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*EHR IMPACT*

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Report on

# The conceptual framework of interoperable electronic health record and ePrescribing systems

Version 1.0

April 2008



**European Commission**  
Information Society and Media

## About EHR IMPACT

The EHR IMPACT study was commissioned by DG INFSO and Media, unit ICT for Health, and will result in ten independent evaluations of good practice cases of interoperable electronic health record (EHR) and ePrescribing systems in Europe and beyond. The goal of the study is to support ongoing initiatives and implementation work by the European Commission, Member States governments, private investors, and other actors. The study aims to improve awareness of the benefits and provide new empirical evidence on the socio-economic impact and lessons learnt from successfully implemented systems.

## Full project title

Study on the economic impact of interoperable electronic health records and ePrescription in Europe

## Contract detail

Contract Number: 30-CE-0161851/00-30

Starting Date: January 1<sup>st</sup>, 2008

Ending Date: December 31<sup>st</sup>, 2008

## Number and title of deliverable

This report is deliverable D1.2 of the EHR IMPACT study. It provides the conceptual framework of interoperable electronic health record and ePrescribing systems, on the basis of which all further study work takes place.

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This study is conducted by: 

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Bonn, April 2008

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## EXECUTIVE SUMMARY

The EHR IMPACT study investigates the socio-economic impact of eHealth utilisation, with specific focus on interoperable Electronic Health Record (EHR) and ePrescribing systems in Europe. Core of the project is a detailed analysis and evaluation of the socio-economic impact at ten implemented and ongoing European good practise cases of interoperable EHR and ePrescribing systems.

This document provides the conceptual and methodological framework on which all further study work is built. It defines the relevant terminology and domains and gives an overview of the research process. This includes identifying relevant issues to be taken into account when further developing the state of the art evaluation method. This report also deals with the guidelines for case study selection.

The fundamental challenge of health systems is to serve a demand that has unlimited scope for increase, with limited resources. Ageing populations, raising expectations, and advances in life sciences drive demand for quantity and quality of health services. The difficulties that lie ahead are in reconciling individual needs stemming from those developments with the available financial and non-financial resources. Over the last years, political awareness of the potential of eHealth to help address these challenges has been continuously rising on European, as well as on Member State level.

Nonetheless, health systems remain complex and demanding, and eHealth is no exception. Researching definitions of the key terms of this study showed that there are no unique concepts behind either EHR or ePrescribing. Even interoperability is often understood and used in different ways by different people. We also had to discover that the visionary definitions, comprising 'holy grails' of beneficial attributes and functionalities, cannot realistically be expected to be found implemented now or in the very near future. Thus, we had to operationalise the concepts by defining them in broad terms, focusing on key aspects, such as allowing the possibility to share at least some patient-specific clinical data. This, together with the critical condition of providing a good learning experience with empirical evidence on impact, is also a primary guideline for selecting potential case studies.

The methodology for evaluation of the socio-economic impact of interoperable EHR and ePrescribing systems is subject of a separate report. However, the conceptual foundations were already set in this document. The methodology builds on cost benefit analysis (CBA), and uses monetary values to index financial, but also non-financial impacts. Negative impacts fall under the cost category, whereas positive impacts are aggregated as benefits. The perspectives of all stakeholders are included in the analysis. The topic of central interest is the development of net benefits, defined as estimated benefits less estimated costs, over time. Critical features of the methodology are that the models adapt to the specific case setting and data, and that the results should be regarded as robust only in their order of magnitude, not the precise numbers.

The EHR IMPACT study is scheduled to be completed by the end of 2008. The first, preparatory, phase is now nearly completed and the second, evaluation phase is already underway. The evaluation phase includes detailed analyses of overall ten case studies of interoperable EHR and ePrescribing systems. In a third phase, the results will be analysed in aggregation, and disseminated to policy makers, decision makers and other targeted actors in the healthcare sector, as well as to the wider public.

# 1 Introduction

The European Commission EHR IMPACT study investigates the socio-economic impact of eHealth utilisation with specific focus on interoperable Electronic Health Record (EHR) and ePrescribing systems in Europe.

Core of the project is a detailed analysis and evaluation of the socio-economic impact of ten implemented and ongoing European good practise cases of interoperable EHR and ePrescribing. The relevant evaluation methodology is based on the eHealth IMPACT (eHI) study<sup>1</sup>, whose model builds on cost benefit analysis (CBA). The case studies analysed in EHR IMPACT will be sustainable solutions in routine operation.

This document provides the conceptual and methodological framework on which all further work is built. It defines the relevant terminology and domains and gives an overview of the research process. This includes identifying relevant issues to be taken into account when further developing the state of the art evaluation method. Further, this report deals with the guidelines for case study selection.

Chapter 2 outlines the European health policy context in general, including reference to the key challenges of healthcare systems, and the eHealth context in particular, against which the overriding goal of this study must be seen.

Chapter 3 then concerns a clear delineation of the domain to be researched as well as definitions of some crucial terms to be used in this work. Because a wide variety of sometimes incompatible definitions of relevant terms exist in both literature and policy documents, this is regarded as mandatory to avoid confusion in further exchanges on these subject matters. Key terms to be defined are: Electronic Health Record (EHR), ePrescribing, the concept of interoperability and what is understood as “operationalising the concept of interoperable EHR and ePrescribing”.

The next section, chapter 4, is about aspects concerning the methodology of measuring the impact of EHR and ePrescribing systems. The conceptual framework will not include details, as these are dealt with elsewhere.<sup>2</sup> In this chapter, the general approach to evaluating socio-economic impact of eHealth, and in particular interoperable EHR and ePrescribing systems, is discussed. Further, some comments on appropriate measurement techniques and the constraints and risks associated with the evaluation work are elaborated upon.

Chapter 5 deals with conceptual tasks concerning good practise case studies. After defining what “good practise” is, this part deals with the approach to identify relevant cases and how to select ten of them. We present the selection guidelines, which are developed on the basis of, among other things, the experience of the study team from the eHealth IMPACT study. The respective pre-selection template used to gather initial information on potential sites is included in the Annex.

In the last section, chapter 6, of the conceptual framework the research plan of the study is presented in some detail. This includes a clear overview of the three phases of the study - preparation, evaluation, and summary analysis - an overview of the work packages and work tasks, and a detailed time planning.

As a summary of this conceptual framework the chapter 7 includes the most important aspects and key terms of the conceptual framework and also some conclusions concerning the further workflow of the project.

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<sup>1</sup> [www.ehealth-impact.org](http://www.ehealth-impact.org)

<sup>2</sup> Deliverable D1.3 of this study: Methodology for evaluating the socio-economic impact of interoperable EHR and ePrescribing systems

## 2 The political context of eHealth

### 2.1 Common values, principles, and key challenges in EU health systems

The final goal of all health system activities is to promote, maintain, improve, re-establish or at least stabilise the health status of citizens - independent of their personal situation. This includes care for patients with chronic conditions and ill-health prevention. The key challenge of health systems is to maximise the quality and quantity of these activities, and to assure appropriate distribution of service provision. Of course, this maximisation and optimisation problem is subject to budgetary and other constraints. These include not only limited accessibility of financial resources, but quite often also availability of qualified staff, the level of scientific development in medicine, biology, and even information and communication technologies (ICT).

In order to guide decision making associated with the above described issues, the European Council has agreed on a set of goals and priorities of Member States in the field of healthcare. These are summarised in a very succinct way by the "Council Conclusions on Common Values and Principles in European Union Health Systems"<sup>3</sup>. Universality, access to good quality care, equity, and solidarity constitute a set of overarching values that are shared across Europe. Universality refers to the universal, i.e. for everyone, access to healthcare; solidarity relates to the financial dimension of ensuring accessibility to all; equity emphasises that access should be according to needs, regardless of ethnicity, gender, age, social status, or ability to pay. Member States are also concerned by differences in the quality of health services across the Union, as well as issues of prevention through promotion of healthy lifestyles.

Despite following different approaches, all EU health systems aim at ensuring healthcare provision that is "patient-centred and responsive to individual need".<sup>4</sup> The health systems of the European Union are a "fundamental part of Europe's social infra-structure".<sup>5</sup> Evidence shows that current performance is scoring well in international comparisons: out of the 27 EU Member States, 18 are in the top 45 worldwide in terms of life expectancy<sup>6</sup>. No Member State is in the bottom 50 countries world wide. Infant mortality in 14 out of the 25 countries world-wide with lowest rates, are Member States. None are among the 40 countries with highest infant mortality rates.<sup>7</sup>

Nevertheless, while safeguarding the values listed above, Member States have to make the systems financially sustainable. Europe is in a privileged position in that the 27 EU Member States are able to afford to spend over € 1 trillion on healthcare per year<sup>8</sup>. Already, the health and social services sector is the dominant employment sector of the European Union. In 2002, with more than 15.5 million people employed - more than 9% of European employment, it was more important than retail with roughly 13m and business services with somewhat more than 13m. The gross value added of from the health sector amounted to

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<sup>3</sup> Council Conclusions on Common Values and Principles in European Union Health Systems. Document (2006/C 146/01), published in the Official Journal of the European Union on 22 June 2006, pp. 1-5

<sup>4</sup> *ibid.*

<sup>5</sup> *ibid.*

<sup>6</sup> Spain is the first Member State on the 7th place with 80.9 years; Top of the list is Andorra, with 83.5 years.

<sup>7</sup> Figures based on The Economist (2007), Pocket world in figures 2008 Edition, ISBN: 978 1 86197 844 8

<sup>8</sup> Figure for 2005. Source: The Economist (2007), Pocket world in figures 2008 Edition, ISBN: 978 1 86197 844 8

around 500 billion Euro - more than 6% of European Union GDP -, topped only by business services with about 515 bn Euro.<sup>9</sup>

The challenges that lie ahead are in reconciling individual needs with the available finances, as the population of Europe ages, as expectations rise, and as medicine advances. The scope for increase of the financial resources to meet this demand is limited. The resulting pressure presents a challenge to safeguarding the values and principles of European health systems. An integral part of the strategy towards sustainability is a shift in focus towards preventive measures, which is expected to reduce the cost burden by avoiding the occurrence of disease and associated treatment costs.

## 2.2 eHealth on the political agenda

Information and telecommunication technologies in health can be used in a beneficial way in the course of addressing the key challenges faced by healthcare systems, and policy makers increasingly recognise this potential. ICT-enabled solutions supporting the provision of effective, efficient, good quality, seamless healthcare are an old dream, already discussed and conceived about 40 years ago, but never successfully implemented at a larger scale.<sup>10</sup> Both technical advances and pressing needs to cope with ever increasing demands on healthcare systems have led to a renewed interest in such applications. The EU has for more than 15 years now supported technology-focused research in this field.

It seems that we now finally will see large scale implementations of eHealth solutions, not the least instigated and stimulated by the EU eHealth Action Plan<sup>11</sup> imbedded in the wider context of realising the Lisbon Strategy<sup>12</sup>, and the consequent EU and Member State activities. The creation of a European eHealth area<sup>13</sup>, free patient mobility<sup>14</sup> and empowering the citizen through eHealth tools and services<sup>15</sup> are now key policy objectives of the Union, also firmly embedded within the framework of the i2010 Initiative.<sup>16</sup> Late in 2007, the Commission published a communication on “A lead market initiative for Europe”<sup>17</sup>, in which eHealth is identified as one of six markets in which Europe can and should gain a competitive edge.

European investment levels in healthcare ICT have remained almost static at around 1% to 1.5% of total healthcare expenditure. But now, a new set of common political imperatives is driving demands for additional funding to establish effective healthcare ICT infrastructures:

<sup>9</sup> Karl A. Stroetmann, Veli N. Stroetmann: Electronic business in the health and social services sector - The use of ICT and e-business in 2003/04. Sector Impact Study No. 10-I. The European e-Business Market W@tch, Brussels/Bonn, May 2004. These are only rough figures due to considerable differences in national statistics on which these data are based.

<sup>10</sup> Ed Hammond, the “grandfather” of eHealth in the USA, started already in 1967 to programme his first version of an EHR. In Germany, in the early 70’s, a huge project (DOMINIK) based on main frame computers failed dismally, and also the early dreams of global satellite-based telemedicine networks developed during the same years never became reality beyond the military and research environments.

<sup>11</sup> Commission of the European Communities - COM (2004) 356: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making health care better for European citizens: An action plan for a European e-Health Area, Brussels, 2004-04-30

<sup>12</sup> See Presidency Conclusions of the Lisbon European Council, 22-24 March 2000.

<sup>13</sup> Commission of the European Communities - COM (2004) 356: e-Health - making health care better for European citizens: An action plan for a European e-Health Area, Brussels, 2004-04-30.

<sup>14</sup> CEC (2004): Follow-up to the high level reflection process on patient mobility and health care developments in the European Union. COM (204) 301 final, Brussels, 20.04.2004.

<sup>15</sup> This was the overriding topic of the 2004 European Presidency eHealth conference in Cork, Ireland, in May 2004. Cf. Wilson, P., Leitner, Ch. and Moussalli, A. (2004): Mapping the Potential of eHealth, Empowering the citizen through eHealth tools and services. Maastricht: European Institute of Public Administration.

<sup>16</sup> Commission of the European Communities - COM (2005) 229: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: “i2010 - A European Information Society for growth and employment”, Brussels, 1.6.2005

<sup>17</sup> Commission of the European Communities - COM (2007) 860 final: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: “A lead market initiative for Europe”, Brussels, 21.12.2007

- Pressure to secure acceptable levels of patient safety
- Expectation of ‘consumer-type’ access to health services
- Need for radical improvements in service productivity
- Impact of increasing complexity of healthcare processes.

These developments are expected to generate a considerable expansion in healthcare ICT with growth rates of up to 10% and more p.a.<sup>18</sup>

Countries that have moved the new investment in healthcare ICT infrastructure systems from planning stages to execution are moving their ICT spend from 1% - 1,5% of healthcare expenditure to 2% - 3% and above. Countries currently implementing or considering increases in spending on ICT that will probably exceed 3% of healthcare expenditure for at least a short period this decade are Denmark, Ireland, and the UK.

This development illustrates the recognition by policy makers across Europe of the enabling value of eHealth solutions in ensuring the highest possible health level for citizens. In the conclusions to the High Level eHealth Conference 2006 in Malaga, Spain, the participants, policy makers on EU and national ministerial level, as well as CEO level industry representatives and distinguished researchers and experts, acknowledged that “Europe can benefit from eHealth that focuses on ensuring better:

- Prevention of diseases
- Prediction of diseases
- Personalisation of healthcare
- Participation of Europe’s citizens in their own healthcare improvement
- Increased patient safety throughout all stages of the healthcare process
- Productivity and performance of Europe’s healthcare systems, and of Europe’s third healthcare industrial pillar
- Monitoring of indicators and production of regular data and reports on health status.

eHealth can also underscore and underpin other current concerns of healthcare authorities throughout Europe, such as:

- Providing support to health professionals by making up-to-date information available on disease prevention and management
- Assessing means of cross-border healthcare purchasing and provision
- Understanding and monitoring of health professionals’ mobility
- Creating interaction and organisational links among the public health community in Europe
- Creating a network of health impact assessment and health systems
- Creating an operational network of Member States’ patient safety contact points.”<sup>19</sup>

In April 2007, the Member States and the European Commission made a common declaration summing up the conclusions of the 2007 eHealth Conference in Berlin, stressing the following key issues:

1. National well-organised eHealth infrastructures are pre-requisite for cross-border solutions

<sup>18</sup> Cf., e.g., Frost and Sullivan: European Electronic Medical Records Markets, 2007: “The European EMR market is currently worth €349.6m and will reach €1.15bn by 2013.” See

[http://www.ehealthurope.net/news/strong\\_growth\\_predicted\\_in\\_european\\_emr\\_market](http://www.ehealthurope.net/news/strong_growth_predicted_in_european_emr_market)

<sup>19</sup> Draft Final Conference conclusions - High Level eHealth Conference 2006, Málaga, Spain; <http://www.ehealthconference2006.org/images/stories/Conclusions.pdf>

2. European standardisation will open up market opportunities
3. Existing national roadmaps must be taken into account
4. Implementation of eHealth services require greater synergies with research and education
5. Agreement on common standards by all EU Member States is essential
6. The eHealth industry and other stakeholders must be involved.

