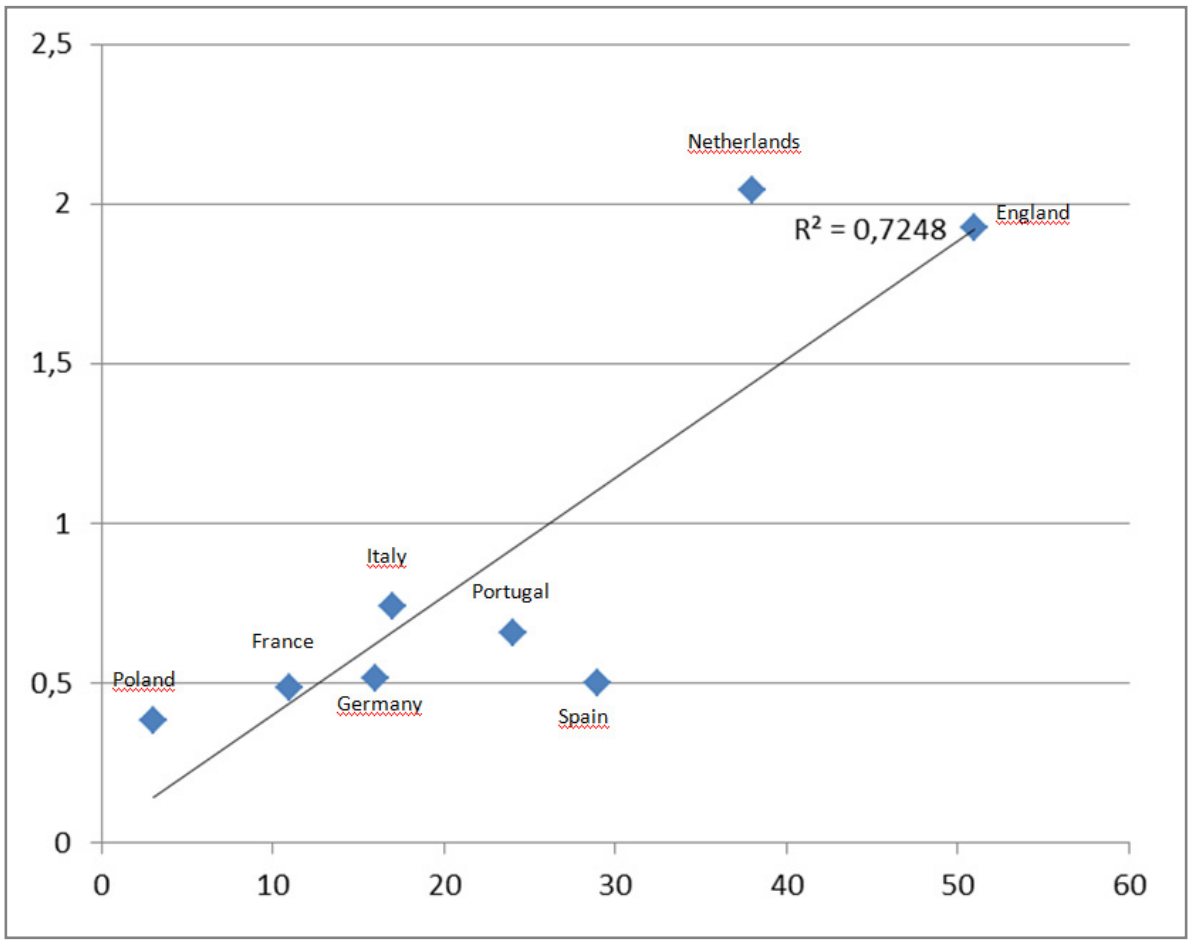
The countries in the second group include France, Germany, Italy, Poland, Portugal, and, which all have a much lower HIT/staffing ratio that ranges from 0.8 % to 0.4 %.

These estimations are established based solely on the HIMSS Analytics Europe database. They should therefore be confirmed by local authorities and compared with existing data sources when and if available. Those results should be examined with caution, since they are based on self-reporting sources, and inclusion criteria are dependent on the definitions of the skills/jobs involved that vary among the countries concerned. Furthermore, in most of the cases, data are available only for the hospital sector, which in general gathers the vast majority of HIT human resources. Outsourced staffing, when they exist, might also not be accounted for.

In France, as an example, the HIMSS data yield too few institutions to allow for a reliable analysis. Nevertheless, the staffing ratio observed by HIMSS Analytics Europe is consistent with the estimate of the overall hospital IT staff of between 5,000 to 6,000 jobs by one of the major HIT professional

organisations. With an average of 1.21 IT staff for 100 hospital beds (0,012) in a recent study of 140 hospitals (College Français des DSIO de Centres Hospitaliers, 2013), the average IT staffing ratio is one HIT Staff to 218 hospital staff (1/218) compared to one (1/206) to 206 in the HIMSS Analytics Europe database.

