Patient access to the electronic health record

Report of the eHealth stakeholder group

June 2013

1. Introduction

The EU Digital Agenda[1] highlights that for eHealth technologies to be successful it is essential to "incorporate the right of individuals to have their personal health information safely stored within a healthcare system accessible online". To achieve this, specific actions have been foreseen, including giving Europeans secure access to their medical data, implementing digital literacy policies, fostering EU standards and interoperability, helping disabled people to access content and proposing a recommendation to define a minimum common set of patient data (see also Annex II).

In order to provide input on this important element of the Digital Agenda, the eHealth stakeholder group[2] decided to create a subgroup that was given the mandate to gather the members views[3] on the topic and in particular on the main obstacles and the possible solutions. The members were also asked to refer to what they considered relevant examples of electronic health records systems at national or regional level[4].

The information was gathered mainly from the members of the stakeholder group on the basis of a semi-structured questionnaire and via consultation of their own membership network in order to have an EU wide perspective. Additional information and references were collected via a limited literature review and desk research on relevant web sites.

The concept of electronic health record is constantly evolving and there is a multitude of definitions[5] and interpretations. For the purpose of this document electronic health record (hereafter EHR) is defined as "a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes"[6].

2. The potentials of the electronic health record

The EHR is an important instrument to improve safety, quality and access to health care. The ageing of the population and the consequent higher number of people affected by chronic diseases and multiple morbidities combined with, increased citizens' expectations for high quality health services, the shortage of health care providers and rising costs are challenging the sustainability of health care systems across Europe. In addition, the increase in mobility of the population7 and of health professionals8 requires that health

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[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A Digital Agenda for Europe*,COM/2010/0245 final.
[2] https://ec.europa.eu/digital-agenda/en/news/ehealth-stakeholder-group-members
[3] The paper didn't focus on legal aspects linked to the electronic health record. The electronic health record is the focal point of many other EU and national on-going initiatives and projects: this paper is not meant to replace or complete work undertaken in any of these initiatives and projects.
[4] The examples collected are not the results of a comprehensive mapping exercise nor of an in depth scientific research. Therefore some of the information provided might be incomplete or not updated.
[5] For a comprehensive overview of different definitions of EHR based on a literature review you can consult: Hayrinen et al. *Definition, structure, content, use and impacts of electronic health records: A review of the research literature.* International Journal of medical informatics n. 77 (2008) 291–304.
[6] Commission recommendation on cross-border interoperability of electronic health record systems (C(2008) 3282), 2008.
[7] Impact assessment of the proposal Directive on the application of patients' rights in cross border health care, Commission staff working document COM(2008) 414 final.

records should become available on an 'as and when' basis from more locations. These complex factors create an urgent need to increase collaboration notably between health professionals but also between health and social service providers and to drive progress towards a patient-centric and cost-effective model. This transformation will require more than technology: it will require organisational and social innovation and a shift to a more open, collaborative, and integrated system. In this context the possible benefits of EHR can be substantial.

EHRs have the potential to empower consumers and patients by providing them with easier access to their health information, allowing them to exert more control over their health records, thereby becoming more responsible and more active in their own care while facilitating communication with their health professionals.

Furthermore, storing and transferring patient information electronically can significantly reduce clinical errors - provided that the information is accurate - and improve patient safety. For example, fast access to critical health data could be a matter of life or death especially during emergencies (e.g. allergy or medicines interactions).

EHRs allow health professionals to communicate more quickly[9] and accurately by identifying relevant information more easily and to better plan complex treatment procedures. They can contribute to the avoidance of cases where, for example, the same examination is performed twice, a better understanding of the patient's history and also ensure continuity of care. From a patient's perspective this means a higher quality of care. From a health professional perspective this means a chance for a better patient-health professional relationship. From a policy perspective, it means more sustainable healthcare systems[10,11].