Interoperability and electronic health records have entered explicitly the cooperation plans of Member States: “There will be an increased focus on the deployment of eHealth systems, setting up of targets for interoperability, use of electronic health records, and reimbursement of eHealth services.”<sup>20</sup> The delegates, acknowledging the increasing mobility of European citizens, also defined the very concrete next steps of cooperation:

“Large Scale Pilots will test the application of improved patient summaries in different health contexts such as medical emergencies and prescription dispensing. [...] As part of this joint initiative, progress will be made in relation to improving interoperability; use of electronic health records; deployment of research results; and development and coordination of eHealth standards essential to cross-border applications.”<sup>21</sup> Meanwhile, a Large Scale Pilot (LSP) on eHealth is about to be launched. It targets two eHealth application fields: a core patient summary useful in case of an unexpected, initial encounter between a European citizen and a doctor from a country different from the patient’s country of residence, and (pan-European) ePrescribing. The pilot will run for three years, so the results of the EHR IMPACT study will be available in time to be fed into this other project. The concrete experience, implementation processes and lessons learnt from the sites selected and analysed in detail will be communicated to and discussed with the project team of the LSP.

Personal Health Systems (PHS) were the focus of an EU conference in 2007.<sup>22</sup> The vision for PHS to take healthcare out of the hospital, bring it to the home and embed it into people's lives was clearly voiced. “As in the U.S., they are still in the early stages of deployment in Europe. The following are two key points articulated at the conference:

- Successful deployment of Personal Health Systems (PHS) presupposes the existence of favourable policy and political support. To obtain this support, there is a need to continue to collect large scale clinical evidence which demonstrates how PHR systems contribute to improved patient well-being, patient safety, quality of care, and affordability.
- Empowerment of patients and their families through use of health IT systems is critical to the future of healthcare. Again, while there are many isolated success stories, there is a need to collect more evidence and clearly document the cost/benefits. Further collaboration between the U.S. and Europe could accelerate progress.”<sup>23</sup>

In its draft paper on interoperability<sup>24</sup>, the EC notes that “the single most important characteristic of an electronic health record is its ability to share information among different authorised users. In technical terms, this requires both the interoperability of information in the electronic health record and the interoperability of electronic health record systems which exchange and share this information.”

Furthermore, it is noted that “at the level of monitoring and evaluation of eHealth interoperability in Europe, there is a need for: ...

<sup>20</sup> eHealth Conference 2007, Final Declaration of Member States and the European Commission, 17 April 2007

<sup>21</sup> *ibid.*

<sup>22</sup> [ec.europa.eu/information\\_society/events/phs\\_2007/](http://ec.europa.eu/information_society/events/phs_2007/)

<sup>23</sup> Peter J. Groen, Douglas Goldstein, Jaime Nasuti (2007): Personal Health Record (PHR) Systems: An Evolving Challenge to EHR Systems. <http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html>

<sup>24</sup> European Commission: Draft revised document in preparation of draft recommendation of the Commission on eHealth interoperability. Brussels, 16.07.2007

- Member States and the European Commission. Strengthen and expand the opportunities for annual checkpoints at which all the relevant stakeholders are invited to share experiences, progress, and good practices.
- Member States and the European Commission. Both parties should define the quantitative and qualitative criteria, and milestones, to measure the progress of the interoperability of eHealth (in particular for electronic health records) and the benefits achieved by the systems and services developed by the Large Scale Pilots.”

## 3 Domain delimitation and definitions

To lay the ground for the work in the EHR IMPACT study, in this chapters we outline and discuss key definitions and concepts. First of all, we start with some conceptual issues and definitions concerning the healthcare value system, its actors, and that role ICT-enabled solutions can and will play in future. Then we define the key terms of the study - EHR, ePrescribing, and interoperability. This procedure is coherent in terms of trying to always account for the overall context of single aspects. Therefore we try to conceptually focus not only on definitions of key terms but moreover to enable a general and well funded discussion on EHR and ePrescribing systems and their role in new healthcare models enabled by ICT.

### 3.1 The healthcare value system and its actors

Healthcare policy makers and strategists inevitably will have to find some way in which to deliver more and more complex services to meet increasing demand and expectations for promotion and maintenance of health, treatment and care. Radical transformation of the healthcare delivery process is needed<sup>25</sup>, supported by and making use of the latest information and communication technologies and recognising the reality of consumer influence. Health systems evolve to provide a full service package, focusing on health rather than care, and regarding citizens as customers, rather than “just” patients. Figure 1 shows a schematic model of health and healthcare processes depicted as a healthcare value system.<sup>26</sup>

In the centre of the figure is the core generic service delivery system, which consists of inter-related value chains of individual health service providers, in economic terms ‘producing’ health: promoting good health, and providing healthcare and long-term care. Supporting processes and tools, inevitably connected to the core processes, surround this system. Only as a system of interrelated processes do they effectively lead to healthy, or at least less ill, citizens.

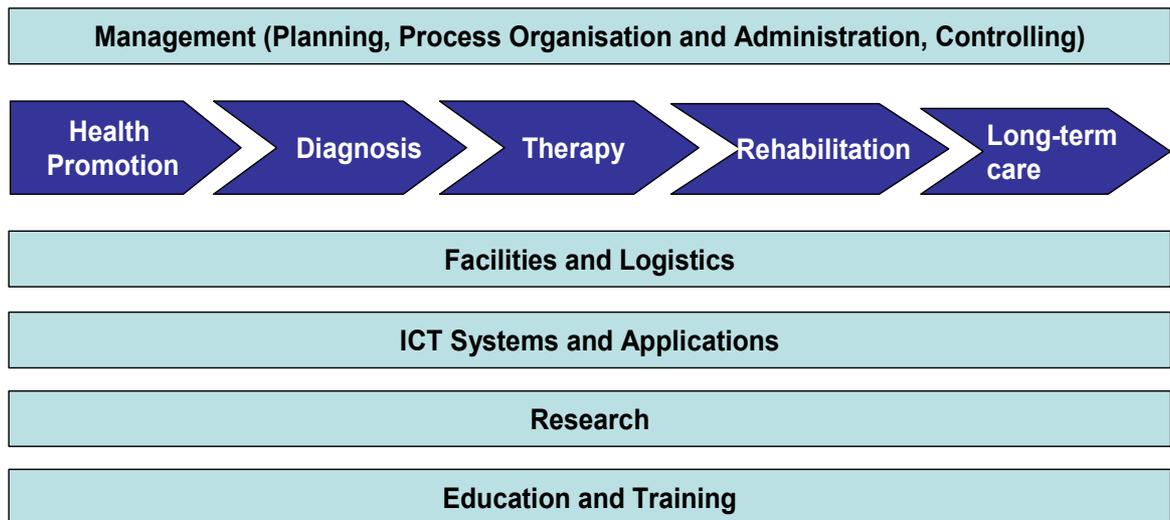
The vision of interoperable EHR and ePrescribing systems is that they will improve not only the processes along the core ‘health production’ processes, but also the interconnection with all supporting procedures, including the public health role. This is why it is important to understand the framework of these interconnections.

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<sup>25</sup> In line with Jean-Claude Healy’s views; Cf. J-C Healy, *Integration and Informatics and Communication Technologies (ICT) in the EU national health systems: status and trends*, Swiss Medical Informatics (SMI 52), 2004

<sup>26</sup> On the concept of value system cf. Porter, M. *Competitive Advantage*. New York: The Free Press, 1985, p. 34: “Gaining and sustaining competitive advantage depends on understanding not only a firm’s value chain but how the firm fits in the overall value system. ... Competitive advantage is increasingly a function of how well a company [here: a healthcare provider] can manage this entire system. Linkages not only connect activities in-side a company but also create interdependencies between a firm and its suppliers and channels.”

Figure 1: The Healthcare Value System



Source: © empirica (2006)

*Health promotion*, as the first element in the core service delivery system, refers to the citizen in healthcare. Citizens should be given reliable materials to help themselves. This includes, for instance, information on what to do against bird flu or why tetanus vaccination is important. It is the duty of public health in general, but also of doctors and citizens themselves. Prevention of illness is here considered as a part of health promotion.

*Diagnosis* is the act or process of identifying<sup>27</sup> and determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory and other data, medical information and knowledge. It is an activity often shared between hospitals, GPs and specialists, and laboratories. EHRs and PHRs are key supporting and guiding tools in this process, particularly also when connected to decision support systems, ePrescribing as part of wider CPOE systems, and linked to prognostic input based on evidence-based medicine tools.

Three different generic, but in reality often overlapping forms of medical intervention may follow diagnosis if treatment is called for:

- **Therapy** is the medical or other (like physiotherapy or nursing) treatment of illness understood here as acute, usually relative short-term, often intensive treatment.
- **Rehabilitation** is also part of the process of restoring a patient to good health or useful life, but usually through medium-term treatment. In contrast to therapy it is often more focused on regaining or re-learning specific functions through medium-term interventions and training.
- **Long-term care** refers to the treatment of and care for chronically ill or disabled people not expected to recover totally again, focusing on assuring at least a certain level of quality of life and preventing or slowing down the worsening of the disease.

The distinction between these three kinds of treatment is fluid and relates to the intensity and duration of care, age and other factors. Clearly, EHR and ePrescribing systems may play an even more important, supportive role in this phase of the healthcare value system.

Further to these patient and / or directly health oriented processes, there are important supporting processes to healthcare.

- **Management**, including administration, concerns the planning, organisation, delivery and control of all health and support services.

<sup>27</sup> Including (unsuccessfully) attempting to identify.

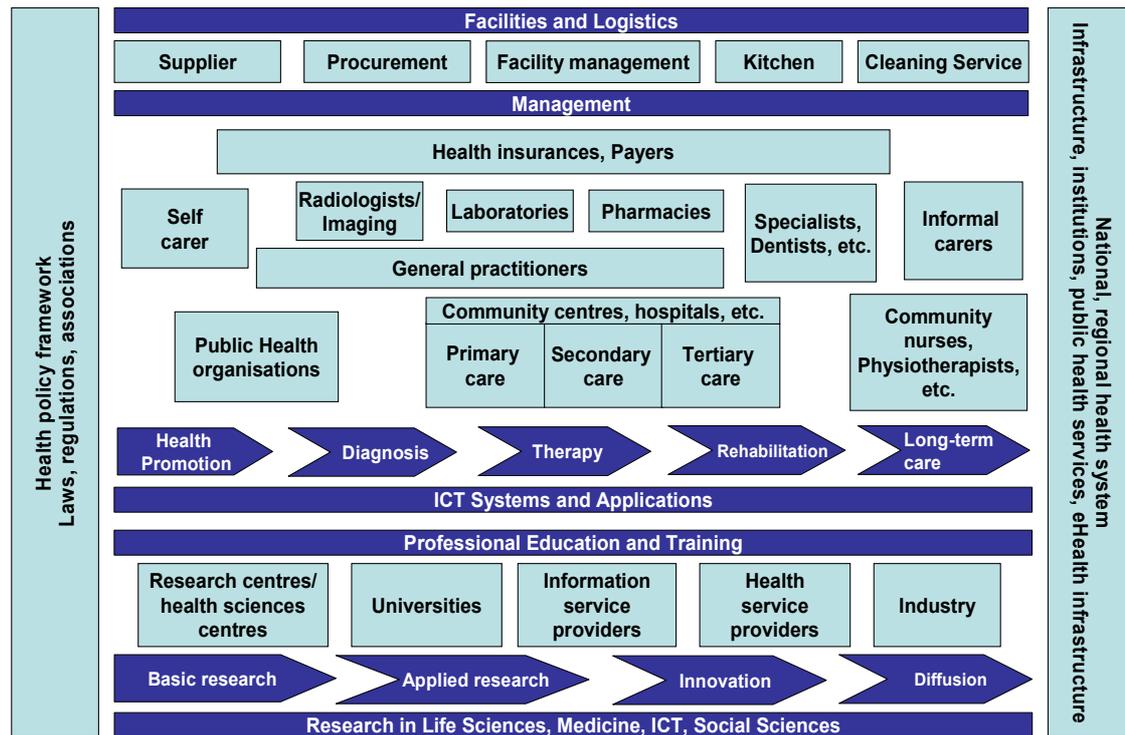
- Facilities and logistics refer to the management of buildings and goods, the procurement and supply. More generally it is the task to ensure the right things are at the right time at the right place.
- Research brings up new or improved ways of promotion, diagnosis, or treatment. In this respect, it is an important instrument changing core health processes.
- Education, training, continuing medical education (CME) and continuing professional development (CPD) are strongly connected to healthcare provision, but also to clinical and basic research.

Complex, advanced and highly interoperable EHR systems can already today and will more so in future play a key role in binding together and integrating these widely varying actors, functionalities and elements in providing optimal health services to all citizens. In this conceptual framework, ICT systems and applications compose one of the supporting tiers. eHealth aids every stage of the health delivery chain and across the healthcare value system. Further to that, ICTs can, and should, be seen as spreading also across the vertical dimension, being an integral part of all tiers in the figure, if these various functions are to be carried out efficiently. This is related to the requirements of sharing information across all tiers. However, eHealth solutions such as electronic health record and ePrescribing systems have to be interconnected in practice, sharing or allowing cross-system access to data, in order to deliver. This stresses the importance of their interoperability.

Modern healthcare is focused on making the best use of finite resources in order to balance the medical outcomes produced with the needs of all stakeholders in the healthcare arena. Responsibilities and interests of different participants in healthcare are diverse: A physician has interests that differ from those of the patient who receives treatment. A hospital differs from a doctor's office. Health insurances negotiate on the payment of medical services with doctors and their associations. Medical care is dependent on data in order to create the basis and transparency for balancing all the different needs and interests of these stakeholders.

In order to stress the role of information availability and exchange in healthcare, Figure 2 presents an attempt to map the processes of the healthcare value system together with the main organisations involved. The aim is to illustrate the complexity of information flows: Each of the institutions shown needs information from most other organisations, sometimes along several channels. And this all does not even include all the information and data flow within each of these organisations.

Figure 2: Mapping Processes to Organisations



Source: © empirica (2006)

Nowadays it is not conceivable how all these communication channels can be maintained without the use of ICT, particularly advanced EHR systems. Yet for centuries, it has always been communication, the exchange of data, information, and knowledge, which has bound medical and healthcare processes and actors together. In recent years, the fast developments in ICT, and solutions based on them, have led to a new quality and scale of such exchanges and interactions.

