

The added value of electronic health records (EHRs): Linking patient care, clinical research and public health

Executive Summary

Recently, the European Commission has undertaken efforts to raise awareness among EU member states and within the healthcare, life sciences and IT industries of the remarkable potential of implementing electronic health records (EHR). Workshops pointed up the formidable challenges of reconciling privacy regulations, technical compatibility, and cooperative processes. The added value of EHR implementation could enable “eHealth” applications that can modernize healthcare and vastly improve clinical research. The interoperability of EHRs will also provide a range of tangible and far-reaching benefits for the patient, the public health sector, the life sciences and IT industries, and provide EU member states with an important innovation tool. The resulting recommendations will demand strong political support, new organisational structures, and funding. None of this will be easy, but the alternative of doing nothing could have a large, negative impact across the EU.

Introduction

The recommendations discussed here result from two workshops held in Brussels (October 2007 and March 2008) entitled “*Primary and secondary use of EHR: Enhancing clinical research*” and “*Toward integration of clinical care and clinical research for better health and high quality healthcare*” respectively.

These meetings were held under the auspices of the European Commission: DG Information Society & Media, the European Federation of Pharmaceutical Industries & Associations (EFPIA), the European Institute for Health Records (EuroRec) as well as stakeholders from clinical care, IT vendors, the legal profession and patient advocacy groups.

The three key areas were:

- Technical interoperability – how can information captured electronically, on a variety of electronic systems be shared and used to improve patient care and medical research?
- Operational interaction models & governance processes – how can existing or new healthcare stakeholders work together to develop and promote the efficient and secure use of healthcare data for improved patient care and medical research?
- Data privacy & legal issues – how can individual privacy be respected while medical data are shared and analysed to improve patient care and enhance medical innovation?

The high level recommendation endorsed by all parties:

EU member state authorities should create a forum that allows various actors involved in EHR system implementation to agree on priority areas, which will encourage the systematic use of EHRs to enhance patient care and to facilitate medical research. These areas include (but are not limited to):

- Developing guidelines for a Trusted Third Party to ensure that any data exchange between research organisations and data holders is carried out (according to regulations) by a neutral and trusted third party.
- Encouraging a harmonised interpretation of healthcare data privacy legislation by EU member states; acknowledging that re-use of patient data for secondary uses is a key enabler for realising the full benefits of eHealth
- Enforcing technical standards to enable system interoperability within the healthcare domain, and between the healthcare and medical research domains

All of the above should fully respect the protection of personal data and patient confidentiality.

Background

The positive benefits of timely and secure access to patient data have been recognised by health providers across the EU. The widespread use of electronic health records (EHRs), when combined with the proper organisation, regulatory framework and skills, should lead to improved health care, patient safety and efficiency. However, the potential contribution of EHRs to a wider public health agenda has not, to date, been fully recognised by all stakeholders. Aggregated and anonymised EHR data (at local, regional and national levels) has the potential to bring great benefits to public health, clinical research, evidence-based knowledge translation, and pharmacovigilance.

Acknowledging these strengths and opportunities, but also the challenges still to be overcome, a group of healthcare providers, government authorities, representatives from the pharmaceutical and IT industries, and the legal profession and patient groups, came together in October 2007 and March 2008 to explore new opportunities in using EHRs. Workshop sessions covered not only the use of EHRs for direct patient care, but also for clinical research, technological development and innovation. This document highlights some of the recommendations, - including political engagement - to realise the full potential of EHRs and respect the fundamental privacy rights accorded every person in the EU.

The added value of Electronic Health Records

Public healthcare services are an essential part of the European social model, and the right to high quality healthcare is at the essence of European citizenship. eHealth applications are a key way to maintain current standards and help further develop our health systems. The more effective use of patient data, medical knowledge, and recommendations for treatment are needed to meet the policy goals of improved patient safety, comprehensive chronic disease management or combating old and new diseases. To realise this, EHRs, based on internationally agreed standards, are an important tool to enable wider collaboration not only in care provision, but also for research and knowledge creation, management, and quality assurance.

One of the greatest potential benefits of standardised computerisation of health data is the huge opportunity of combining, aggregating and analysing electronic records for clinical research. By ensuring compatibility between the various computer applications, even greater benefits can be expected. The resulting knowledge can provide widespread feedback for clinical practice via new guidelines, alerts, or other decision support. The use of patient data for determining individual treatment and re-use of such data in related contexts can be used together to deliver the expected benefits.