Finally, with patients prior consent, EHRs can be useful for health research purposes and for policy decisions: if managed appropriately, if the security data is assured and if the data can be fully anonymised, huge amount of health data could be easily collected and be used in various scientific studies, including epidemiological analysis, evaluation of health care procedures, pharmacovigilance etc.

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[8] According to the Directive on the application of patients' rights in cross border health care (2011/24/EU) , a 'health professional' is a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment.

[9] M. L. Gates, P.W. Roeder, A Case Study of User Assessment of a Corrections Electronic Health Record, Perspectives in Health Information Management, 2011.

[10] A. Galego et Al, Assessing the Cost of Electronic Health Records: A Review of Cost Indicators, telemedicine and EHealth, Volume 16, 2010.

[11] R. Hillestad et al. Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs, Health Affairs, Volume 24, 2005.

3. Main obstacles

3.1 Lack of guarantees of privacy and confidentiality
While acknowledging that data protection cannot be fully ensured by "traditional" storage and communication systems like paper copies and faxes, one of the biggest challenges identified by the stakeholder group regarding the uptake of the electronic health record is the security of the system in relation to privacy. The unauthorised disclosure of a medical condition or diagnosis or other sensitive information could negatively impact an individual's personal and professional life. The storage, transfer and processing of health information using ICT tools open a new risk scenario in the processing of personal health data. Exposing patients to the risk that their health information could accidentally or maliciously end up in the hands of unauthorised parties - including employers or insurance companies- and that their data is transferred (sold) to a third party without consent could jeopardise public trust in health systems and could increase the likelihood that patients will not release all the relevant information.

The electronic health record poses challenges in ensuring that only authorised health professionals gain access to information for legitimate purposes related to the patient. The possibility of abuse is significant and the risk increases when systems become more interconnected. As a consequence most of the stakeholder group members consider that there is still lack trust in the security of the system and are reluctant to use it. Among stakeholders, there remains in general uncertainty over the "who and how" can access and modify data and who is responsible for it.
On the other end, although they express several concerns, most patients and health professionals think that overly strict data protection and security systems should not hinder the transfer and sharing of health information[12], and ultimately the health service. This insofar as effective security and informed consent provisions and procedures are put in place and the users are properly informed about them[13].

Other important hindering factors are the different legislative frameworks applied in the different Member States and the different level of data protection among countries.

3.2 Lack of equal access to the internet, clarity of expectations and IT literacy
In some countries people do not have access to the internet and/or to a broadband connection and often the cost of internet access is an obstacle for its use. Many people also lack the literacy and IT skills necessary to use the system (digital exclusion[14]).
A study from the European Commission in 2007 showed that only 60% of all general practitioners use a computer during a consultation (EU27). The national percentages varied from 100% in Finland to only 8% in Italy. The electronic communication and exchange of data between hospitals and general practitioners within Europe happened, on average, in only 20% of cases. This national data varied from 76% in Denmark to 0% in Romania,

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[12] G. Perera et Al.Views on health information sharing and privacy from primary care practices using electronic medical records, International Journal of medical informatics 80 (2011) 94–101.

[13] http://www.eu-patient.eu/Documents/Projects/ChainOfTrust/EPF-report-web.pdf

[14] http://ec.europa.eu/public_opinion/archives/ebs/ebs_381_en.pdf

indicating that there are large differences between the European countries and that there is still a long way to go before the use of ICT becomes a reality. It is thus important to avoid a two-tier European approach to EHRs in order to avoid new health inequalities.

Accessibility issues are closely related also to factors which include age[15], physical and/or sensory impairments. In addition, whilst the proportion of 'digital natives' is increasing, there is still a significant proportion of the public who doesn't have access to their EHR per se because of a complex mix of their capacity, the competencies of their clinical practitioners and the stage of ICT policy and deployment in health in their countries. Finally, a major barrier is linked to the language and to the ability to understand complex medical terms which require literacy skills that a wide part of the population doesn't have.

Developing health literacy is essential to make sure that patients understand the nature of the health record, what the data they see means to them, and, most importantly, how they can make use of this information in the most effective and safe way.