## 3.2 Defining key terms

“Bad decisions get made because people aren’t talking about the same thing when they use the acronyms.”<sup>28</sup> There are a number of different acronyms for most of the terms dealing with complex applications. eHealth applications are usually complex and deal with recent ICT developments and research findings so new, that lack of standardised definitions are inevitable. But this does not mean that definitions are impossible or even to be neglected. It rather stresses the great importance of delimiting and defining keywords relevant for this study. The following sections deal with the main keywords of the study: Electronic Health Records (EHRs), ePrescribing and the concept of Interoperability.

### 3.2.1 Electronic Health Record (EHR)

#### 3.2.1.1 EHR - the basic concept

The electronic health record (EHR) has been a key research field in medicine as well as in medical informatics for many years. A commonly used definition describes the EHR as

<sup>28</sup> Dave Garets and Mike Davis, Electronic Patient Records, Healthcare Informatics online, October 2005. [http://www.providersedge.com/ehdocs/ehr\\_articles/Electronic\\_Patient\\_Records-EMRs\\_and\\_EHRs.pdf](http://www.providersedge.com/ehdocs/ehr_articles/Electronic_Patient_Records-EMRs_and_EHRs.pdf)

“digitally stored healthcare information about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times”<sup>29</sup> In other terms, EHRs are repositories of electronically maintained information about individuals' lifetime health status and healthcare, stored such that they can serve the multiple legitimate users of the record. Quite obviously, this is a rather idealistic definition and concept, probably not yet brought to real life anywhere worldwide. Systems consistent with this definition can be found only in rather confined local or regional contexts, and for persons born only recently so that indeed complete lifetime data are available. Furthermore, to meet this challenging definition, usually an interoperable system connecting partial EHRs stored at various healthcare providers and other actors will be necessary.

The EHR should include information such as observations, laboratory tests, diagnostic imaging reports, treatments, therapies, drugs administered, patient identifying information, legal permissions, and allergies. This information is stored in various proprietary formats through a multitude of medical information systems available on the market.<sup>30</sup> Making EHRs interoperable will contribute to more effective and efficient patient care by facilitating the retrieval and processing of clinical information about a patient from different sites. Transferring patient information automatically between care sites will speed up delivery and reduce duplicate testing and prescribing. Automatic reminders will reduce errors, improve productivity, and benefit patient care.

Given the complexity of the above comprehensive definition of EHR, we prefer to talk about EHR systems rather than a unique, stand-alone complete EHR. An EHR system can include parts of a comprehensive record, allow limited sharing, or be focused on a particular health service provider organisation rather than the all health-related data about people. Although partial, these are the kinds of solutions that can be found in routine operation at the moment. Including them in the framework of this study is not only necessary for pragmatic reasons, but also has a deeper meaning: The gathered experience, although with solutions of limited scope, are indispensable in identifying the real benefits from EHRs. In the following, we will use the terms ‘EHR’ and ‘EHR system’ interchangeably.

### 3.2.1.2 EHR – state of the art and future developments

Since the rise of electronic versions of healthcare records, a huge number of acronyms have been used to reference and categorise the different variations of electronic healthcare records (EHCR).

The definitions have often been controversial or vague and therefore acronyms were used wrongly and inconsistently. The Medical Records Institute<sup>31</sup> differentiates between 5 levels of EHCRs - see Table 1 - including (from the lowest to the highest level of sophistication) Automated Medical Record (AMR), Computerised Medical Record (CMR), Electronic Medical Record (EMR), Electronic Patient Records (EPR), and Electronic Health Records (EHR).

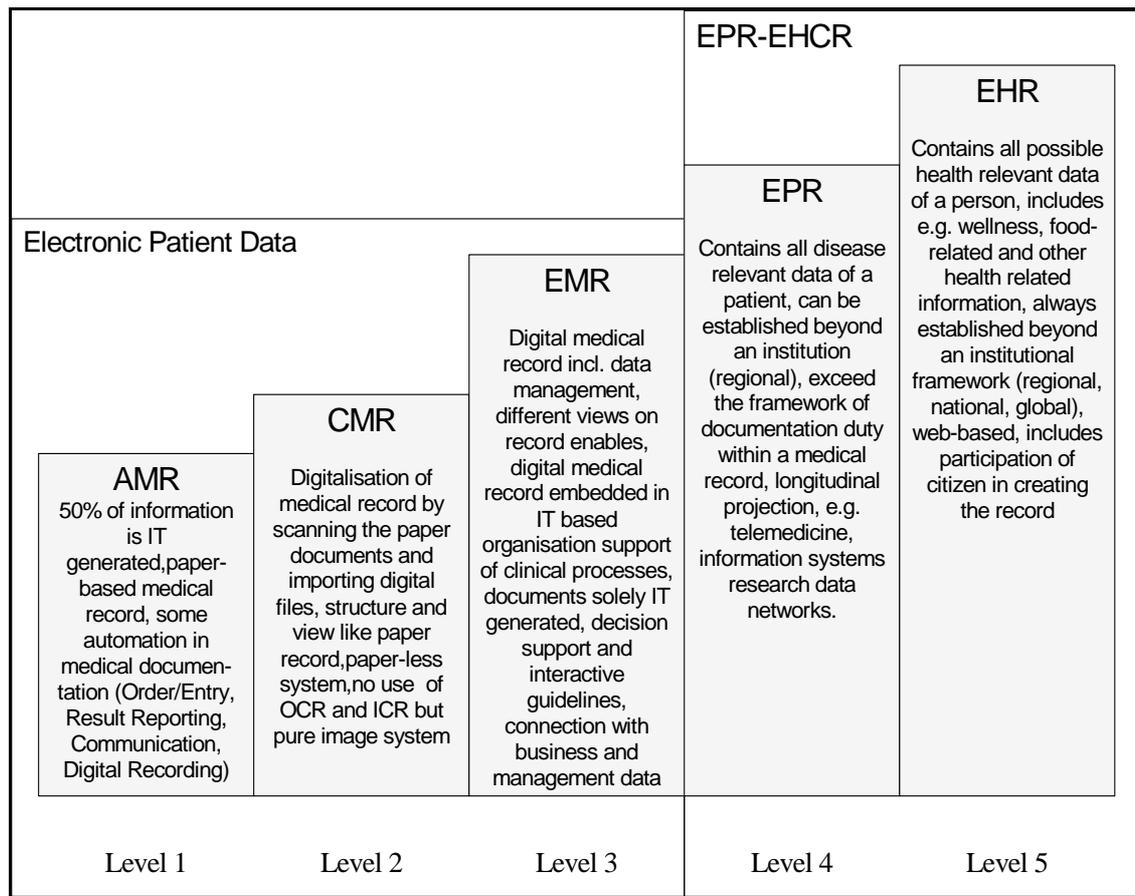
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<sup>29</sup> Iakovidis I. (1998) “Towards Personal Health Record: Current situation, obstacles and trends in implementation of Electronic Healthcare Records in Europe”, International Journal of Medical Informatics vol. 52 no. 128, pp. 105 -117

<sup>30</sup> Eichelberg M et al. (2006) Electronic Health Record Standards - a brief overview, conference paper for Information Processing in the Service of Mankind and Health: ITI 4th International Conference on Information and Communications Technology

<sup>31</sup> Edwards E., Gartner Research (2007) Electronic Health Records: Essential IT Functions and Supporting Infrastructure, Jan. 2007, [http://www.gartner.com/DisplayDocument?id=499747&ref=g\\_sitelink](http://www.gartner.com/DisplayDocument?id=499747&ref=g_sitelink)

Table 1: Five Levels of Electronic Healthcare Records (EHCR)



Source: adapted from Waegemann (2002) and Blobel B (2003)<sup>32</sup>

The capabilities of an Electronic Health Record System allow for a number of primary and secondary uses:

Table 2: Primary and Secondary Uses of Electronic Health Record Systems

<b>Primary Uses:</b>	<b>Secondary Uses:</b>
<ul style="list-style-type: none"> <li>• Direct Patient Care</li> <li>• Patient Care Management</li> <li>• Patient Care Support Processes</li> <li>• Financial and Other Administrative Processes</li> <li>• Patient Self-Management</li> </ul>	<ul style="list-style-type: none"> <li>• Education</li> <li>• Regulation</li> <li>• Quality Assurance and Surveillance</li> <li>• Research</li> <li>• Public Health</li> <li>• Policy Support</li> </ul>

Source: Adapted from IOM (2003)<sup>33</sup>

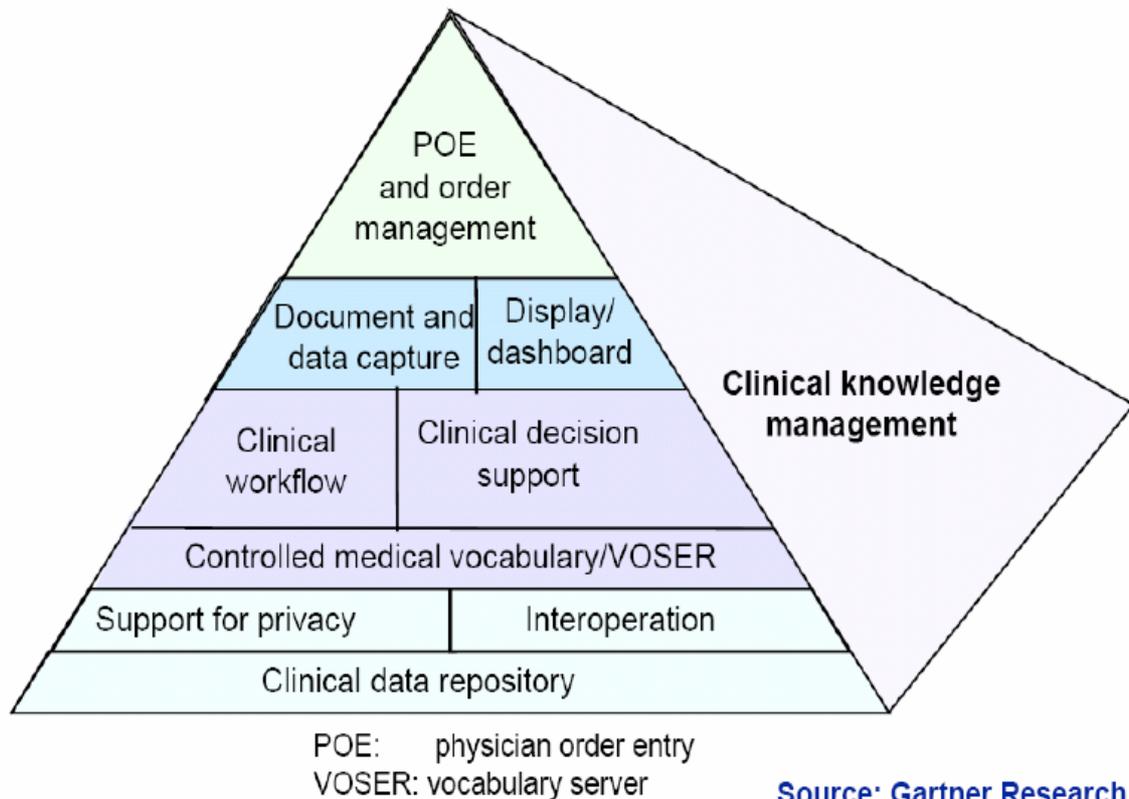
These core capabilities of EHR systems are illustrated by the following figure:<sup>34</sup>

<sup>32</sup> Blobel B (2003) Architecture and Tools for Open, Interoperable and Portable EHRs, in: Nerlich M, Schaechinger U (Eds.) Integration of Health Telematics into Medical Practice, IOS Press.

<sup>33</sup> Institute of Medicine of the National Academies (2003) Key Capabilities of an Electronic Health Record System, The National Academies Press, Washington, DC.

<sup>34</sup> Edwards E., Gartner Research (2007) Electronic Health Records: Essential IT Functions and Supporting Infrastructure, Jan. 2007, [http://www.gartner.com/DisplayDocument?id=499747&ref=g\\_sitelink](http://www.gartner.com/DisplayDocument?id=499747&ref=g_sitelink)

Figure 3: Core Capabilities of EHR



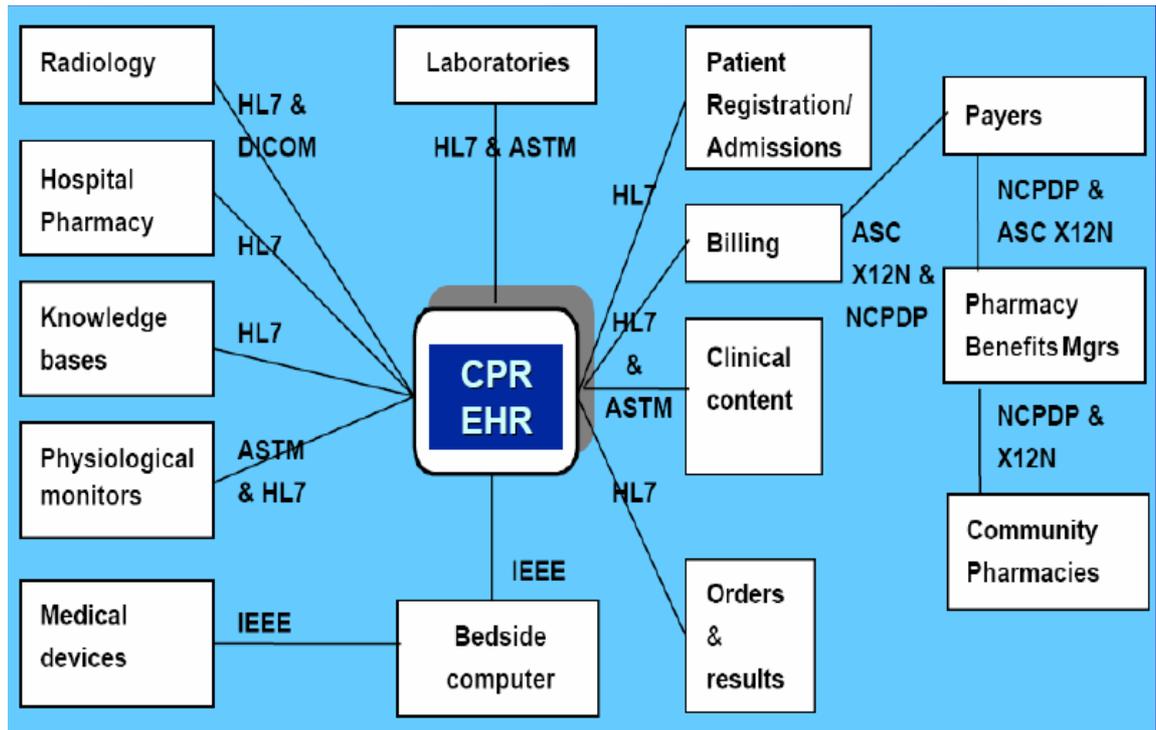
It is expected that over the near to medium-term future, healthcare providers will largely complete their transition to the use of health information systems that include EHR systems - maintained by health service provider organisations such as hospitals and nursing homes - and Personal Health Record (PHR) systems - maintained by individuals. Such health information systems will allow:

1. Longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or healthcare provided to an individual;
2. Immediate electronic access to person- and population-level information by authorised, and only authorised, users;
3. Provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and
4. Support of efficient processes for healthcare delivery.<sup>35</sup>

From a technology perspective, such systems are quite challenging and require a substantial amount of standardisation and interoperability. The following Figure 4 illustrates the complexity and identifies some of the standards already trying to address this challenge.

<sup>35</sup> Institute of Medicine of the National Academies (2003) Key Capabilities of an Electronic Health Record System, The National Academies Press, Washington, DC.