While the benefits of EHRs in direct patient care are widely recognised, the benefits from secondary use of data that has been de-identified and aggregated for medical research purposes is grossly underestimated, or even overlooked. Despite the importance of this, only marginal levels of collaboration have developed between healthcare, patients, the life science industry, the research community and others to explore how the growing adoption of EHRs can contribute to common research initiatives to adapt healthcare systems to 21st century needs. It is time to develop a greater understanding and enhanced political engagement for the wider use of EHR information.

Interoperability – a win-win situation

There are many benefits in the widespread adoption of interoperable EHRs and linking them to clinical research systems. For healthcare delivery, the secure exchange of health information enables safer and more efficient care through avoidance of errors and duplicative examinations, even across linguistic and cultural borders. On a higher level, it will allow for evidence-based decision support tailored to the patient's needs.

From a *patient* perspective, provided their records are suitably protected against unauthorised access, widespread implementation of EHRs can foster patient empowerment through easier access to personal medical records, a more holistic approach to healthcare through closer co-ordination between care providers and the patient, ultimately resulting in safer and more evidence-based diagnosis and treatment.

From a *public health* perspective, the re-use of such data would allow more successful management of public health issues realising vital aspects of the “digital public health vision”:

- Enhance processing of various indicators, benchmarks and trends on public health issues with respect to populations/groups; settings/facilities; regions/geographic units,
- Reconcile environmental variables, to better understand health factors, to identify emerging trends in public health, and to more effectively manage public health problems

From a *life sciences* perspective, analysing data from interoperable EHRs would contribute, e.g., to more transparent and safer care through faster and more targeted drug development and increased clinical safety. Interoperability of EHRs and their integration with clinical research systems will facilitate multinational clinical trials, esp. for personalized medicine, where small subpopulations could benefit from innovative drug treatment policies.

From a *clinical research* perspective, linking EHRs with clinical trials has major potential to increase the recruitment rate of patientsⁱ (Ohmann & Kuchinke, 2007). The re-use of EHR data for clinical research and basic research systems will support and enhance research capabilities (and associated activities), and provide a new, potentially global source of evidence to generate new medical and healthcare knowledge (e.g., to develop new tools and speed up the translation of such research findings to the actual point of care, and improve pharmacovigilance).

From a *technology industry* perspective, wide EHR deployment would stimulate a whole high-tech market segment (healthcare technology), helping promote EU market strength and global market share, and attracting R&D investment into the EU.

From an *innovation* perspective, interoperable EHRs could benefit knowledge discovery and sharing (among EU member states), and support, e.g., life science and pharmaceutical development, production of new analytical software tools for health data, and creation of skills and jobs within the EU. By encouraging R&D and technology development, the development of interoperable EHRs could stimulate innovation, contributing to economic growth in Europe.

The context of European Commission activities

The roots of European policy to foster the widespread implementation of interoperable EHR systems are grounded in the European eHealth Action Plan of 2004. Recently, the EU identified eHealth as one of six particularly promising market segments in a Lead Market Initiative. The Initiative aims to accelerate the development of the eHealth market by removing barriers to growth in specific eHealth markets through specific policy actions. The upcoming *European Commission Recommendation on Cross Border Interoperability of Electronic Health Records* will address activities needed at both the member state and EU levels. Furthermore, concrete progress in these fields is to be expected from the *European Smart Open Services (S.O.S)* large scale pilot project, to be undertaken by the Competent Authorities of 12 EU member states and about 30 industrial players.

Key actions needed to bringing closer care and research

Coordinated and collaborative activities are needed to realise the huge benefits for individual citizens, the healthcare systems, and for society at large. However, no stakeholder group on its own can initiate and implement all the actions needed to make this happen. All must work together to address factors that are barriers to progress, and support those elements that can facilitate faster advance. Concentrating on selected recommendations, actions are called for at various levels:

POLICY & LEGAL LEVEL: To avoid a further fragmentation of the European eHealth applications market and allow for the re-use of patient data for the outlined purposes, strong support for interoperable EHRs by EU member states is essential.

The processing of personal data relating to a person's health is particularly sensitive and requires special protection. Whenever feasible, information from EHR systems should be used only in anonymised or de-identified formⁱⁱ. If, however, processing personal data in EHR systems is necessary for a specific medical purpose, then it must fully comply with the rules for protection of personal data. The current EU Data Protection legal framework prohibits in principle, the processing of personal data relating to a person's health contained in EHRs, other than for certain health-related purposes by persons subject to a legal obligation of professional secrecy. However, EU member states may derogate from this general prohibition on processing sensitive categories of data where important reasons of public interest so justify, e.g. for wider medical purposes in areas such as public health or scientific research, together with specific and suitable safeguards that protect the fundamental right of personal data protection. So far, there is little awareness or co-operation among EU member states on uniformly applying data protection principles in respect to EHR implementation.