Other indicators could help confirm the pertinence of these preliminary findings. A recent survey of EU hospitals (European Hospital Survey, 2013) documents the bandwidth connections of hospitals in 30 countries (EU28 + 2). A good correlation was found between the IT staffing ratio for the eight countries documented in HIMSS Analytics Europe database and the percentage of hospital with broadband internet connection above 100 Mbps (Figure 3). More importantly, there is a clear distinction between the two groups considered earlier.




% Internet Broadband connection>100 Mbps

**Figure 3:** HIT Staffing ratio vs Internet broadband connection>100Mbps

These additional findings could help enable a discussion about the existence of a potential "eHealth digital divide", witnessed by the different approaches wherein IT staff resources are considered alongside other indicators. Additional data are needed to include more countries (among them the Nordic EU Member States, and Norway, which are considered to be the overall leaders in eHealth, and which show a consistent leadership across a range of eHealth indicators).

## 5. The need for further studies

Further studies on these issues should be encouraged at the national, regional and international levels in order to address the specific needs of the HIT workforce and its evolution. The important, apparent difference found between the two groups compared briefly in this article should be considered with attention, mostly for countries belonging to the second group, that are willing to engage in ambitious IT programmes that would stimulate the deployment of CPOE in hospitals.

A study of the conditions of deployment and maintenance solutions (including patient records and electronic prescribing) could usefully be used across Europe, in a way similar to that which Hersh has applied to the USA. In Europe, the transition to EMRAM level 6 (a level where CPOE has been implemented) would result in a doubling of the staffing ratio (going from 0.5 HIT staff per 100 healthcare professionals for EMRAM levels 0 to 5, to nearly one per 100 on average as observed for the 25 institutions that have reached the level 6 of EMRAM in the EU). One may assume that, (even when taking into account outsourcing and a sharing of the available workforce among several hospitals, only a properly sized IT team will guarantee the required security needed at the level EMRAM 6 where critical software are used by caregivers.

Other issues pertaining to local specificities, such as the overall organisation of the healthcare and hospital sectors, outsourcing and externalisation of HIT, financing and investment capacities, pricing, purchasing power, and productivity, also require additional studies.

## 6. Conclusions

The health sector should assess its human resource needs to ensure that both a successful deployment of solutions could be pursued and the security of essential and critical clinical solutions will be always guaranteed. A sufficient workforce represents a prerequisite or condition for the success of computerisation programmes, a major component of health policies aimed at improving the quality of care, and the control of the growth of health spending.

In addition, the HIT industry also needs additional resources to support the development, deployment and maintenance of adapted and competitive solutions. In many respects, the necessary increase of human resources is becoming a critical issue for many countries and raises the issues of training, skills building, curricula and career paths. Preliminary findings show a potential eHealth digital divide among a few of the most advanced European countries. International comparisons that could take into account the specificities and particularities of countries in relation to their on-going HIT programs is also of interest and could help to establish a better understanding of HIT staffing needs. The use of a common framework should be encouraged at the EU and international levels in terms of workforce qualifications as well as the assessment of the level of HIT in hospitals and, when possible, in the healthcare systems as a whole.

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# EU-US Memorandum of Understanding and Europeanisation: eHealth Services Standards of Care

Europe needs appropriate and sound investments in healthcare. Good examples in clinical practice shows where the opportunities are in integrated care, cost effective and redesigned health systems, as well as in the use of eHealth as a support mechanism for clinicians. Although there are differences between the European Union (EU) and the United States (US) (and even among EU Member States), fostering cooperation to change challenges into opportunities necessitates taking practical actions to address solutions at the frontline and must go beyond a mere exchange of good practices. Nurses are well placed to identify innovative ways of reengineering health systems and to deploy eHealth services adequately. As such, cooperation and joint activities between the EU and US on investing in the nursing workforce, particularly on eSkills development and on standards of care, will help to turn the healthcare sector into a key driver of well-being, productivity and growth.

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> “The EU-US MoU can drive Europeanisation with the design of eHealth services standards of care to safeguard quality and safety in times of austerity.”

# 1. Introduction

Investing in delivering care that has proven to be cost-effective is key to improve healthcare systems in the EU. Focusing on sustainable health systems and people's health implies allocating European resources where concrete changes and reforms can make a difference for each individual. Nurses see many opportunities for investing in health in order to turn the healthcare sector into a key driver of well-being, productivity and growth. Building on good 'frontline' examples and experiences, policy-makers need to embrace the evidence for strengthening the link between EU health policies, international cooperation with the United States, and national health systems reforms.

# 2. Process of European Integration

The current European economic and societal challenges are to strengthen the cooperation among the EU Member States in the hope of finding common solutions to common challenges. The healthcare sector is one of the most sensitive policy areas, both in the EU and the US. While the EU has no direct competence in healthcare due to the subsidiarity principle (Greer, 2005) – but rather each Europe Member State – the EU institutions are embarking on innovative ways to reform the continent's healthcare systems. Although Greer (2007) argues that the treaties that constitute the EU and allocate powers to the European institutions have limited impact with regards to health policy (Hervey, 2008; Mossialos & McKee, 2004), health services became part of the European Single Market in which Mutual Recognition of Professional Qualifications of nurses are a key component.