Figure 4: EHR Communication Standards

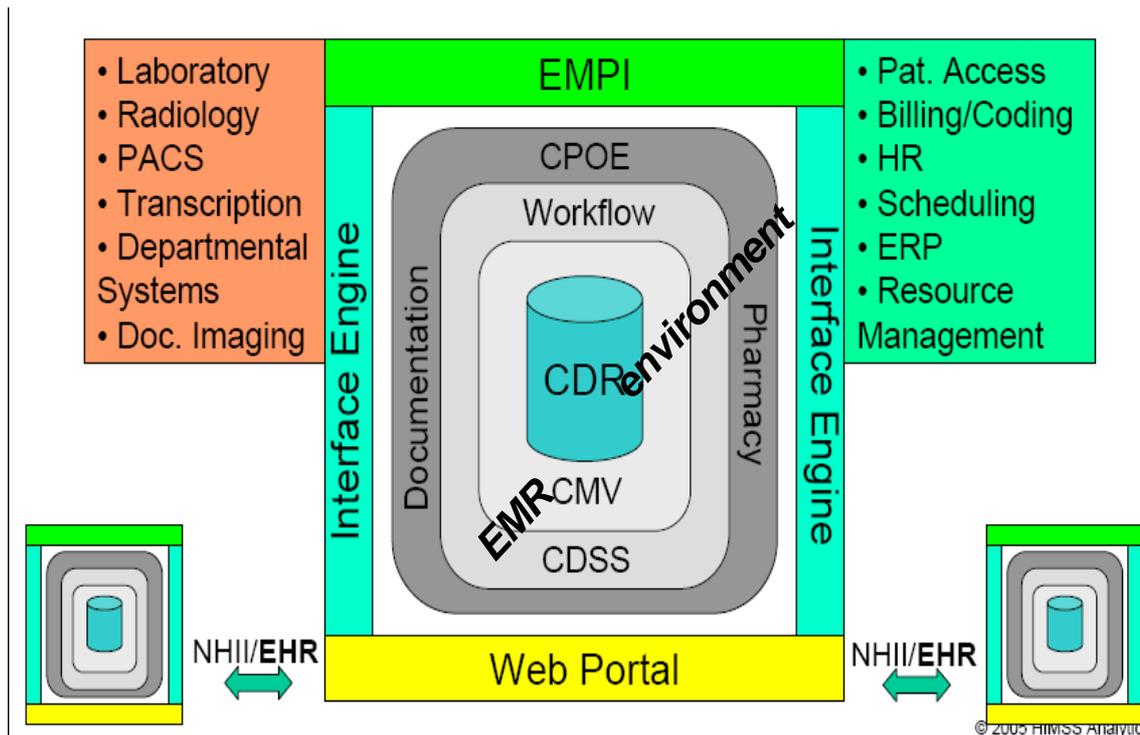


Source: Musoğlu (2005)<sup>36</sup>

An advanced EHR includes a number of support services like CDR - Clinical Data Repository; CDSS - Clinical Decision Support System; CMV - Controlled Medical Vocabulary; CPOE - Computerised Provider Order Entry; EMPI - Enterprise Master Patient Index; ERP - Enterprise Resource Planning; HR - Human Resources; PACS - Picture Archiving and Communications System. This is illustrated in Figure 5 below.

<sup>36</sup> Musoğlu E. (2005) Evolution and future of Electronic Health Records, HIBIT 2005

Figure 5: EMR and EHR Environments



Source: Adapted from D. Garets, HIMSS Analytics (2005)<sup>37</sup>

### 3.2.1.3 Reality check: adoption of EHR

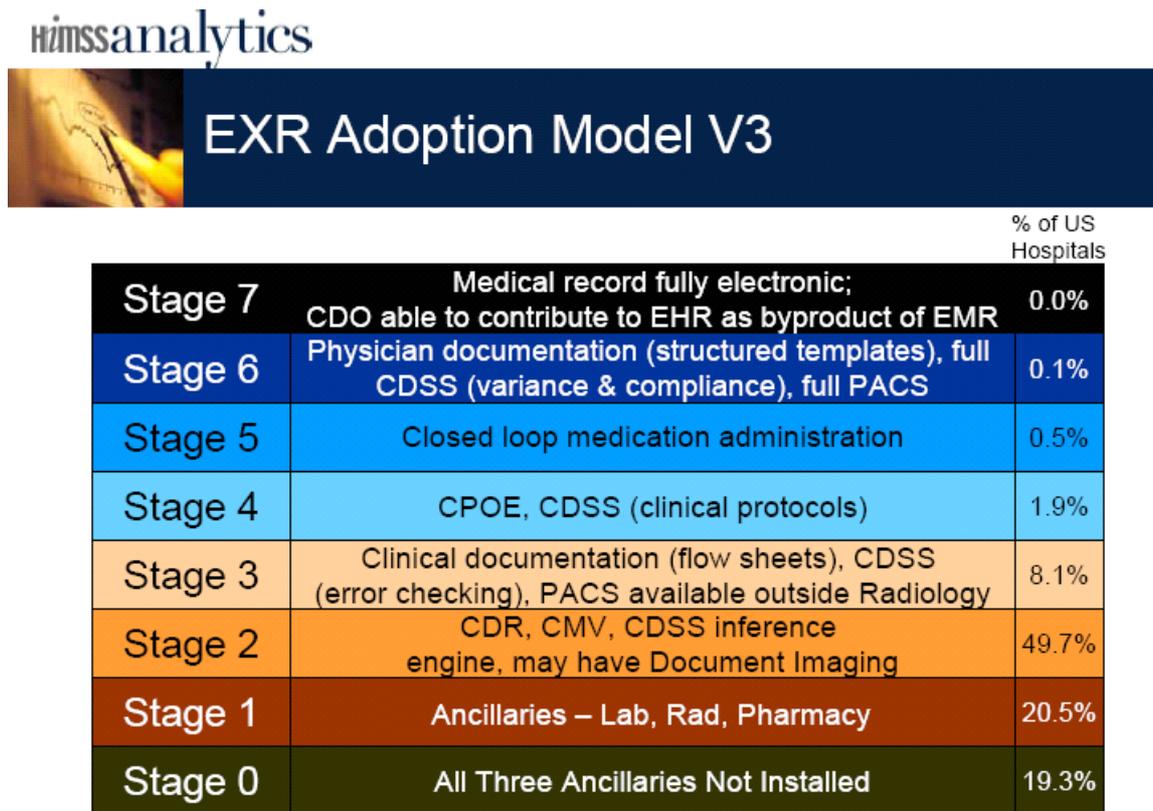
The above discussion very clearly indicates that a clean, simple and easy to operationalise concept of an EHR (system) does not exist. Rather, in reality we will observe many types, stages of development and disparate application fields for EHRs, respectively of implementations on the way towards indeed realising the vision of having “digitally stored healthcare information about an individual’s lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times.”<sup>38</sup> However, the various aspects outlined above strongly support us when identifying and selecting suitable candidates for case studies.

As a reality check, we include here a graph on the adoption of EHR systems and their variants in the USA, which further supports our point made in the preceding paragraph. It is well known - e.g. from some HINE data - that the situation in Europe is very similar to the US experience.

<sup>37</sup> Garets D, Davis M (2005) EMRs and EHRs: Concepts as different as apples and oranges at least deserve separate names, Healthcare Informatics online: McGraw Hill

<sup>38</sup> Iakovidis I. (1998) “Towards Personal Health Record: Current situation, obstacles and trends in implementation of Electronic Healthcare Records in Europe”, International Journal of Medical Informatics vol. 52 no. 128, pp. 105 -117

Figure 6: Adoption of EHR Systems in USA Hospitals



As of 23 Jan 08

© 2008 HIMSS Analy

Source: HIMSS Analytics (2006)<sup>39</sup>

### 3.2.1.4 The concept of PHR

A PHR has been defined as “an electronic, universally available, lifelong resource of health information maintained and owned by an individual.

The personal health record (PHR) is different from an electronic health record (EHR) system maintained by a healthcare provider organisation. The PHR is maintained by the individual patient. These individuals own and manage the information in the PHR, which comes from both multiple healthcare providers and the individuals themselves.”<sup>40</sup> This means, “the PHR is maintained in a secure and private environment, with the individual determining rights of access. The PHR is separate from, and does not replace, the legal record of any provider.”<sup>41</sup>

PHR systems focus on the “patient's time away from the healthcare professional” in providing and collecting clinical information and services such as:

1. Fitness data, as well as data from routine medical checkups recommended for the age group
2. Automatic interpretations and/or suggestions based on the data entered
3. Import data from other health devices
4. Keep track of medical appointments and generate automatic reminders to the consumer

<sup>39</sup> Garets D (2006): The Real Story on Interoperability: Implications for Provider Organizations, presentation

<sup>40</sup> Peter J. Groen, Douglas Goldstein, Jaime Nasuti (2007): Personal Health Record (PHR) Systems: An Evolving Challenge to EHR Systems. <http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html>

<sup>41</sup> The Role of the Personal Health Record in the EHR. Jpurnal of AHIMA 76(7), Juli-August 2005.

[http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_027539.hcsp?dDocName=bok1\\_027539%20\(accessed%20July%2018,%202006\)](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_027539.hcsp?dDocName=bok1_027539%20(accessed%20July%2018,%202006)).

5. Over the counter medication record
6. Help consumers inform themselves and increase their awareness on health and disease
7. Keep consumer-oriented information material and serves as a portal to some published literature on health and disease.

The 'holy grail' of the PHR is the ability to collect and collate data from all points of the healthcare compass - consumers, physicians, hospitals, insurers, labs, pharmacies, and others. This data typically comes in different formats and using different vocabularies, and it must be normalised within a single, common nomenclature. As easy as it sounds and although data and format standardisation is considered of the highest importance among all players in the healthcare arena, the complexity and semantic difficulties make it the most challenging part of the EHR movement. But, "the trend is unmistakably underway" and many standardisation organisations - such as HL7/CEN/ASTM/IHE - will be offering solutions over the next decade.<sup>42</sup>

### 3.2.2 ePrescribing

Like the term EHR (system), ePrescribing (system) is not a well-defined fixed term, but rather covers a wide variety of eHealth solutions all related to drugs and administering of medications.

#### 3.2.2.1 Definitions of ePrescribing

Back in 2004, the eHealth Initiative (EHI) defined electronic prescribing as "the use of computing devices to enter, modify, review, and output or communicate drug prescriptions"<sup>43</sup>. The EHI distinguishes between six levels of ePrescribing, each of which includes expands on the functionalities of the previous one. The levels are shown in Figure 7 below. EHI argues that the highest benefits are associated with improvements in the communication between patients, prescribers, pharmacists, and all other potential and actual stakeholders involved in the drug management process. These communication improvements are in tern only delivered by ePrescribing systems of the higher levels. Nonetheless, some benefits, identified as "quality improvement, reduction in errors, and improved workflow efficiency"<sup>44</sup>, can be observed at lower level ePrescribing systems as well.

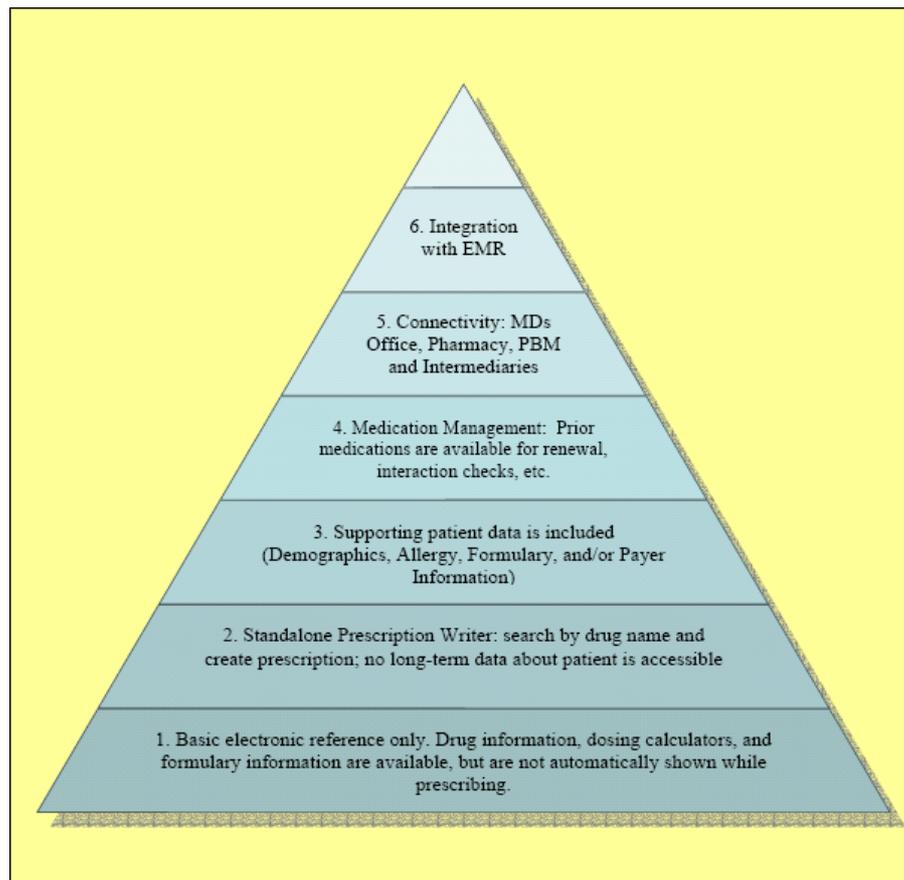
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<sup>42</sup> Cf. Krohn R (2007) The consumer-centric personal health record - it's time, *Journal of Healthcare Information Management*, Vol.21 (1):20-3. - Ball M, Gold J (2006) Banking on Health: Personal Records and Information Exchange, *Journal of Healthcare Information Management*, Vol.20 (2):71-83.