ORGANISATIONAL LEVEL: The penetration of EHR systems in hospitals, community centres and private practices is steadily increasing. These systems are usually isolated and not connected to other healthcare information systems. Each system also involves a wide range of stakeholders, including clinicians, public health authorities, insurers/payers, academic and industrial researchers, IT vendors, pharmaceutical companies, regulatory authorities, patients and third party information brokers (i.e. organisations involved in anonymising, linking, or aggregating data), who often have only a limited

understanding of each other's needs outside their immediate areas of interaction. In order to get the most out of EHR systems, organisational structures and interactions should be optimised. This includes the creation of organisational structures and mechanisms to allow the interacting health sector stakeholders to be involved in EHR system implementations in order to meet multiple healthcare needs: patient care, research and public health.

TECHNICAL & SEMANTIC LEVEL: Without agreement on general IT concepts and technical standards, individual, isolated and disparate EHR systems and solutions will prevail. The development of software tools that support interoperability and integration between EHRs and between EHR entries, and electronic data capture (EDC) for clinical trials and basic research data are urgently needed. The use of patient data in EHRs for seamless, collaborative care provision and for the various re-use opportunities mentioned earlier is only feasible if electronic "machines" can exchange and manipulate patient data, but also that all those involved in health services understand and act on this information, even when operating in different languages.

The following high-level recommendation addresses the broad range of issues mentioned above:

KEY ACTIONS – EU member state authorities create a forum to allow those involved in EHR system implementation to agree on the priority areas that encourage the systematic use of EHR to enhance patient care and to facilitate medical research.

- Develop guidelines for Trusted Third Party engagement
- Encourage harmonisation of EU member state interpretation of healthcare data privacy legislation, acknowledging that re-use of patient data for secondary uses is a key enabler for realising the full benefits of eHealth
- Enforce the technical standards needed to enable system interoperability within the healthcare domain, and between the healthcare and medical research domains. This might include support for open software tools enabling interoperability and integration between EHRs and between EHR, EDC and basic research systems. Identify priority areas for improving semantic interoperability, e.g., field(s) of clinical practice that are of high patient safety relevance and where it is most urgent to bridge the gap between current and good practice.

All of the above should fully respect the protection of personal data and patient confidentiality.

What happens if we do nothing?

The recommendations listed above will demand strong political support, appropriate organisational structures, and public and private funding, and in particular, a strong professional commitment across the full range of health system stakeholders. We must recognise that the alternative of doing nothing will have large, negative implications across the EU. First, we run the risk of fragmented parallel non-standards-based developments in multiple sectors, entailing a substantial duplication of costs and human effort. Secondly, a failure to work jointly across the healthcare, drug development, and life sciences sectors will forego a crucial opportunity to boost key EU markets (pharmaceuticals, health technology and devices, and eHealth solutions) and counter global competition. Thirdly, if we do not address the reengineering of healthcare in an integrated manner across the range of healthcare stakeholders by implementing at least basic EHR components, we run a significant risk of failing to more effectively address patient safety and quality of care through sharing of patient data and best practice, of not harvesting the benefits possible for clinical research and faster drug development, and of missing the opportunity for the rapid generation of new medical knowledge. Ultimately, as shown by comprehensive empirical evidence, this will cost lives as well as euros. It would also leave the EU, member states, patients, and the healthcare industries far behind other large nations (such as the U.S.A., Japan or Canada).

ⁱ Ohmann, C. & Kuchinke, W. (2007) "Meeting the Challenges of Patient Recruitment: A Role for Electronic Health Records", *International Journal of Pharmaceutical Medicine*, 21 (4): 263-270.

ⁱⁱ E.g. (1) **De-identified Data**, have had information that identifies data subjects replaced with codes (that are not derived from information related to the data subject), such that absent a disproportionate amount of resources, it is only possible to trace the data back to data subjects by referencing the key code. Or (2), **Anonymised Data**: may have at one time contained personal identifiers but have subsequently had removed all identifiers that would enable identification of the data subject based on reasonably available means, and any links enabling the data to be traced back to individual subjects have been broken. Anonymized Data are not Personal Data.. - Ref. International Pharmaceutical Privacy Consortium (IPPC).