The process of the "Europeanisation of domestic policies" has always been challenging (Radaelli, 2004), and especially since 2008 when austerity measures have started to test solidarity, equity and even Eurozone membership. Although national governments have always shaped Europeanisation by deploying strategies that reflect their own preferences and interests, thus influencing the formulation and definition of EU institutional functioning and policy-making (Börzel, 2012), a united European voice is needed to face societal, economic and political challenges and to keep both peace and prosperity high on the political agenda.

# 3. Going Beyond Exchange Mechanisms

In this context, civil society engages in promoting and ensuring good governance, as the policy actors countering the influence of the state and the liberalisation of the services market. Despite the evidence showing that the differences among Member States are so huge that it is difficult to talk about a European health framework (European Social Observatory, 2010), it is precisely at this challenging economic, social and political period of time that national governments should go beyond the collecting and sharing of good practices to reach a common understanding on addressing key healthcare challenges in times of downturn of the economy.

Take the example of nurses going beyond their limits of health service delivery, and facing daily the dilemma of providing high quality care in an environment obsessed with quantitative data to make cost-cutting decisions. As such, nurses pro-actively identify innovative ways of re-engineering their local healthcare systems in order to provide the level of care needed to meet the increasing societal challenges (European Commission, 2012a). In these circumstances, it might be crucially important to upscale innovative models of integrated care throughout the EU, scaling up what already exists and boosting the deployment of eHealth services. Cost-effective, high quality and safe regional and national healthcare systems are dependent on nurses developing and implementing high-quality ICT-based solutions in the process of care (Sheikh et al., 2011).

## 4. Integrated Care

Evidence shows that eHealth services are paramount to managing the current challenges through supporting a person-centred and integrated care partnership (Lupari, 2011). Self-directed care must be ensured with the integrated support of carers, together with a forecasted highly skilled health and social care workforce managing the delivery of patient-centric care (Kelly, 2005; WHO, 2010; Eurostat, 2012). In this respect, the European Federation of Nurses Associations (EFN) argues that it is socially and economically unsustainable to maintain the traditional vision of healthcare delivery, focusing on a curative and medical approach (EFN, 2012). An urgent shift towards delivering a more preventable, efficient and integrated care is urgently needed without jeopardising subsidiarity.

Prevention is considered a key element in personalised healthcare implying the adoption of citizen-centric approaches. Information and communication technology (ICT)-based services have been developed to support prevention in healthcare. There is a need to build on the existing evidence around good practices to foster further the deployment of preventive eHealth services (C3 Collaborating for Health, 2011). Nursing research has shown already that, when appropriately supported by ICT-based solutions, particularly telehealth and telecare, the delivery of innovative healthcare becomes more sustainable and more effective (Lupari, 2011). Particular benefits are reported in the areas of prevention and self-management of non-communicable diseases (NCD), facilitating the delivery of healthcare in communities and at home (EPPOSI, 2012). This evidence shows that there is a prominent role for ICT in supporting the reorganisation of healthcare services towards integrated care (EC Health for Growth Programme 2014-2020, European Innovative Partnership, 2012).

## 5. Cost-effective Solutions

However, a study led by the Royal College of Nursing (RCN), in collaboration with Bournemouth University (Baker et al., 2007), highlighted some concerns regarding the deployment of eHealth services. The research stressed the lack of nursing input into the design of new systems, in which nurses were not allowed to be part of the new design since its conception. It is therefore logical that there is fear that new computerised systems will take nurses away from direct patient care, leading to the loss of the nurse-patient relationship, and thus not reflecting the nursing care profession and patients' needs (Baker et al., 2007). In order to prevent this shift, it is essential to invest in health and social care personnel's skills and capabilities to support people in need (European Commission, 2013). The identification of these skills, together with the exchange of good, innovative, implemented and cost-effective solutions and approaches is not only obvious but also increasingly needed (European Commission, 2012b). In this context, the policy initiatives set out in the Digital Agenda for Europe (European Commission, 2010) ensure that the European Commission, closely cooperating with Member States and different stakeholders, are the driving forces for developing proposals in the field of eHealth services and, more importantly, their implementation into the field work of six million nurses in Europe.