<sup>43</sup> eHealth Initiative (2004), *Electronic Prescribing: Toward Maximum Value and Rapid Adoption: Recommendations for Optimal Design and Implementation to Improve Care, Increase Efficiency and Reduce Costs in Ambulatory Care*, Washington, D.C. April 14, 2004

<sup>44</sup> *ibid.*

Figure 7: Graduated Levels of Electronic Prescribing



Source: eHealth Initiative (2004)<sup>45</sup>

The distinct feature of the EHI definition is the focus on medications. The definition explicitly states that ePrescribing is about drug prescriptions. In the UK, Connecting for Health (CfH) defines ePrescribing also with focus on medications only, but includes more than the prescribing process alone: “We [CfH] define ePrescribing as “the utilisation of electronic systems to facilitate and enhance the communication of a prescription, aiding the choice, administration or supply of a medicine through decision support and providing a robust audit trail for the entire medicines use process”.<sup>46</sup> ePrescribing systems should provide:

- “Computerised entry and management of prescriptions
- Knowledge support, with immediate access to medicines information
- Decision support, aiding the choice of medicines and other therapies, with alerts such as drug interactions
- Support during administration
- Computerised links between hospital wards/departments and pharmacies
- Ultimately, links to other elements of patients' individual care records
- Improvements in existing work processes
- A robust audit trail for the entire medicines use process”<sup>47</sup>

<sup>45</sup> eHealth Initiative (2004), Electronic Prescribing: Toward Maximum Value and Rapid Adoption: Recommendations for Optimal Design and Implementation to Improve Care, Increase Efficiency and Reduce Costs in Ambulatory Care, Washington, D.C. April 14, 2004

<sup>46</sup> <http://www.connectingforhealth.nhs.uk/systemsandservices/eprescribing/> last accessed: 16.04.2008

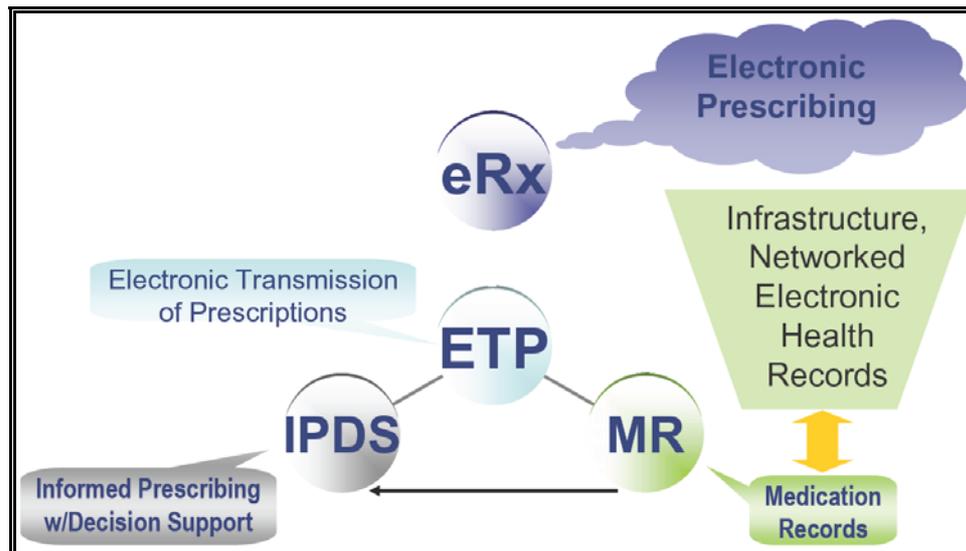
<sup>47</sup> <http://www.connectingforhealth.nhs.uk/systemsandservices/eprescribing/> last accessed: 16.04.2008

In specifying the functional specification of ePrescribing systems, CfH slightly contradicts its own definition, as “aiding the choice of medicines *and other therapies*” is required from vendors, which moves the concept away from the strict focus on medications.

A common feature of the definitions quoted above is that in the most advanced stages, ePrescribing is seen as part of a wider system of EHRs.

The i2-Health project<sup>48</sup> described three main components of the ePrescribing process (“eRx”): Informed Prescribing with Decision Support (IPDS), Electronic Transmission of Prescriptions (ETP), and Medication Records (MR). They are illustrated in figure below.

Figure 8: ePrescribing and Medication Management



Source: i2-Health/EHTEL/empirica (2007)

### 3.2.2.2 ePrescribing and CPOE

According to one definition of ePrescribing, it is “the process of prescribing medications using an outpatient computerised physician order entry (CPOE) system that electronically exchanges prescriptions directly with the pharmacy and/or pharmacy benefits manager (PBM)”.<sup>49</sup> CfH sees this differently and makes explicit that CPOE “is only one part of the overall medicines use process. For instance, for ePrescribing to add most value it needs to incorporate computerised guidance for healthcare professionals in the form of decision and knowledge support.”<sup>50</sup> This is consistent with the i2Health considerations.

On the other hand, the concept of CPOE can be seen as not limiting, but extending the concept of ePrescribing, as it includes all treatments and not just medication prescriptions. CPOE has been defined as a process whereby the instructions of physicians regarding the treatment of patients under their care are entered electronically and communicated directly to responsible individuals or services. In the past, such orders were hand-written or verbally communicated, which led to medical errors.<sup>51</sup> Clinical decision support systems (see above) are built into almost all CPOE systems to varying degrees, providing basic computerised advice regarding drug doses, routes and frequencies, as well as more sophisticated information like drug allergy, drug-laboratory values, drug-drug interactions,

<sup>48</sup> [www.i2-health.org](http://www.i2-health.org)

<sup>49</sup> Virk, Pushwaz et al. (2006): Analyzing Transaction Workflows in an ePrescribing System: in AMIA 2006 Symposium Proceedings Page - 1129; PMID: PMC1839364; <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1839364>

<sup>50</sup> <http://www.connectingforhealth.nhs.uk/systemsandservices/eprescribing/> last accessed: 16.04.2008

<sup>51</sup> For this definition see <http://en.wikipedia.org/wiki/CPOE>. Compare also FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach and Bonnabry Pascal (2003) Information Technologies for the Prevention of Medication Errors. Business Briefing: European Pharmacotherapy 2003 1-5.

checks and guidelines.<sup>52</sup> CPOE are applied in a variety of physical and technical environments using currently available vendor software, but CPOE is also very resource-intensive, time consuming, and expensive.<sup>53</sup>

In many instances, CPOE systems will be implemented as part of a larger hospital or clinical information system (HIS or CIS) and thus “interoperable” with the medical record and other patient information.

Proponents of CPOE systems argue that they have led to reductions in transcription errors, which in turn have led to demonstrable improvements in patient safety. Furthermore, CPOE systems that include - or are connected with - data on patient diagnoses, current medications, and history of drug interactions or allergies can significantly reduce prescribing errors.<sup>54</sup> CPOE systems also improve the quality of care by increasing clinician compliance with standard guidelines of care, thereby reducing variations in care.

Some of the beneficial impacts claimed for such systems have been outlined by Overhage<sup>55</sup> as follows:

- Improvement of clinical processes, which decrease lost orders, transcription time, and cost
- Reduction of ambiguity secondary to illegible handwriting and incompleteness of written orders
- Support of cost-effective decision making, improving formulary compliance; cost-effective medication ordering; appropriateness of medication administration, route, dosage, duration, and interval
- Decrease in test redundancy; and improvement in consequent, contingent, and corollary orders.

To use a concrete case for illustration, at Wirral Hospital NHS Trust (UK) the introduction of structured, ICT-supported medication handling pathways drastically reduced errors in the prescription of specific high risk drugs. For instance, an error rate of 82% in the prescription of low molecular weight heparin (identified by an audit) was eliminated. Similarly, in paediatrics, structured pathways led to reductions of specific error rates from 26% to just 4% for paediatricians and from 76% to less than 7% for non-paediatric specialists. Furthermore, the introduction of an automated dispensing system reduced the risk of medication errors while electronic prescription improved the legibility and completeness of prescriptions. Moreover, the use of ICT applications supporting work processes freed staff for clinical activities at the bed-side.

However, many physicians express concern that CPOE based ordering takes longer than paper based ordering. Features of CPOE that can reduce the time burden to physicians include the use of predefined collections of orders for complex conditions (for example, initial management of the patient after bypass graft surgery), access to CPOE from locations other than the hospital or office, adequate training, easy access to patient and reference data, and progressive familiarity with the application.

<sup>52</sup> Bonnabry Pascal (2003) Information Technologies for the Prevention of Medication Errors. Business Briefing: European Pharmacotherapy 2003 1-5.

<sup>53</sup> It is estimated that five percent of hospitals now have CPOE, but the implementation is costly; see FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach.

<sup>54</sup> Bates, D.W., L.L. Leape, D.J. Cullen, N. Laird, L.A. Petersen, J.M. Teich, E. Burdick, M. Hickey, S. Kleefield, B. Shea, M. Vander Vliet, and D.L. Seger (1998) Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *Journal of the American Medical Association* 280(15): 1311-1316. Bates, D.W., J.M. Teich, J. Lee, D. Seger, G.J. Kuperman, N. Ma'Luf, D. Boyle, and L. Leape. 1999. The impact of computerized physician order entry on medication error prevention. *Journal of the American Medical Informatics Association* 6(4): 313-321. Leapfrog Group. 2000. Leapfrog Patient Safety Standards: The Potential Benefit of Universal Adoption. Available online at: <http://www.leapfroggroup.org>.

<sup>55</sup> Overhage et. al (2002) Does National Regulatory Mandate of Provider Order Entry Portend Greater Benefit Than Risk for Health Care Delivery? The 2001 ACMI debate. *Journal of the American Medical Informatics Association* Volume 9 Number 3 May / Jun 2002. 201.

Generally, economic return on investment for a CPOE project may be difficult to calculate because baseline costs of key processes are hard to determine; several benefits are not easily amenable to measurement (for example, improved interdepartmental communication and strategic positioning); and many organisations do not currently measure rates of medication errors and adverse drug events. CPOE should be viewed as supportive technology for such organisational initiatives as quality improvement, patient safety, and cost containment. In addition, it is important that CPOE be considered part of an organisational strategy to achieve the previously mentioned objectives, rather than as an information technology initiative.

Indeed, some authors have drawn attention to the potential danger of CPOE use. Studies in the US, UK, and Australia have found that “commercial prescribing systems often fail to uniformly detect significant drug interactions, probably because of errors in their knowledge base. Electronic medication management systems may generate new types of error because of user-interface design, but also because of events in the workplace, such as distraction affecting the actions of system users.”<sup>56</sup> Han et al. (2005) found an unexpected increase in child mortality after the introduction of a commercially sold computerised physician order entry system.<sup>57</sup>

CPOE should be viewed as supportive technology for such organisational initiatives as quality improvement, patient safety, and cost containment. More research is needed to create and evaluate models of CPOE implementation and to understand the specific challenges that exist for institutions of different sizes and different staffing models.

### 3.2.2.3 ePrescribing in the EHR IMPACT study

Given the above considerations, the EHR IMPACT study is taking a broad perspective regarding the definition of ePrescribing. We prefer to take a longer-term perspective in which ePrescribing is part of a wider health information management system, potentially based on of EHRs. Thus, ePrescribing should include prescribing of any treatment including medications, and also the follow up of the process to the furthest possible point. The three features stressed by the i2-Health definition - decision support, transmission, and record - should be identifiable in any ePrescribing case study analysed by the EHR IMPACT study. CPOE systems consistent with that approach can be regarded as good cases for analysing the impact of interoperable ePrescribing systems.

## 3.2.3 The concept of interoperability

### 3.2.3.1 Complexity of health value system actors and their communication channels

A key aspect of the study and its socio-economic assessment exercise is to analyse the - hopefully beneficial - impact of interoperability. This adds a very demanding, new dimension of complexity to the analysis, as the following considerations illustrate.

When discussing eHealth and interoperability, one has to consider some of the specificities of healthcare in Europe. The European health services sector is a very heterogeneous and complex one, covering diverse actors and types of “businesses” catering to a similarly varied and complex set of “customers”. It is characterised by a wide spectrum of disparate national healthcare systems, varying and shifting public-private mixes of healthcare delivery and financing, a size structure that is dominated by micro establishments in most Member States,

<sup>56</sup> FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach.

<sup>57</sup> Han, Yong et al. (2005): Unexpected increased mortality after implementation of a commercially sold computerized Physician order entry system in: Paediatrics Vol116 No.6 (12/2005) 1506-1512.

and a great number of heterogeneous communication relationships with a complex set of partners and players. Furthermore, the typical healthcare provider caters to a very particular type of client, the majority of whom are either very young or elderly, often disabled and chronically ill patients.

Additionally, the public-private mix, third-party payments by insurance funds or local and federal governments (from the tax base) as the rule, or the asymmetric information available to the various players (patients with often little knowledge; healthcare professionals as the gatekeepers to knowledge; insurance funds that have to pay for what is deemed “appropriate” care by others) render it a rather specific field of ICT application. Furthermore, within hospitals, individual departments typically remain poorly coordinated due to both organisational behaviour of key players and missing interoperability among the manifold systems installed.

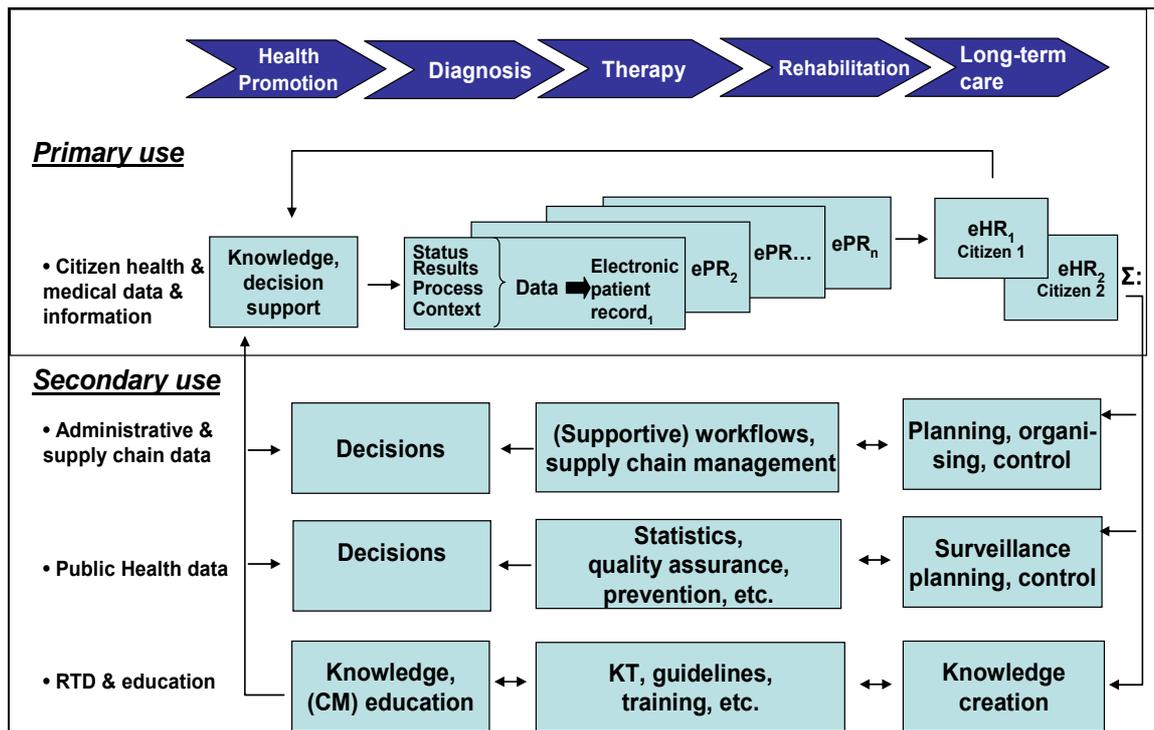
Moreover, inside most European health organisations there is still a lack of real-time recording and access to patient data and often care is poorly coordinated across various actors. These conditions have been identified as a major contributor to medical errors. The intense complexity of the field becomes obvious when one adds health policies and legal and regulatory interventions, as well as privacy and confidentiality issues. This illustrates why it will be rather difficult to find indeed an “ideal” case that allows to demonstrate the full benefits expected from interoperability. Rather, it will only be possible to identify running applications which facilitate at least some exchange of data and information among some of the many players in the healthcare field.

Figure 8 below illustrates some of the key conceptual interoperability issues we have to deal with in this context, and the great potential of interoperability to support the benefits from eHealth. Interoperability is critical not only seamless communications among the directly involved healthcare professionals, but also to exploiting the synergies between clinical data needed for treatment, and such used for management purposes, public health, or clinical research.

The core medical services - depicted at the top of the figure - are those where the medical value added is created and which may - in various steps - be analysed by applying a value chain concept. Depending on the objectives of the analysis, the details to be considered and the institutional context and set-up of the respective health system, a specific value chain may look quite different, but our generic model should be able to cover most, if not all instances one may want to consider.