3.3 Lack of information, trust and acceptance

Interoperability (technical, semantic, organizational, legal) and usability standards in ehealth are still evolving and often do not take into account the human factors[16] associated with the use of the technology. The EHR is going to change the way patients deal with their own health and also how health professionals and patients consider that they should be more informed and increasingly expect to be involved in the decision-making of their own healthcare.

At the moment, many patients and health professionals are unaware of the benefits of the electronic health record. They do not always know how the technology works and how data can be handled. This lack of adequate information hinders the acceptance[17] of eHealth solutions by both patients and health professionals[18]. Education is essential to facilitate trust and acceptance of eHealth solutions, among which EHRs. One of the recommendations of the Chain of Trust Project final report highlights that "training on eHealth and telehealth related knowledge and skills should be included in the health professionals' curricula and be part of Continuing Professional Development programmes according to the different professional needs[19]".

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[15] WB Lober et al. Barriers to the use of a Personal Health Record by an Elderly Population, AMIA Symposium Proceedings,2006.

[16] R. J. Holden Cognitive performance-altering effects of electronic medical records: An application of the human factors paradigm for patient safety, Cogn Technol Work. 2011 March ; 13(1): 11–29. doi:10.1007/s10111-010-0141-8.

[17] E. Ford et Al. Resistance Is Futile: But It Is Slowing the Pace of EHR Adoption NonethelessJ Am Med Inform Assoc. 2009;16:274 –281. DOI 10.1197/jamia.M3042.

[18] A. Boonstra, M.Broekhuis Barriers to the acceptance of electronic medical records by physicians from systematic review totaxonomy and interventions, BMC Health Services Research 2010, 10:231

[19] Chain of trust final report: http://www.eu-patient.eu/Documents/Projects/ChainOfTrust/EPF-report-web.pdf

4. Experiences at national level

4.1 Austria

In December 2012 Austria introduced an Electronic Health Records Act (EHR-Act).These provisions are the legal foundation for a national EHR system based upon a substantial public interest according to Art 8(4) of the Data Protection Directive 95/46/EC. The Austrian EHR-Act pursues an opt-out approach in order to harmonize the interests of public health and privacy issues. Tests are being carried out in three regions and the system should be fully rolled out by 2017. The implementation of the new system has followed a number of other tests and pilots projects. For example, the results of an independent scientific evaluation of the 'e-Medikation pilot project', which was carried out under Austria's electronic health records project - ELGA (Elektronische Gesundheitsakte), were presented in May 2012. The aim of the e-Medikation pilot was to provide support to physicians regarding the electronic prescription of medication in a way to contribute significantly to patients' safety. Throughout the duration of the pilot project, 8 252 patients were registered, and 5 431 patients, 41 general practitioners, 31 specialists, 50 pharmacies, 13 general practitioners with medicine cabinets and 4 hospitals actively participated in the evaluation exercise. On average, at every second visit of a patient to a doctor or a pharmacist, the latter ones would get a warning message in case of drug interactions. At every sixth visit, the system would show a warning message in case intervals between drug treatments would not have been kept; and at in each ninth visit, they doctors and pharmacists would be warned on a possible double prescription. Thanks to the pilot project evaluation, a variety of approaches to increase patient safety but also to minimise the time spent by physicians and pharmacies on prescriptions have been suggested.

4.2 Belgium

At the end of 2004, the Belgian government created BeHealth, a platform for organizing and coordinating "the electronic mutual exchange of information […] between all healthcare stakeholders". As a public institution, the BeHealth platform's main mandate has been to allow several healthcare data exchange systems to flourish in various regions of the country, whilst ensuring that they are all going to be interconnected. Currently restricted to operating at local level, BeHealth is working on connecting the five existing regional hubs (one for Wallonia, one for Brussels and three in Flanders) through the « Hub-Metahub » project (in French). For example, in April 2012, the Wallonia healthcare network, the Wallonia hub, included approximately 30,000 patients, 4,000 health professionals and 17 hospitals. In the year 2011-2012, nearly 900,000 documents were exchanged over the network.