## 6. Redesigning Roles and Responsibilities

Interestingly, some Member States – such as Ireland, the Netherlands, Spain, Sweden, and the United Kingdom – have taken major legislative steps in this direction by introducing the Advanced Nurse Practitioner and Nurse e-Prescribing, in same EU countries with national legislation regulating these concepts (Finland, Germany, Ireland, Netherlands, Norway, Spain, Sweden and the UK). These are two examples on how health systems can be innovative with the deployment of eSkills and eHealthcare

services, even in high intensive care units, such as neonatology, where the technological and medical aspects need to be balanced with the human and caring part of integrated care. Evidence suggests that implementing nurse prescribing is clinically appropriate and cost-effective (An Bord Altranais, 2007; Latter et al, 2011; University of Southampton, 2011; West, 2011). ePrescribing is the next step, allowing nurses to transmit electronically a new prescription or renewal authorisation to a community or mail-order pharmacy. These existing good practices indicate that technology requires a higher skilled nursing workforce with employees who will contribute to the empowerment of patients in the management of their own health and well-being. It is therefore necessary to assure that health and social care professionals have the needed skills, including eSkills, to make optimal use of the available health information technology (European Commission, 2010).

Additionally, when dealing with nursing and social care innovation, it is absolutely required to take into account gender sensitive designs, as more than 90 % of nurses are women. Although the deployment of ICT-based solutions has enormous potential for nurses and social care workers, they both need to be highly supported in this process to be able to develop the required eSkills and at the same time to remain close to the patients' side, freeing up time to deliver high quality and safe care.

## 7. Delivering Guidelines on the Deployment of eHealth Services

In order to enable eHealth services, mainly telehealth and telecare services, to become fully efficient in all EU Member States, the development of standards, protocols and guidelines for the deployment of these services is urgently required.

There is a strong need to work on a harmonised approach to eHealth services to come up with common frameworks. Current knowledge and experiences in national and regional environments call for action to collect, consolidate, assess and disseminate – most suitably in the form of guidelines – and support knowledge transfer from one national/ regional environment and from country to country.

eHealth systems can potentially reshape health and social care through the use of mobile health and personalised nursing care, but progress can only be safe through the use of common agreed standards, thereby facilitating nurses, social care workers and carers to deploy systems and mobile devices (International Telecommunication Union, 2011). When dealing with patient information, patient privacy and information security, standards must foster usability and patients have to remain at the epicentre, having access and ownership to their electronic health records and agreeing on the information flows. It is vital to establish safeguards to allow citizens to use health and well-being applications with trust, in order to sustain safety in an increasingly technologically-enabled healthcare delivery. Nurses are called to play a crucial role in this European innovative approach, which will finally result in common EU standards, facilitating the full and efficient use of eHealth services based on existing best practices in all EU Member States. As such, the deployment of eHealth services becomes beneficial for all EU citizens as it enables them to fully pursue their European rights.

In this context, the Directive on Patients' Rights in Cross-Border Healthcare, adopted in 2011 (European Parliament and Council of the EU, 2011), represents a major step towards the improvement of patients' rights, quality and safety, and the use of technology as a facilitator of change. Delivering continuity of care through ICT services is paramount and should become one of the most relevant criteria for excellence.

Person-centred nursing care, with the use of telehealth and telecare, should contribute to positive patient outcomes by:

- Empowering a holistic and integrated approach towards management of patient care focussing on a systematic and continuous empowerment;
- Increasing the ability of nurses to identify deterioration in a patient's condition early and instigate appropriate interventions;
- Adapting legislation and regulatory arrangements in most European countries towards the reorganisation of healthcare delivery;
- Defining and supporting the conditions and culture change required under which new roles, responsibilities and innovation in care delivery can be built upon;
- Investing in nursing education ensuring appropriate competencies, lifelong learning and continuous professional development (CPD) to high quality and safe care;
- Establishing pattern of career pathways and extended career ladder being conditional to a successful introduction of new skills and the implementation of skills mix;
- Accompanying the development of responsibilities or any transfer of skills with the appropriate remuneration to all the professional groups involved; and
- Decreasing urgently the nurses' administrative workload in order to increase direct patient care.

## 8. The US Experience and the Transatlantic Cooperation

The EU-US exchange of designs and developments helps in making progress beyond current challenges to patient-oriented care and the nurses' role. Some possible solutions to these challenges are 'around the corner'.

As an example, the Division of Nursing within the US Health Resources and Services Administration (HRSA) has several programmes underway that are focused on advancing the health IT skills of the nursing workforce, recognising these skills as essential building blocks to improve access to affordable high quality health care. The advanced nursing education approach incorporates health technology into the curriculum (e.g., electronic health records and telehealth). Thus, nursing students, particularly in these advanced roles, will develop enhanced skills and competences in ICTs and will be prepared to use these technologies at their fullest potential for communication and health care delivery across the entire health care continuum. Improved quality, enhanced safety, and effective/efficient care are the results of integrated eHealth services as a critical component in communication, patient-centred care and patient outcomes.

The US administration is using a balanced focus approach on care, technologies supporting care, advanced nursing role, and all the implications surrounding eHealth. The Obama administration put nurses in a leadership position to reform healthcare by advancing eHealth for promoting individual and community health while fostering innovation and economic growth. These two examples show that the EU-US MoU on eHealth, signed in December 2010, should now move to action.