At the information or knowledge support level, there exists a continuum from still using paper and pencil (and the telephone, already a means of “tele”-medicine in use for more than one hundred years) to applying the most advanced ICT systems to deliver healthcare in a totally new manner - combining process and product innovations to render a new quality of health services.

Figure 9: The Core Medical Value Chain and ICT Based Knowledge Support



Source: © empirica (2006)

### 3.2.3.2 Defining Interoperability

In order to realise the benefits from the increased availability of information and communication, and in particular the possibility of sharing information across all the many organisations and actors as mentioned above, the interoperability (IOp) of systems and teams is crucial. Technical interoperability will ensure that spatial boundaries are eliminated. However, this will not be enough for realising the benefits from the enormous supply of information - syntactic and semantic interoperability are required to make the information usable for all collaborating in delivering healthcare, and the legal-political framework must be such that this can indeed be implemented.

Based on a broad and holistic approach developed by the EU i2-Health project<sup>58</sup> (Interoperability Initiative for a European eHealth Area), this study will apply the following IOp definition:

True European health system interoperability is the ability

- to exchange, understand and act on patient and other health information and knowledge
- among linguistically and culturally disparate clinicians, patients and other actors
- within and across jurisdictions
- in a collaborative manner.<sup>59</sup>

There is growing realisation that interoperability is about continuous change management, implying that successfully establishing and maintaining eHealth interoperability is a long-term endeavour requiring both a permanent structure of institutions or bodies charged with this responsibility, and the organisation of processes for consensus-building and cooperation

<sup>58</sup> [www.i2-health.org](http://www.i2-health.org)

<sup>59</sup> The discussion in this section is based on the work undertaken by the eTEN project "Interoperability Initiative for a European eHealth Area (i2-Health)"; cf. [www.i2-health.org](http://www.i2-health.org)

among all stakeholders involved. Experience also shows that realising interoperability satisfactorily requires focusing on a concrete application context, which requires much more than implementing specific standards. It usually involves, in addition, detailed specifications, agreement among users and industry on use cases and results to be achieved, testing and certification, legal and regulatory compliance.

Realising eHealth interoperability across the whole healthcare domain requires policy and implementation actions at four generic levels - the (1) health policy, (2) organisation/healthcare provider, (3) semantic, and (4) technical & functional levels:

Table 3: Four eHealth Interoperability Levels and Related Issues

<b>Health policy:</b> <b><u>cooperation</u></b>	<ul style="list-style-type: none"> <li>• Vision &amp; strategies</li> <li>• Processes &amp; measures, incentives</li> <li>• Socio-economic (sustainable), legal framework</li> <li>• Accreditation and certification</li> </ul>
<b>Health service providers (Organisational level):</b> <b><u>collaboration</u></b>	<ul style="list-style-type: none"> <li>• Organisational structures and culture</li> <li>• Intra &amp; inter-jurisdictional service processes</li> <li>• Change management, behavioural change</li> <li>• Systems thinking, business process re-engineering</li> </ul>
<b>Semantic</b> <b><u>interoperation</u></b>	<ul style="list-style-type: none"> <li>• Terminologies, classifications</li> <li>• Translation</li> <li>• Data</li> <li>• Structures</li> </ul>
<b>Technical / functional</b> <b><u>interoperation</u></b>	<ul style="list-style-type: none"> <li>• Technical standards</li> <li>• Hardware and software connectivity</li> <li>• Security</li> <li>• User interfaces</li> </ul>

Source: © empirica / i2-Health / SemanticHEALTH (2006)

### 3.2.4 Operationalising the concept of interoperable EHR and ePrescribing

To translate the above discussed concepts and definitions into operational use for the study, we have defined - in a rather pragmatic fashion - the following EHR and ePrescribing interoperability levels:

- 1) Availability/access to stand alone solutions: having EHR and/or ePrescribing solutions
- 2) Potential for interoperability: use of standards and set up allowing information to be shared, but no actual exchange taking place
- 3) Real inter-operation: using the interoperability features - exchange and share information and knowledge with other actors in the system for the purposes of collaboration, thus changing working practices and roles, multi-disciplinary teams, etc.
  - a. Local connectivity
    - i. people *within* teams (wards, departments on one site)
      - doctors
      - other health professionals
      - involving management and administrative actors
      - informal carers
      - citizens/patients

- ii. people *between* teams (wards, departments on one site)
- b. **Multi-site connectivity:** within a multi-site organisation entity
- c. **Regional connectivity:** between organisation entities within a region
- d. **National connectivity:** between organisation entities within a country
- e. **Multi-national connectivity:** cross border and cross Member State

A further level of complexity concerns the dimension of whether also non-clinical actors like from public health or RTD are connected.

Benefits from interoperable EHR and ePrescribing systems will only emerge if the systems have reached the third level - inter-operation. Critics may stress that we have defined the third level of interoperability quite broadly. This, however, is explained by the need on the one hand to operationalise the concept in a way not restricting the study too much, and on the other hand focus on the critical issue. The main point of distinguishing between the three levels is to stress that benefits are related only actual information sharing and exchange, not the mere possibility to do so. The sub-categories of the third level allow a more precise categorisation during the evaluation stage of the study (see Chapter 6), useful for defining the transferability of lessons learnt to initiatives other than the case studies analysed.

## 4 Measuring the socio-economic impact of interoperable EHR and ePrescribing systems

Assessment of qualitative and quantitative impacts of eHealth solutions, including the use of ICT itself, and the provision of health services supported by ICT, is a complex issue. It requires an in-depth understanding of each individual case as well as of the framework conditions of the service imposed by the health system it operates in. Only with these factors in mind can benefits of an application be realistically assessed. The sustainability of an innovative eHealth solution for example, strongly depends on the health system's openness to innovation and available funding. Interoperable EHR and ePrescribing systems of the visionary kind described in Chapter 3 must be innovative and complex, and thus are subject to these challenges.

Deliverable D1.3 of this study, Methodology for evaluating the socio-economic impact of interoperable EHR and ePrescribing systems, will deal with the details and practicalities of the assessment methodology of EHR IMPACT. In this section, we briefly discuss the conceptual issues related to evaluating the socio-economic impact of eHealth in general, and the issues particularly relevant in the context of the EHR IMPACT study. The impact assessment needs to integrate several issues: identifying challenges and needs for change, assessing the role of ICT in the changes occurring, measuring the effect of changes in a comparable way, and enabling a generalisation of the results across time and space.

### 4.1 General approach towards an evaluation methodology

#### 4.1.1 General concepts

For a comprehensive socio-economic analysis, data to measure the benefits and costs for each specific stakeholder are needed. Monetary values have to be assigned for the economic performance to be evaluated. This enables, in the aggregate, potential common patterns, trends and relationships to be identified. The method that supports the linking of these data is cost benefit analysis (CBA). CBA allows different outcomes to be evaluated through common measures, and it can reflect a different allocation of resources before and after an eHealth investment. A key merit of CBA is that it allows for comparative, as well as single-option evaluation over time.

CBA is often described as an economic tool. It should, however, be seen as aiming to assign monetary values to seek to estimate the net benefit over time arising from the costs and benefits of an investment of resources. In this context, the costs and benefits identified reveal all the stakeholders and actors who can be affected by the investment of resources. These stakeholders range from individual people, to the organisations and institutions of a particular society.

Monetary values assigned to costs and benefits should be based on market prices whenever they are available, because prices tend to reflect the best alternative use of the resources available. Some costs and benefits are social, environmental, organisational or cultural, and have no obvious market price to reflect their values. When dealing with these types of impact, 'benefits' should be understood as changes towards a more desired situation, and

'costs' should include items like reduced comfort or extra effort associated with the introduction of eHealth solutions.

An important principle of a sound evaluation methodology suitable to cope with the diversity and complexity of interoperable EHR and ePrescribing systems is that the methodology can be adapted to the healthcare and eHealth setting at each case study site. The data from each site should not need to be adapted to the evaluation model.

Another central feature of the methodology suited to the need of the EHR IMPACT study is that the conclusions from the impact assessments should be used at a relatively high level to inform strategic decisions. The methodology should provide a robust estimate of economic performance over time, and not an incisive tool that produces precise, undisputable numbers. The focus of the methodology is to show whether a particular investment in interoperable EHR and ePrescribing systems can be expected to have a positive or a negative overall impact, measured mainly in net benefits, rather than on the exact aggregated value of the achieved benefits. The same principles apply to the other measures: for example, a 70% share of benefits to citizens should be interpreted as a considerable majority of all benefits, rather than exactly 70%.

### 4.1.2 Questions to ask

Identifying the key impacts of a particular clinical ePrescribing or EHR system, in essence involves a thorough understanding of the current and emerging difficulties related to the old clinical and working practices, as well as the healthcare system in which the new implementation is embedded. The points of impact are usually triggered by a switch to a new model of internal process organisation or even service provision.

ICT can facilitate, enable, enforce, steer, or hinder processes and working practices. For example, care work can be shifted "out of work" so that patients or informal carers become more responsible for tasks that were previously handled by paid employees. This is one side of the impact - the effect of using ICT. The other side is the cost of using ICT. This includes investments in hardware and software, but also procurement, project management, change management, patient information and training.

At the root of rigorous impact assessment lays answering four separate questions:

- What is changing? Is it organisational processes; the care system; patient's involvement?
- How it is changing? Is the impact positive or negative?
- Why it is changing?
- When it is changing? Do acceptance or resistance, potentially triggered by cultural specificities, affect the pace of change?

## 4.2 Appropriate techniques for measuring impact

### 4.2.1 Quantification of impact and assuring comparability

In order to ensure comparability between different impact measurers, they should be quantified into a unified unit system. A pragmatic way of doing this is by assigning monetary values to the identified impacts, both positive as well as negative. Positive impacts of any nature can then be added together under "benefits", whereas negative impacts are aggregated into "costs". It is important to stress that the resulting quantitative measures,

although presented in Euros, do not reflect financial flows or only the economic aspects of impact. They are merely a comparable representation, i.e. an index, of the impact, including economic as well as social, cultural, and organisational aspects. They are not a profit and loss, rate of return, return on investment, balance sheet, or other accounting calculation.

This rationale is explained based on the examples of economic, social, organisational, and cultural aspects of impact and how they can be quantified by assigning monetary values to them.

### Economic aspects

Economic impacts include the monetary expression of costs and benefits over time. Costs are often much easier measured than benefits. However, also for benefits a variety of tools are available for meaningful estimations. Examples are proxy prices, willingness to pay studies or time savings converted into monetary equivalents based on income. Data for modelling these impacts have to be integrated with the analysis of the social aspects. Indeed, some classify benefits for citizens or the system as social rather than economic impacts.

### Social aspects

Social aspects include universal availability of full healthcare services to all citizens, equal access to healthcare, and equal high quality of services rendered. A policy of universal access and quality can have two main sub-aspects. One is a policy of social inclusion; it ensures that there is equity of access to healthcare for all types of citizens, regardless of gender, ethnic background, or ability to pay. The other is geographic inclusion, which ensures equity of access to healthcare wherever citizens live. There can be some overlap between these two social factors, but also some important differences. Social inclusion can depend on the resources or pro-activeness of groups and may require healthcare to be more responsive to the needs of particularly disadvantaged or vulnerable groups. Geographic inclusion can involve responding to, and counterbalancing, the remoteness of communities from main healthcare centres. In this context, the impact of networked EHR and ePrescribing systems may be more attainable and less challenging in terms of offering geographic inclusion than improving social inclusion.

An important aspect is the impact on patients' families and carers, especially for patients with chronic conditions. The beneficial impact of ICT can be measured in terms of willingness to pay<sup>60</sup> for support in dealing with, for example, a specific chronic condition. Willingness to pay is also appropriate as a proxy for factors such as the wellness and comfort of citizens who are not experiencing any health-related problems at that moment.<sup>61</sup>

The social aspect of the impact should be traced in two ways: 1) by qualitative description of the changes resulting from the assessment of the solution 2) by quantifying these impacts and assigning monetary values to them, in order to allow for comparability in size of impact.

### Organisational aspects

Organisational aspects of the impact analysis deal with the question of how interactions are aggregated in the pursuit of a goal. How are responsibilities and power assigned and controlled? How are conflicts resolved? This can be observed at the level of healthcare provider organisations (HPOs), such as changes in power relationships and hierarchy; at the regional level, on relationships and interactions among HPOs and/or HPOs and patients; and also at the health system level, like transnationalisation of healthcare services. Understood in terms of workflows and work practices, the analysis of organisational aspects cannot be

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<sup>60</sup> Ryan M, Scott DA, Donaldson C (2003) Valuing health care using willingness to pay: a comparison of the payment card and dichotomous choice methods, *Journal of Health Economics* 23(2): 237-258.

<sup>61</sup> Donaldson C, Shackley C (2003) Willingness to Pay for Healthcare, chapter 3 in *Advances in Health Economics* edited by Dr Anthony Scott, Professor Alan Maynard, Professor Robert Elliott, Wiley & Sons Ltd.

separated from cultural aspects. Organisational culture, or “the way we do things here”, is a recurrent theme in the management literature when it comes to explaining performance gaps between the US and Japan in spite of American attempts to copy Japanese management techniques.

The main organisational themes related to EHR and ePrescribing systems comprise the impact on leadership, change management, eHealth investment models, organisational structures, mainstreaming eHealth, work processes and, most importantly, clinical practices. Each of these can be an important theme individually. When they are combined in a healthcare setting, they can become the most challenging aspects of making ICT-enabled healthcare perform better than the traditional form of healthcare delivery.

These themes will be addressed in the impact analyses by focusing in particular on organisational changes facilitated by interoperable EHR and ePrescribing systems, as well as those necessitated by them. From the experience gained so far, these changes concern particularly the changes in workflows and related efficiency savings. Monetising the impact will have the aim of enabling the comparability and aggregation of impacts, rather than focusing on financial issues.<sup>62</sup> Despite the monetary expression, organisational aspects usually do not translate into financial flows<sup>63</sup>.

## Cultural aspects

Cultural aspects, on the most general level, are those elements which give meaning to human activity. They therefore permeate every aspect of citizens’ lives. In the domain of healthcare, cultural aspects concern first of all the great diversity of attitudes, behaviour, and knowledge exchange among professional and non-professional staff involved in healthcare, and the impact this has on the quality, efficiency, and processes of services. They also concern the role health and healthcare play in society. Is health an economic commodity that can be bought/invested in, or is it a largely random personal endowment? To what extent are people the makers of their own health?<sup>64</sup> Cultural aspects affect the size and scope of impact and penetration of eHealth in traditional healthcare. They are reflected and measured in observed (or estimated) rates and frequencies of utilising ICT-enabled solutions and processes. Education and training, professional standards and bodies, rules and regulations, attitudes and behaviour all have an influence here and are at the same time influenced to some extent by the introduction of new technologies and organisational models. Cultural aspects enter the analyses mainly as a potential facilitator, or powerful barrier<sup>65</sup>, depending on the regional specificities and the concrete changes required to realise the benefits involved. Accordingly, the change management costs associated with training, education, professional development, and so on will differ<sup>66</sup>.

<sup>62</sup> For example, the time saved by a nurse on handling paper records can be expressed as a fraction of the salary that has been saved.

<sup>63</sup> Early studies of changes in work organisation in national health services started, for example, in the UK in the mid-1980s. Examples include Coombs, R. and K. Green ‘Work organization and product change in the service sector: the case of the UK National Health Service’. In *The Transformation of Work? Skill, flexibility and the labour process*, edited by S. Wood. (1989) London: Unwin Hyman, pp279-294; Coombs, R., D. Knights, and H.C. Willmott (1990) *Culture, control and competition: Towards a Conceptual transformation of the Sociology of Information Technology in Organizations*. *Organization studies*. 13 (1), pp 51-72.