4.3 Czech Republic

Czech doctors, laboratories, hospitals and pharmacies are increasingly using the IZIP system of electronic health records (EZK, in Czech). At the end of April 2012, there were almost 200 million records stored on the system. In December 2011, this number was 100 million. Overall the system has 2.5 million "clients", 1.5 million of which joined during the past two years. The EZK service is offered to those insured with the Všeobecná zdravotní pojišťovna (VZP), the largest state owned health insurer. EZKs contain the complete history

of a patient's medication records and lab tests results since the past seven years. From the doctors' point of view, the EZK provides structured information in accordance with data standard 'DASTA'. Laboratories constitute a good example of how dynamic the growth of health records in the EZK has been. In November 2011, one of the largest Czech laboratories joined the system. Since then, 372 000 lab tests results from this laboratory have been sent to the system. The two regions where the number of health records stored on the IZIP system is growing the most are Vysočina and Karlovy Vary. A second generation EZK is being piloted in both regions, where the hospitals can enter healthcare information on their patients in the system.

4.4   Denmark

Since 2003, patients in Denmark have had access to their EHR record through a national e-Health Portal called www.sundhed.dk. Sundhed provides a shared infrastructure in Danish health care that enables all parties in the health sector to collaborate across professional and IT-related boundaries with the individual patient at the center.

Sundhed.dk has transformed the Danish health care sector from a silo-oriented structure towards a patient-centric structure. This shift in orientation has been achieved by an approach that places emphasis on optimization of work routines, prevention of diseases, taking action in time, supporting the right treatment, using the patient's capacity, and collaboration within the sector.

Sundhed.dk is a public, internet-based portal that collects and distributes health care information among citizens and health professionals. All Danish people have access to sundhed.dk, enabling health professionals to communicate and patients and their families to get an overview of correct and updated health care information, making the health care services more open. Every citizen has his own personal page (available upon identification), which reflects the specific situation of the individual. Everybody can find accurate and updated health care information, e.g. past treatments and diagnoses from book appointments with his/her general practitioner (GP) and send secure e-mails to health care authorities, renew prescription medicines, survey the shortest waiting lists for operations and quality ratings of hospitals, register as organ donor, and get access to local disease management systems in out-patient clinics.

People are also encouraged to participate more actively in their own treatments thanks to .services developed for specific conditions and diseases such as diabetes, and by supporting a number of 'chat rooms' where patients and their relatives can meet others in the same situations and also consult health professionals in relevant wards.

Moreover, the portal provides the 150,000 Danish health professionals with better information to make evidence based decisions. By giving health professionals easy access to the latest patient information from most hospitals and laboratories in the country via the secure portal they get the opportunity to make quick and well-founded decisions in specific situations during treatment. In this way, the patient will experience interaction with the health care services as a much more coherent pathway.
Sundhed.dk is an important supplement to the local EHR systems at the individual hospitals and GPs. The EHR systems at hospitals contain their own patient data, but not data from

other hospitals or laboratories. However, this data can be found via sundhed.dk, and the GP can access information regarding patients they are treating from the hospital records.

Since the initial launch of the portal in 2003, four major developments have taken place regarding the use of the portal:

- A continuing increase in traffic volume. On average every Danish adult visits about 6 or 7 pages on the portal during a year.
- A gap in the degree of use between different age groups no longer exists. While the population between 30 and 40 years of age started out with the most extensive use, it is now used equally by the population between 60 and 70 years of age. The two groups vary in the degree of use of specific services.
- The citizens' use of personal services and access to personal health data has increased. During 2010 when the distribution of the unique personal internet-id shared with the financial sector took place, the share of page views that took place for a user who had logged on increased from 20 percent to 40 percent.
- While the initial focus was on making existing data useful and accessible to the citizens themselves and the different health professionals treating them, there is now increasing focus on letting patients contribute to the portal in different ways.