In the US, as in many European countries, nurses have established successful non hospital treatment centres for non-communicable diseases and are in the forefront in terms of delivering care in new settings and closer to patients' homes (WHO, 2013). There is an economic and a qualitative incentive in creating the optimal skills mix, as nurses deliver care 24-hour a day, seven days a week, in contrast to most other professions.

Within the EU, the nursing profession skills and competencies are politically discussed in different sectors in the European Commission – Directorate General (DG) Internal Market, DG Employment, DG Connect and DG Sanco – showing the importance of the profession in redesigning healthcare systems.

The EFN is committed to strategically and coherently focus on the competencies of the nursing workforce, including redefining and clarifying professional and occupational qualifications, roles and responsibilities, alongside creating a comparable data warehouse for workforce planning at EU level.

## 9. Conclusions

To conclude, nurses coordinate healthcare from a patient perspective and therefore have the opportunity to act as a patient advocate in healthcare situations. Nurses play a central role in shifting traditional healthcare approaches towards integrated care. Investing in health infrastructure, including eHealth and ICT solutions facilitating communication among professionals, will foster a transformational change in the healthcare system. It will particularly reinforce the shift from a hospital-centred model of health services to community-based care and integrated services.

Common challenges require common goals and ambitious solutions that can be better achieved by strengthening global cooperation in the area of eHealth. Despite country-based specificities, there is a common shared vision as regards the understanding that eHealth must support and advance healthcare.

eHealth services facilitate this process of change and foster the mutual understanding of common challenges. Therefore developing and sharing eHealth strategies by using standards and guidelines for optimal deployment of eHealth services is paramount. Building on common principles, guidelines and standards for effective, sustainable and integrated care enables a better collaboration within the EU, but also realises the European rights of free movement and equitable access to health and social care across Member States. Joint activities between the EU-US could map examples and guidelines for high quality care already existing in both sides to further develop common optimal standards for care.

Even if eHealth services are seen key in this debate, skills and competences of health professionals cannot be forgotten. The EU-US MoU paves the way for collaborating to identify current trends eSkills and eCompetences within the health and social care field and to address new developments in the health workforce education, particularly in nursing, as to redefine and benchmark harmonised skills and competences that will help further develop the health and social care sector, making an effective use of all resources, eHealth services in particular.

In the current period of EU austerity, joining and pooling forces towards achieving change for the individual citizen and patient will make an overall difference. Nurses remain committed to reinforcing collaboration with the EU civil society, EU key stakeholders and US counterparts to further orient policy-makers and politicians in selecting the right priorities when investing in health for it to become a key driver of well-being, productivity and growth.

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# The EU-US eHealth cooperation: A transgovernmental approach

The paper endeavours to put the EU-US eHealth cooperation within a political framework. It promotes the idea of institutionalism by indicating the changes brought about by globalisation and how they have created transgovernmental networks in which the traditional concept of the nation state has changed. It is argued that the progression to institutional transgovernmentalism, where governmental subunits and various other actors are not related to the government, provides a theoretical framework that can be applied to explain the transatlantic eHealth cooperation.

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Keywords

eHealth, institutionalism, regime theory, transatlantic cooperation, transgovernmentalism

> “eHealth transatlantic cooperation can be understood within the theoretical context of institutional transgovernmentalism.”

# 1. Introduction

Cooperation between the European Union (EU) and the United States (US), or transatlantic cooperation, in the era of globalisation is on the verge of acquiring a deeper institutional structure. This paper highlights the paradigm of eHealth transatlantic cooperation in an era of denser transnational networks when the need emerges for policy adjustments and re-formulations in various fields so as to produce better results. By placing the EU-US eHealth cooperation in a broad political context, the paper will argue that globalisation cultivates the need for deeper ties, not necessarily in the realm of the state but in the transgovernmental domain. In this sense, the aim is to emphasise eHealth transatlantic cooperation as a paradigm as well as to understand it within the theoretical context of institutional transgovernmentalism.

The paper is divided into the following parts: First, it explores whether health is global. Second, it briefly describes the globalisation concept to emphasise the emergence of transnational networks. Third, it analyses the transition to institutional transgovernmentalism as a framework that can largely explain some recent efforts for cooperation in the global system. Fourth, it explores the various stakeholders, and example initiatives, involved in the EU-US transatlantic initiative on eHealth. Finally, it concludes by linking these concepts to eHealth by attempting to position the transatlantic cooperation into a political theoretical framework.