<sup>64</sup> Leichter HM (2003) *Evil Habits and Personal Choices: Assigning Responsibility for Health in the 20<sup>th</sup> Century*, *The Milbank Quarterly* 81(4):603-626.

<sup>65</sup> Coiera E (1999) *The impact of culture on technology: How do we create a clinical culture of innovation?* *Medical Journal of Australia* 171:508-9. Also: Narine L and Persaud DD (2003) *Gaining and maintaining commitment to large-scale change in healthcare organizations*, *Health Services Management Research* 16:179-187.

<sup>66</sup> Although not from the eHealth domain directly, the following article provides useful illustrations of the consequences of IT induced change in organisations. Lynne Markus, M (2004) *Technochange management: using IT to drive organizational change*, *Journal of Information Technology* 19(1):4-20. The costs of change in a general internal medicine practice introducing an Electronic Health Record is described in Baron RJ et al. (2005) *Electronic Health Records: Just around the Corner? Or over the Cliff?*, *Annals of Internal Medicine* 143(3):222-226.

## 4.2.2 Constraints in measuring the socio-cultural impact of ICT in healthcare

These complexities associated with technological change at both the individual and the organisational level make it clear that assessments of cultural and social impact have to be treated with caution. Attitudes towards new technology can be discerned through personal interviews, but even at the level of a single healthcare organisation, survey results from the entire staff would only provide a very approximate picture of the eventual impact of a technological innovation. A review of culture assessment tools by Scott et al. found that a complex, multi-dimensional quantitative measurement of organisational culture in healthcare relies mainly on interviews, surveys and direct observation.<sup>67</sup> To complicate matters further, the initial objectives, values and expectations attached to the introduction of a particular technology might very well change throughout the process of implementing that technology. It is beyond the scope of the EHR IMPACT study to go into such resource-intensive measurements, yet some estimates on the basis of interviews with case site owners are possible. Among the difficulties faced by researchers using these methods is to get “beyond the public faces” to discover the “private face” of those representing a healthcare organisation.<sup>68</sup>

A wealth of literature exists on the role conceptions of doctors and nurses<sup>69</sup>, the role of organisational culture as a facilitator or barrier to change<sup>70</sup>, and the doctor-patient relationship, which some observers see as endangered by the depersonalisation facilitated by eHealth.<sup>71</sup> It is also generally known that technology is subject to social interpretation and even political instrumentalisation.<sup>72</sup> It is inevitable that the impact analysis of cultural, social, and organisational consequences of eHealth has to start with qualitative assumptions. However, quantitative indicators of socio-cultural impact can, and should, support the qualitative analysis and be fed into the overall socio-economic assessment framework.

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<sup>67</sup> Scott T, Mannion R, Davies H and Marshall M (2003) The quantitative measurement of organizational culture in healthcare: a review of the available instruments, *Health Services Research* 38(3):923-945.

<sup>68</sup> Scott T, Mannion R, Davies H and Marshall M (2003) The quantitative measurement of organizational culture in healthcare: a review of the available instruments, *Health Services Research* 38(3):923-945.

<sup>69</sup> See for example: Krogstad et al. (2004) Doctor and nurse perception of inter-professional co-operation in hospitals *Int. J. Qual. Health Care* 16(6): 491 - 497.

<sup>70</sup> See for example: Lawton R, Parker D (2002) Barriers to incident reporting in a healthcare system, *Qual Saf Health Care* 11:15-18 and Davies et al. (2000) Organisational culture and quality of health care, *Quality in Healthcare* 9: 111-19.

<sup>71</sup> Anderson JG et al. (2003) The Impact of Cyber Healthcare on the Physician-Patient Relationship, *Journal of Medical Systems* 27(1): 67-84.

<sup>72</sup> Lehoux P, Blume S (2000) Technology Assessment and the Sociopolitics of Health Technology, *Journal of Health Politics, Policy and Law* 25(6):1083-1120.

## 5 Good practice case studies

### 5.1 Defining good practice cases

What is indeed a good practice will always depend on the national, cultural, and structural context, i.e. what might be judged by some as good or best in one context may not be applicable at all in another context or “not work” for other reasons like legal requirements or expectations and attitudes of citizens. Examples of ‘good practice’ can provide useful learning experiences for others, are likely to stimulate creativity, self-reflection and the transfer of good ideas. They can usually be thoughtfully transferred, respectively adapted, from situation to situation. Thus, for the purposes of the study, we define the good practice cases of interoperable EHR and ePrescribing systems as follows:

“A good practice case is a proven real life implementation of an EHR or ePrescribing system that enables beneficial re-organisation of clinical and other workflows, interactions, and processes, especially by interoperable data exchange and information sharing. It should represent a good learning experience for Europe or for the country / region concerned, though not necessarily an ideal solution or one without any problems.”

It must be noted that the above definition will exclude a wide variety of “cases” quite often regarded as good practice, like experimental or pilot implementations, initiatives that have just started, etc. Experience has shown that many such applications were not economically sustainable once the RTD or start-up funding ended, the experimental character and the specific interest connected with such activities vanished, the technology applied did not stand the praxis test for an extended period of time, or the longer-term costs associated with the application were simply too high.

### 5.2 Identification of potential case studies

Guided by the above mentioned definition, the study team aims to identify appropriate cases from a number of sources: the eHealth IMPACT data base ([www.ehealth-impact.org](http://www.ehealth-impact.org)) with more than 70 entries as well as the unpublished list of potential entries to the Good eHealth project database ([www.good-ehealth.org](http://www.good-ehealth.org)) with over 400 listings are very valuable sources for identification. In addition, the experience and knowledge in the eHealth field, continuously enriched at various conferences, workshops, and expert meetings related to ongoing projects, of the team members and other associated experts will be a valuable source of potential good practice cases. A number of associations including doctors’, pharmacists’, and patients’, as well as industry players will be directly approached. Last, but not least, case studies from the emerging database [www.epractice.eu](http://www.epractice.eu) will be taken into consideration.

For documentation of identified cases the study team has developed an ‘identification template’ suitable for describing a case in a short but concise way. The template balances between the aim to get precise and extensive information already from the beginning and being a document that can be handled quickly. This process already contains some kind of pre-selection to offer only reasonable cases for final selection. The pre-selection template is included in the Annex to this report.

## 5.3 Lessons learnt from the eHealth IMPACT and other studies

As this research requires, as a core activity, the selection of well qualified case sites and detailed descriptions and analyses of the healthcare services provided, we regard it as useful to point at particular risks when undertaking such work.

The eHealth IMPACT study undertaken in 2005/2006 was concerned with collecting case studies and developing a method to assess the economic impact of eHealth solutions in general. A crucial feature was that even after a quite lengthy, well-prepared and organised identification and selection process with strong support by the EC, two sites selected for detailed analysis failed in the end to deliver the information needed, or failed on initial cooperation promises during the evaluation proceedings. This required the project team, coordinated by empirica, to release the sites from their obligations, and to replace them with other sites. This was achieved successfully and relatively rapidly, however with some cost and delay to the project. That was an essential lesson learned that is reflected in the approach taken in this study.

Another relevant lesson is that it usually takes quite some time and considerable efforts to gain access and trust of case owners to obtain more than just shallow PR information, and even more persistence to be allowed to access internal data (both on costs and utilisation) to better judge an implementation. We learned that at least two (and sometimes even more) site visits per case are necessary in order to build the required relationship between site owners and the study team.

In addition, it usually turned out that additional visits and communications were necessary to clarify concepts, data and information needed; overcome related barriers of language and arrive at a common understanding; meet key promoters and actors of the case application who usually have heavy schedules; and to obtain feedback for validation of results and final permission to make public use of key results the research unearthed.

Similar observations were made by the study team during a number of follow-up, independent evaluation studies it has completed based on the eHealth IMPACT methodology. In one case, the evaluation had to be terminated before completion because it became obvious that the solution did not achieve the expected benefits.

These and other aspects need to be taken into account when planning and executing the research to be undertaken. Our concern is to focus on "real", proven and reliable cases, not simply to accept what is being published by marketing departments. Therefore we have already approached a number of cases and received reassuring feedback regarding the willingness to cooperate.

## 5.4 Selection of case sites: guideline-led expert decision

For selection, we have developed a selection guideline considering lessons learnt, as well as the experience and know-how of several experts, that aids the study team in deciding which cases should be analysed in detail. In the process of selection, the steering committee and advisory board will help to balance - taking political considerations into account - different selection criteria against each other: e.g. country coverage, application fields, implementation level, degree of interoperability already achieved, etc.

During the kick-off meeting in January, we proposed a first batch of case studies to discuss and decided to start with the following two sites: HUG (University Hospitals of Geneva), a case from Switzerland, and the ECS (Emergency Care Summary) Programme of NHS Scotland. A second batch of 8 case studies will be selected in due course, at the latest during the first advisory board meeting.

As discussed above, the terms EHR (system) and ePrescribing cover quite heterogeneous eHealth solutions. There does not exist the typical, ubiquitous “prototype” application we could search for. In order to reflect and cover this heterogeneity adequately, but also reflect our definition of good practice, we have decided on the following selection guidelines:

- Implementation of some core clinical record components, such as medication records, lab results, radiology, referral or discharge letters, etc., including the extent to which these data are structured
- Functionalities of solutions include items such as workflow support, decision support features, alerts, automated order application (e.g. CPOE), etc, and have reached a certain level of maturity
- Support for, and connection to administrative and management components, scheduling and supply management, quality control, etc. is available, or at least potentially possible
- Level, type and extent of networking and interoperability, as discussed in section 3.2.4 above, including cooperation and data exchange with the social care sector are taken into account.
- Compliance with national and European legislation and data protection regulation (including position with regard to the issues discussed by the Article 29 Data Protection Working Party<sup>73</sup>)
- Transferability and replicability - we seek a balance between outstanding solutions, which often are of limited replicability because of specificities of the involved people and context, and solutions that may be of less outstanding, yet fit for mainstream deployment
- Coverage: 10 case studies can not give a complete picture of all applications available in Europe. So necessarily there needs to be a balance between certain factors like:
  - Country
  - Areas (GPs’ EHR systems, nation-wide EHR systems, hospital EHR systems as part of HIS, specialists’ EHR systems, personal EHRs, ePrescribing at hospital or community pharmacy level...)
  - Scale (national, regional, local solutions)
  - Current level of deployment (number of users) and/or potential for deployment
- Pragmatic factors -These factors are at least equally important:
  - Commitment of site “owners”
  - Availability (before/currently/after) of data and willingness to provide the information needed

The last factor is not a criterion for good practice as such, but is important for the quality of evaluations. Our experience shows that lack of commitment is a critical risk factor for success of the study. In order to mitigate that risk, we have allocated budgetary resources for compensating some of the non-trivial efforts requested from site teams.

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<sup>73</sup> And more specifically the issues presented in the recent “Working document on the processing of personal data relating to health in electronic health records (EHR)”, ARTICLE 29 Data Protection Working Party, 2007, WP131; 00232/07/EN

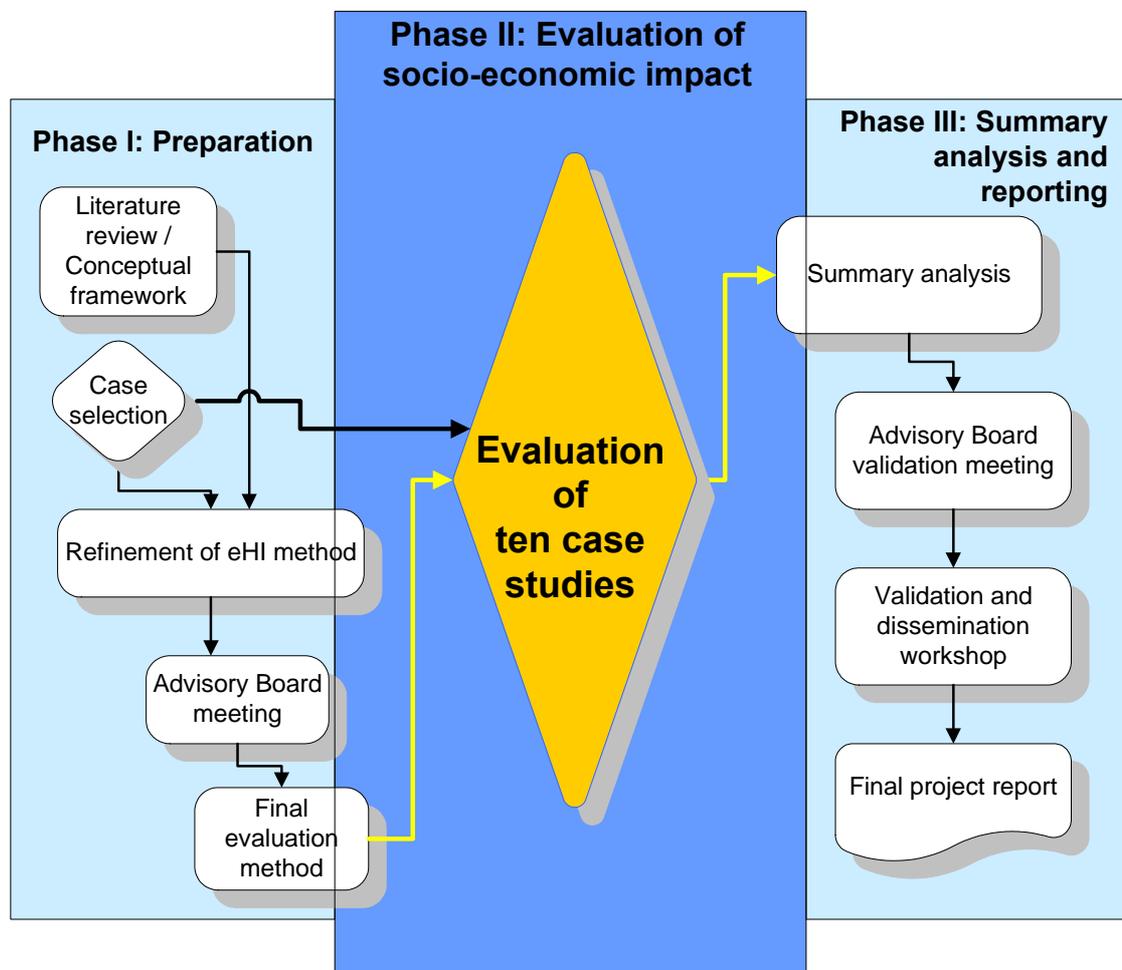
## 6 Research process and work plan

This last chapter of the conceptual framework provides a comprehensive overview of the developed workplan. It characterises the three phases - preparation, impact evaluation, and summary analysis and reporting -, and discusses key issues that will arise in the context of the research process foreseen. The chapter closes with an overview of the study's time schedule.

### 6.1 Study phases

The research process and workflow rely on three subsequent operational phases that interact in a rather straightforward fashion as is visualised in Figure 9 below. The figure presents the study approach from a process view perspective and identifies key work steps.