4.5   Estonia

Estonia implemented a national electronic health record (EHR) in 2009. The EHR is built on Estonia's X-Road network, a secure gateway service architecture that hosts 3 000 eServices available to Estonian citizens. In January 2010, the eHealth Foundation launched a companion health insurance system for claims, reimbursement and prescription management. All end users of Estonia's EHR system can access their full personal health records. Physicians and patients have equal viewing access. And with nearly half the country's residents using the system within two years of its launch, the project appears viable for the long term. To date, the rate of ePrescriptions in Estonia's healthcare system is around 80 %. A full 100 % of radiological images, excluding dental, are now stored in the picture archiving and communication system (PACS). More than 95 % of the country's doctors are currently using the EHR.

4.6   Finland

The Finnish data system service for healthcare services, pharmacies and citizens is called, KanTa, the National Archive of Health Information. The services include the electronic prescription, Pharmaceutical Database, My Health Information, and Patient Records Archive. Under the Act on the Electronic Processing of Client Data in Social and Health Care Services, public healthcare organisations are obliged to enter patient records in a nationally centralised archive. Deployment of the centralised archive is mandatory for private healthcare organisations, if they have an electronic system for long-term storage of patient records. The deployment is optional for healthcare units in Åland. Under a change in legislation effective from 1 January 2011, the Ministry of Social Affairs and Health (STM) is responsible for the strategic steering of electronic data management related to social and health services, as well as deciding on the implementation of important projects. The operational management of the work is the responsibility of the National Institute for Health and Welfare (THL). In addition, THL is in charge of the code sets used in the KanTa Services. As from 1 January 2012, THL also promotes and supports the deployment of data

system services. The Social Insurance Institution of Finland (Kela) is tasked with the construction of the electronic prescription and Patient Records Archive data system services, as well as My Health Information for the citizens. The Population Register Centre (VRK) is responsible for the certification service for healthcare, and the National Supervisory Authority for Welfare and Health (Valvira) is responsible for the role and attribute services and related coding. Patient Records Archive are used via pharmacy and patient record systems. Kela is not constructing separate user interfaces for them. That is why deployment of the services requires changes to data systems used by pharmacies and healthcare services. The government is funding the set-up costs of the KanTa data system service, as well as making a provision in the budget for operating costs. The user charges for each service payable by clients will come into force in phases 2012-2015. The charges are set by a Ministry of Social Affairs and Health Decree at levels corresponding to the costs of providing the services.

4.7 France
France has implemented the Dossier Medical Personnel (DMP), accessible to patients through Web services and under the responsibility of the regional ARH agencies. In order to access the DMP the health professional need the consent of the patient who can also choose to deny access to certain health professionals. The DMP has been the subject of controversy in France with an appeal to the Council of State to declare it unconstitutional. The Council rejected the claim, but the government has subsequently instituted greater safeguards. Further, France has implemented the Dossier Pharmaceutique. According the French Pharmacists association, more than 25 million of Dossier Pharmaceutic have been implemented, and 97,6 of the pharmacies are connected.

4.8 Germany
Although plans for the introduction of a EHR system have been harboured by the Federal Ministry of Health for over ten years, there are still no electronic health records in Germany. The topic is widely discussed but progress has been marred by ongoing discussions between stakeholders including politicians, insurers, health professionals, and data protection experts. This has also contributed to widespread resistance and concerns over data security in the media and amongst the general population. However, as a compromise solution a basic electronic health card was introduced in 2011. It is available to citizens and has scope for development, but currently it only fulfils very limited functions (e.g., photo identification and double functioning as EU health card). There is no possibility yet for patients to track their records but tests are ongoing to extend the card's utility.