# 2. Is health global?

In recent years policy makers have realised that the needs and the structure of the health sector have changed (or were in need of change). The term 'global health' came to the fore, when trying to describe the health problems, issues and concerns that transcend national boundaries and can be influenced by circumstances or experiences in other countries. The term 'global' emphasises the existence of some inherent features that go beyond physical or geographical distance: for instance, a potentially contagious person or product can now travel anywhere in the world within just one to two days. Such facts lead to two interconnected realisations: first, current health issues and trends can be better addressed by cooperative actions and solutions; second, coping with new health threats requires principles to be agreed on a number of internal and external policies and actions, i.e., policies that are wider than those of one nation only.

eHealth is largely an answer, among others, to the rising and widespread health challenges. It is a response to the evidence that health needs at both global and local levels are complementary and that the distance-independent services of eHealth can indeed offer solutions with regard to public health challenges. The term 'global eHealth' was articulated in 2003 by the World Health Organization (WHO), which referred to the *"sustainable global integration of information and communication technologies into the practice of protecting and promoting health across geo-political, temporal, social and cultural barriers – including research and education – in order to facilitate health, public and community health, health systems development and epidemiology"* (World Health Organization).

In order to understand the transition to this global aspect of eHealth and to comprehend the transatlantic initiatives to further promote the concept of eHealth, globalisation processes are described.

In the current globalised context, distance is no longer an issue: at the same time the dense and complex networks of trade and financial transaction flows and the easy transmission of knowledge, information and technology have rendered the old traditional divide between the core and periphery obsolete (Dicken, 2003: 9). It could be argued that the material interests of newly emergent actors

(like multinational corporations), besides the traditional nation state, are rendered transnational, which leads to the more effective integration of global processes (Underhill, 2000: 823). However, the current state of play is more complex, as will be described below.

It is important to conceptualise the term globalisation in terms of space, while paying attention to the word 'processes', which indicates that globalisation is an evolving phenomenon rather an end-state (Lowi, 2001: 133). Consequently, the globalisation trend is constantly shaped by dynamics and factors that are geographically and functionally unequal (Dicken, 2003: 1).

What largely defines globalisation in terms of space is the simple axiom that everything can be located anywhere: if a particular location does not prove beneficial a service can be relocated elsewhere with the greatest of ease (Dicken, 2003: 20). This does not mean that all spaces are equal or that geographic location is of no importance. It means that the distance between spaces has been reduced and that there is an extremely high level of interdependence and interconnection among them.

To better understand how globalisation has altered the concept of space, this paper turns to Jan Aart Scholte's holistic approach (Scholte, 1997). According to Scholte, globalisation refers to a process through which social relations acquire qualities defined by relatively reduced distance or border characteristics, in such a way that human lives are gradually played out in a world which resembles a single place (Scholte, 1997: 14). The fact that many phenomena, like global warming, have a global reach and have common implications for all countries, makes globalisation a distinct phenomenon by underlining the concept of supraterritoriality (Scholte, 2000). The term implies that global social, political and economic processes exhibit low responsiveness to geographical borders.

Technology is one of the massive catalysts transforming the globe into a supraterritorial ('global') entity. However, it is not the only one. There are three more particularly significant factors that strengthen globalisation and are nested in terms of processes. The first is the emergence of a global consciousness, namely the awareness that we live in a single place and are concerned by all the events that take place in it. The second relates to some crucial alterations in the nature of capitalism and especially in the operation of multinational enterprises and internationalisation of production. The third refers to the development of regulatory frameworks, in the form of supranational institutions (like the World Trade Organisation), which bind their members to specific provisions and regulations (Scholte, 2000: 89-100).

In attempting to define the massive change on the global scene, two assumptions need to be underlined.

The first focuses on the globalisation of production and the emergence of global production networks. These spread production beyond geographical borders and barriers, which results in the networking and interdependence between what is 'national' and what is 'global' (Dicken, 2003: 19). This radical change, driven by economic globalisation, leads to what Robinson calls the transition from the world economy to the global economy (Robinson, 2004: 10). According to this characterisation, the world economy mirrors a condition in which national markets are connected via international trade, and nation states mediate between the barriers of a world of many different national economies. In contrast, the new global economy has rendered ever more transnational capital able to reorganise production relations in such a way that they exceed both national economies and nation states. In this respect, national production systems adapt to the new global needs.

The second stems from Ulrich Beck's (Beck, 2005) perception. It describes a scene in which the spheres between 'national' and 'international' have been dissolved and replaced by what has come

to be known as global domestic politics (Beck, 2005). All processes are largely defined by a 'meta-game', according to which globalisation has reshaped the traditional 'old' forms of politics which were based on the application of rules to forms of politics that change the rules. All these changes take place in a global environment where actors are intermeshed in very high levels of interdependence. The essence of this transition is based on a radical change in the roles of actors: according to Beck, "Institutions no longer prescribe the space and the framework within which organisations engage in political action; instead, it is organisations that are breaking out of the institutional box and are forcing a reconsideration of the 'national *a priori*' of political action" (Beck, 2005: 2-3). To elucidate, on the one hand, when Beck refers to institutions, he means the formal and informal codes of behaviour that serve to facilitate or to prescribe certain forms of national and international political practice (e.g. state control over a limited territory, diplomacy, legal sovereignty, welfare state policies). On the other hand, when Beck refers to organisations, he means particular actors with a certain number of members, financial and spatial resources at their disposal and a given legal structure.