Figure 10: Study Approach - Process View



Source: © empirica (2007)

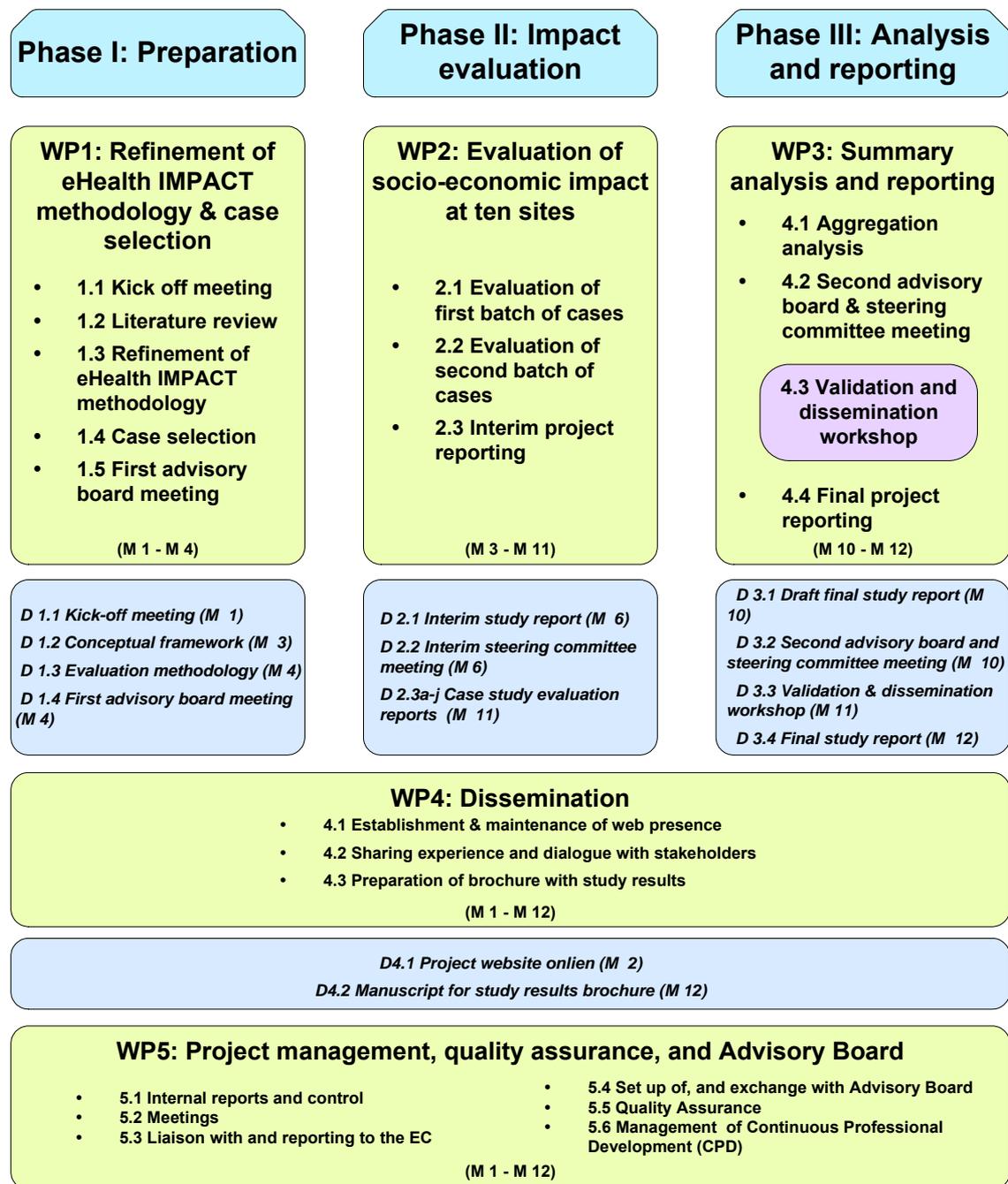
The work of the study is subdivided into three broad phases. The first, preparation phase, involves a review of the literature and other sources, agreeing on key working definitions and the conceptual framework described in this document, as well as selection of the ten case studies to be evaluated. Furthermore, work in phase one includes refining, adapting to the

concrete setting of interoperable EHR and ePrescribing systems, and validating by an advisory board the state-of-the-art evaluation methodology. The second phase, evaluation of socio-economic impact, overlaps with the preparation work in that the refinement of the methodology will have to be based not only on the conceptual framework developed, but also on concrete examples. Thus, evaluation of two case studies has already started during the methodology refinement and adaptation work.

The bulk of the workload, both in the second study phase and the study as a whole, is then concentrated in the evaluation of the ten case studies. The evidence-based outputs of phase II will be analysed, synthesised and aggregated in phase III, summary analysis and reporting. Again, an overlap between the phases is foreseen. The summary analysis has to start before the ten separate evaluations have been finalised in order to allow enough time for an open discussion and validation of results with the steering committee and the advisory board of the study, as well as a wider expert community. At the late stages of individual evaluations, the available numerical outcomes and analytical insights allow aggregated preliminary conclusions to be drawn. The preliminary findings will be presented and discussed first at a joint steering committee and advisory board meeting and then at the validation and dissemination workshop foreseen. The final evaluation results and the outcomes of these events will then be integrated into a final report, including a brief to EU and Member State policy makers that addresses the need to improve awareness of the benefits of interoperable EHR and ePrescribing systems. We anticipate that by the end of the project a document ready to be published by the EC like in the case of the eHealth IMPACT study will be available.

Figure 10 provides an overview of these phases and their relationship to the five workpackages, work tasks and main outputs of the study:

Figure 11: Overview Phases and Workpackages



## 6.2 Time planning

The following work schedule presents a very tight time line for overall work, requiring full use of the foreseen 12-month time frame, and which is based on relatively ideal assumptions. It assumes that work will be able to progress without any major interruptions or failures. However, dates at which certain work will have to be performed may become difficult to adhere to. Depending on holidays and vacation times in different Member States<sup>74</sup> adjustments in

<sup>74</sup> For example, from mid-June to end of July, Northern Member States are on vacation, and in more southern countries the break usually extends from some time in July to early September. Experience from other studies shows that during these times, as well as over Christmas and New Year, as well as Easter, decision makers and experts are

timing may be required. This concerns also the timing of the workshop, which will have to be confirmed based on the availability of the invited experts.

Also, our experience shows that for the critical fieldwork of evaluation, face-to-face interviews are essential, which requires the presence of key staff on site, with the risk of delays due to availability and different priority settings within site organisations. Best results have been obtained when involving local experts and eHealth solution promoters who have a good integrative understanding of medical/clinical, health policy, ICT-related, as well as managerial issues, and who are aware of new developments and emerging technologies - qualifications which are in extremely high demand and make it very difficult to schedule face-to-face or telephone meetings.

All of this should be taken into account when reviewing the overall schedule, in order to obtain optimal results rather than finishing the study in too short a time period thereby jeopardising the validity and quality of the output.

Table 4: Project Time Line

<i>Work package/Months</i>	1	2	3	4	5	6	7	8	9	10	11	12
<b>WP 1 Refinement of eHealth IMPACT methodology</b>												
D 1.1 Kick-off meeting	X											
D 1.2 Conceptual framework			X									
D 1.3 Evaluation methodology				X								
D 1.4 First advisory board meeting				X								
<b>WP 2 Evaluation of ten case studies</b>												
D 2.1 Interim study report						X						
D 2.2 Interim steering committee meeting						X						
D 2.3a-j Case study evaluation reports											X	
<b>WP 3 Summary analysis and reporting</b>												
D 3.1 Draft final study report										X		
D 3.2 Second advisory board and steering committee meeting										X		
D 3.3 Validation and dissemination workshop											X	
D 3.4 Final study report												X
<b>WP 4 Dissemination</b>												
D 4.1 Project web-site online		X										
D 4.2 Manuscript for study results brochure												X
<b>WP 5 Project management, quality assurance and advisory board</b>												

difficult to reach, and priority in organisations is put on running the day-to-day activities with a limited number of staff.

## 7 Summary and conclusions

This report constitutes the conceptual framework of the EHR IMPACT study. At the very beginning, we outlined common values, principles and key challenges in EU health systems, and the enabling and facilitating functions of eHealth, as perceived by European policy makers. Next, we presented domain delimitations and definitions of the key terms, which include Electronic Health Record (EHR), ePrescribing, and Interoperability. Chapter 3 also dealt with operationalising the concept of Interoperable EHR and ePrescribing systems. Chapter 4 delineated the conceptual approach towards the methodology for analysing and assessing the socio-economic impact on case studies. The details of the methodology are addressed elsewhere. Chapter 5 presented our understanding and approach, as well as specific definitions concerning the identification and selection of ten good practice examples of ongoing initiatives for detailed case study analyses. The overview of the study approach and workplan are covered in chapter 6.

The fundamental challenge of health systems is to serve a demand that has unlimited scope for increase with limited resources. Ageing populations, raising expectations, and advances in life sciences drive demand for quantity and quality of health services. The challenges that lie ahead are in reconciling individual needs with the available resources. Over the last years, political awareness of the potential of eHealth to help meet these challenges has been continuously rising on European, as well as on Member State level.

Nonetheless, health systems remain complex and demanding, and eHealth is no exception. Researching definitions of the key terms of this study showed that there are no unique concepts behind either EHR or ePrescribing. Even interoperability is often understood and used in different ways by different people. We also had to discover that the visionary definitions, comprising 'holy grails' of beneficial attributes and functionalities, cannot realistically be expected to be found implemented now or in the every near future. Thus, we had to operationalise the terms by defining them in broad terms, focusing on the key aspects of allowing the possibility to share at least some patient-specific clinical data. This, together with the critical condition of providing a good learning experience with empirical evidence on impact, is also a primary guideline for selecting potential case studies.

The methodology for evaluation of the socio-economic impact of interoperable EHR and ePrescribing systems is subject of a separate report. However, the conceptual foundations were already set in this document. The methodology will build on cost benefit analysis (CBA), focusing on net benefits over time, and uses monetary values to index financial, but also non-financial impacts. Negative impacts fall under the cost category, whereas positive impacts are aggregated as benefits. Critical features of the methodology should be that the models adapt to the specific case setting and data, and that the results should be regarded as robust only in their order of magnitude, not the precise number.

The EHR IMPACT study is scheduled to be completed by the end of 2008. The first, preparatory, phase is now nearly completed and the second, evaluation phase is already underway. The evaluation phase includes detailed analyses of overall ten case studies of interoperable EHR and ePrescribing systems. In a third phase, the results will be analysed in aggregation, and disseminated to policy makers, decision makers and other targeted actors in the healthcare sector, as well as to the wider public.

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# APPENDIX 1: CASE STUDY PRE-SELECTION TEMPLATE

## *Case pre-selection template*

### *Study on the Economic and Societal Benefits of Interoperable Electronic Health Records and ePrescription in Europe*

empirica is currently undertaking, for the EC, a study on assessing the economic impact of networked/interoperable EHR in (1) hospitals, among (2) GPs and specialists, of (3) interoperable medication records/ePrescribing systems, and (4) personal health record (PHR) services provided, e.g., on the web.

Presently, we collect information on potential cases which may qualify to become one of 10 case studies which have to be undertaken. We will assemble between 15 and 20 potential cases, from which later to choose in agreement with the EC according to the specific functionalities of the solution, the geographic location of the case, its exemplary nature, etc.

Basic requirement is an eHealth system/solution which exchanges some personalised clinical patient data (medication, laboratory, ...) not only across a hospital, but preferably also with other hospitals, or with pharmacies, GPs, ..., perhaps also labs etc.

If the case proposed by you is approved by the EC and the board of experts advising the study, we will (together) undertake a more detailed study of costs involved in establishing and running the solution, and of the benefits estimated to accrue to various stakeholders like patients, professionals, the healthcare provider organisation, the payers/insurances etc. This will require access to some basic cost data, interviews with persons involved etc.

Benefits for you/your organisation could be the public relations effect of being a case in a European study which can be expected to receive wide coverage and attention even beyond the EU (cf. our earlier study in this field available at [http://europa.eu.int/information\\_society/activities/health/docs/publications/ehealthimpact\\_sept.2006.pdf](http://europa.eu.int/information_society/activities/health/docs/publications/ehealthimpact_sept.2006.pdf)), the networking with our eHealth expert team (and perhaps the EC colleagues and with North American colleagues in case you would like to get involved in a deeper exchange - we plan to extend the study to North America), and also some financial reimbursement for your efforts and/or that of the persons involved in the healthcare services supported by the selected eHealth solution.

Thank you in advance for providing us with an overview of the EHR and/or ePrescription system you are involved in. We will keep you informed about the further process of our work.

Please write directly into this MS WORD template if possible. Otherwise, please print this form and, where necessary, add the answers at the end of the template.

For further information and for returning this form, please contact:

Alexander Dobrev at <mailto:alexander.dobrev@empirica.com>

Tel.: +49 (2 28) 9 53 0-0

Fax: +49 (2 28) 9 85 30-12

empirica Communication & Technology Research, Bonn, Germany

[www.empirica.com](http://www.empirica.com)

1. Short descriptive name of the case:

—

2. Short overview of the environment in which the EHR / ePrescription solution is implemented:

Please indicate whether the system is used predominantly in primary, secondary, or tertiary care. Another classification, if relevant, can be used. A solution may also be implemented across these care sectors. Also, please indicate whether the system is implemented in/allows the exchange of data among hospitals, GPs or specialists practices, laboratories, pharmacies,... Ideally, it will be a combination of two or more types of organisations, maybe even a part of a local or regional “health network”.

—

3. Short description of the solution

Please describe in a few sentences key aspects of the solution:

—

The solution is in operation since the year \_\_\_\_

4. Components or functionalities of the EHR solution

Please list key elements or functionalities of the EHR system or ePrescription solution. (like: medication records, referral letters, lab results, decision support,... Indication of the extent to which data is stored in a structured way, as free text, or image would be appreciated.

—

5. Users and beneficiaries

Please indicate key users and beneficiaries. Please note down the number of users and/or beneficiaries for each category:

Physicians in a hospital or community centre

Physicians in their own practice

Nurses

Management

Patients

Family or other informal carers

Third Party Payers (like health insurances, the government, ...)

Healthcare provider organisation(s) involved

Pharmacies

Midwives

Psychiatric Nurses

Pharmacists

Pharmacy technicians

Physiotherapists

Occupational therapists

Social workers

- \_\_\_ Medical records staff
- \_\_\_ Medical secretaries
- \_\_\_ Clerical staff involved in direct patient care
- \_\_\_ Support and clerical staff in pharmacies
- \_\_\_ Clerical staff in social services
- \_\_\_ Others: please specify: \_\_\_\_\_

#### 6. Networks and interoperability

Exchange of data in networks and interoperability will be particularly important for the study at hand. Thus, please classify the system into one of the following three categories:

- (1) Potential interoperability - use of standards, but no actual data exchange, sharing, and re-use of clinical data or medical information on patients: [ ]
- (2) Limited connectivity - sometimes patient data is exchanged or shared with other healthcare providers, and/or re-used for research, Public Health, and/or administrative purposes.
- (3) Extended actual connectivity - patient data is regularly and routinely exchanged or shared with other healthcare providers, pharmacies, labs, etc., and/or re-used for re-search, Public Health, or administrative purposes.

Please identify by ticking one of the boxes: (1) [\_\_\_] ; (2) [\_\_\_] ; (3) [\_\_\_]

If the application contains a network of organisations, please specify the number and types of organisations connected.

#### 7. Contact person and details

Please provide us with the name and contact details of a person whom we can approach for further information.

—

#### 8. Any other information you may want to add:

—