Globalisation also affects the character of the state. The undergoing transformation of the state can be seen in various different lights. Some argue that it is shrinking (Sbragia, 2000), that it is being hollowed out (Strange, 1996), or that is shifting (Dicken, 2003). The main idea behind all these perceptions is that the state (in its traditional conception) is becoming increasingly unable to govern alone in a world characterised by transnational challenges and increased interdependence both economic, and political. Furthermore, this is also evident in the eHealth field, where cooperation is increasingly promoted above and below the nation state (supranational, regional and local level). There are many actors that operate in a transgovernmental way and can efficiently promote cooperation.

All these developments take place within a decentralised and anarchical global system. This means that there is no hegemonic power, no world government, or dominant power that can exercise direct power and control the foreign or domestic policies of other central states of the global system (Nye, 2003). Thus, states have learned to cooperate in the absence of a formal governing authority to mediate their interests and enforce agreement among them. Consequently, globalisation has been cultivated the idea among states (especially states that retain a central role on the global chessboard) that they can have better policy results if they move from confrontation and competition to cooperation. This, in turn, has led to the creation of many institutions that could facilitate the power-play among states and support their bargaining processes. Such a bargaining process, especially in an institutionalised basis above and below the nation state, is also evident in the case of eHealth transatlantic cooperation.

To facilitate its understanding, the role that institutionalism takes within a globalised environment must first be described.

## 3. Transition to transgovernmentalism

A common feature in theoretical analysis after the Cold War was the quest for a structure that could take over and guarantee stability in the international system. It was evident that the system had to operate without the existence of a hegemonic power (Keohane, 1984). Theories of neoliberalism and institutionalism then emerged to help analyse possible ways of cooperative discourse. Fundamental to this field is Keohane's (1984) contribution, which founded liberal institutionalism. He stripped the international system from the concept of the hegemon, argued that cooperation can take place without hegemonic power at the wheel and that future cooperation would mostly rely on international institutions.

Keohane claimed that international regimes could function without the US's guidance. Once created, regimes could strengthen cooperation without the use of a dominant nation: "Common interests of the leading capitalist states, bolstered by the effects of existing international regimes, are strong enough to make sustained cooperation possible" (Keohane, 1984: 43). The concept of liberal institutionalism has been further developed in the works of Risse-Kappen (1995) and Ruggie (1998) who argued that international institutionalisation does not always result in supranational organisations.

Many international institutions take the form of what came to be known as regimes, which can be broadly defined by their 'patterned behaviour' (Puchala and Hopkins, 1983), the existence of specific rules (Keohane, 1989), or principles, norms and decision-making procedures (Krasner, 1993). Consequently, institutionalism is a process whereby the coordination and pattern of behaviour between various actors is established and developed (Ruggie, 1998). Moreover, this approach to regimes explains the emergence of international institutions in terms of the functions that these institutions perform (Keohane, 1984: 14). For example, states create regimes because they provide information to the regime participants that reduces the costs of the participants' transactions in a policy area. According to Peters (1999), institutions could be broadly characterised by:

- Formal and informal structures, including networks and shared norms;
- Patterned and sustainable interaction between actors;
- Constraints on the behaviour of its members; and
- Some sense of shared values.

These, in turn, draw our attention to a concept rather relevant to institutionalism called regime theory, which focuses on the formation of international rules and institutions and highlights the role that power, interests and knowledge play in the emergence of international regimes (Hasenclever et al., 1997: 1). This can be applied in the case of the EU-US cooperation in various policy fields.

In this respect, the EU and the US have established various transatlantic institutions as a means of encouraging discourse between policy-makers so as to lead to interest convergence or norm compliance in different policy sectors. Thus, transatlantic cooperation was institutionalised by three fundamental agreements signed in the 1990s (the transatlantic declaration, the New Transatlantic Agenda and the Transatlantic Economic Partnership) (Steffenson, 2005).

This trend is evident in the eHealth field with the initiative promoted by the European Commission and the US Department of Health to sign a Memorandum of Understanding (MoU) on December 2010 in Washington D.C. The MoU aims to create new markets and growth opportunities for industry in the eHealth sector on both sides of the Atlantic. The document addresses issues like the need for a joint vision on international interoperability standards for electronic health record (EHR) systems and the strategies to develop a skilled health IT workforce. The MoU on eHealth is a case in point of how institutionalism can be developed into a regime, where institutional arrangements emerge from states' efforts to coordinate their actions in order to reap joint gains (Young and Osherenko, 1993: 14).

In the three years since the signature of the MoU, the EU-US cooperation on eHealth has deepened, and has taken on new forms of expression which can be called transgovernmental cooperation. This development can be rooted in the theory of transgovernmentalism: this is a form of cooperation characterised by transgovernmental networks, which are patterns of regular and purposive relations among government-like units working across the borders that divide countries from one another and that demarcate the 'domestic' from the 'international' sphere (Slaughter, 2004).

The transgovernmental approach differs from the interstate approach in two fundamental ways. First, the transgovernmental approach focuses on interactions among government subunits, whereas the interstate approach emphasises interactions among states. Second, it assumes that government subunits can act autonomously from states, whereas the interstate approach treats states as unitary actors. This transgovernmental approach reflects what is happening with the EU-US cooperation on eHealth, in which governmental subunits and various other 'organisations' (to borrow Beck's (2005) terminology), cooperate in the EU case, above and, in the US case, below the state to structure policies in the light of their common interests.

## 4. EU-US cooperation on eHealth

By employing as a model the regime theories as part of transgovernmentalism, the cooperation between the EU and the US on eHealth can be seen as trying to coordinate action in order to reap joint gains and thus develop behavioural patterns and sustainable interaction between actors.

The goal of EU-US cooperation on eHealth would be to identify common principles that can be agreed with relative ease, and to use these to encourage the development of domestic policy that is in line with eHealth principles that can gradually acquire more global qualities. The outcome would be the removal of administrative and political barriers to EU-US eHealth and perhaps even a more international form of eHealth.

The initial areas of cooperation between the EU and the US in the field – in so far as the MoU is concerned – focus on the development of internationally recognised and used interoperability standards for EHRs and on the promotion of strategies for development of skilled health IT workforces. Further areas of cooperation such as benchmarking, data collection, research, innovation and public policy coordination are also on the EU-US agenda.

It is important to note that these efforts involve actors who are not governments per se but who stem from a very broad array of fields. In trying to summarise some of the main actors in this transatlantic eHealth cooperation, it can be concluded that the efforts are largely promoted by governmental subunits and organisations that are creating new boundaries for political action. Some of these actors are:

- Individual researchers.
- Research institutions, which form strategic alliances with universities and research centres to gain and/or enhance know-how.
- Businesses, which set cooperation targets to the internationalisation of business, the cultivation and implementation of eHealth initiatives, programmes and applications with the view to use knowledge resources.
- Governments, intergovernmental arrangements, and the EU. They aim at improving the quality of national science bases and joining forces for addressing complex problems and global challenges.
- International initiatives, which are created by sub-governmental or non-governmental units, and not only address global challenges but also enhance cooperation. These initiatives include the International Society for Telemedicine & eHealth (ISfTeH), the International Educational and Networking Forum for eHealth, Telemedicine and Health ICT (Med-e-Tel), and the Healthcare Information Technology Standards Panel (HITSP).

All these actors not only interact with each other domestically and with their foreign and supranational counterparts, but they also perform some of the basic functions of governments such as implementation. This conceptual shift brings about a strengthening of transnational cooperation, higher impact, establishment of wider collaboration networks, cultivation of expectations for technological advancements, and better access to specific expertise.

A specific case in point, where eHealth was promoted by the functioning of transgovernmental regimes, was the ARGOS project, which supported EU-US cooperation on eHealth and was funded and run by the European External Action Service (EEAS). ARGOS created a transatlantic observatory promoting mutual understanding between EU and US stakeholders (among others, both the Eurorec institute for Health records and the American Medical Informatics Association) on interoperability and certification, indicators and tools, modelling and simulation of human physiology. The observatory was funded with a twofold target in mind: to improve the health and well-being of citizens through accelerating eHealth strategy development and through supporting large-scale eHealth infrastructure implementations; and to support research and development in eHealth to promote the benefits that can emerge from the pursuit of consistent strategies.

In this context, globalisation and the different needs it brings about establish deeper cooperation ties among a number of different actors that do not necessarily derive from the state or the government, but rather from what is referred to in this paper as the transgovernmental domain. Joining transgovernmental forces in the eHealth field can thus lead to further facilitation of EU-US collaboration and provide favourable conditions for: promoting interoperability of programmes, procedures and rules; aligning programmes that facilitate the twinning of projects; establishing joint laboratories and networks of centres of excellence; improving communication, raising awareness and visibility; designing appropriate funding approaches; agreeing on standards; and shaping researcher mobility for institutional collaboration.

## 5. Conclusions

In the survey conducted, 124 profiles from five social networks have been identified. About half of this paper has underlined how globalisation leads to deeper institutional structures by discussing the EU-US cooperation on eHealth. This transatlantic cooperation is treated here within a political perspective. The argument is that the theory of institutional transgovernmentalism is capable of helping to analyse and comprehend how eHealth transatlantic cooperation works. In addition, it conveys the idea that, in an era of globalisation where networks are denser, cooperation can be efficient when promoted by sub-units that operate both above and beyond the state and its government. Thus, actors other than the traditional actors, take the initiative to promote institutionalisation and enhance collaboration on a transatlantic basis.

This kind of cooperation can be further broadened in the years to come, not only by various non-state actors, but also by the European Commission, which operates ‘above’ the level of the nation state and can enhance or supervise the creation and function of institutional arrangements with a niche focus. This might form a requirement for the future: to further establish cooperation in a transnational manner with help from a supranational body.

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