4.9 Ireland
Electronic medical records are poorly developed in Ireland: there are examples of EHR operating in some general practices, but not to any uniform system; EHR use in hospital practice is much less developed but there is an acknowledgement that this deficiency needs to be addressed and a number of pilot projects are currently underway between primary care/general practice and hospital services as well as between hospitals. At its core is the understanding that each person should have a unique health identifier that would be used in all healthcare situations. Many hospitals in Ireland have introduced the (PACS) radiology communication system. The government plans to introduce a Health Information Bill shortly

that will, hopefully, add impetus to movement on the wider application of electronic systems in healthcare delivery in Ireland.

4.10   Italy

The Ministry of Health has recently released new guidelines on EHR and on security issues. The idea is to create for the Italian Health Service a national interactive network where GPs are the most important actors. At a regional level many patient summary pilots are running and are highly developed. Some have already fully deployed a patient summary that includes administrative data and medical history. At national level there are also several patient summary pilots which are strongly linked to the "EGovernment Plan 2012".Italy is also involved in the European epSOS project where the Italian activities focus on the trans-regional transfer of medical data and the establishment of a patient summary as well as ePrescription.

4.11   Malta

Malta has recently introduced a Government portal for online access to health records. The portal is called myHealth. Patients and the doctors can choose who can access health data through this portal. The system is being implemented in phases. So far, the following data are accessible: inpatient discharge letters from 2008 onwards from the Mater Dei Hospital. Medicines' entitlements, some laboratory results and medical image reports (from 2008 onwards and hospital appointments. The information has to be released to patients by the doctor/s they are linked to in myHealth in order for patients to access it.

Patients may approach one or more doctors through myHealth, to give the doctor/s access to their data and to access results and reports released to them by their doctors in myHealth. Patients and doctors can also set up email notifications and SMS reminders for appointments. The site is secured by the Government's electronic identity (e-ID) system, so the service is available to all those who have a Maltese e-ID and their e-ID delegates.

4.12   Netherlands

After investing almost a decade and several hundred million euros in developing a national federated EHR, the underlying legislation presented by the Ministry of Health was rejected by the Parliament due to privacy concerns.[20] The ownership and operation of the infrastructure has since been transferred to a private not-for-profit organization in which healthcare providers, patients and health insurance companies have a controlling role. After tackling the most important privacy concerns, including a change from opt-out to opt-in for patient's participation in the national information exchange, the exchange has resumed full operation as of January 2013. Patient access to both health record access logs and the health information made available is part of the agreed development plan for the next three years.

According to a proposed amendment of the Citizen's Service Number Act, health care providers must provide patients a digital copy or digital access to their medical records.

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[20] Decision by the first chamber of the Dutch parliament on the framework law on electronic exchange of health information, April 5th 2011.

They also must provide a "client service desk" for health record consultation. At the "service desk" consumers can not only access their record but also indicate to which (groups of) health care organizations information might be provided or the permission withdrawn. How this counter can operate in practice still needs to be assessed. The Federation of Patients and Consumer Organisations in the Netherlands (NPCF) has been tasked with developing a framework for the development of a personal health record, which includes access to health information as maintained by healthcare providers and made available through the national federated EHR.

4.13   Poland

With an Act of April 2011, the Polish Government launched a plan for the introduction of a national EHR system. The act provides for the creation of the Medical Information System (SIM) which will provide access to information on a patient's given, awarded and planned healthcare. These data will be processed and made available in electronic form. The infrastructure intended to support the SIM will be an electronic platform for the collection, analysis and sharing of digital content for medical events. This platform will provide access to information about given and planned healthcare. It will also facilitate the exchange of data contained in electronic medical records which are needed to ensure continuity of treatment or conduct a diagnostic procedure. The implementation will start in 2014. The ongoing pilot project on EHR and eprescribing seem to be successful.

4.14 Portugal

In view of the national record system being fully rolled out – as indicated in a report by the government agency Administração Central do Sistema de Saúde published in February 2010 - a healthcare telematics network (RTS) has been set up in the Aveiro region.

The telematic health network (RTS) is a secure digital network that connects various healthcare institutions in the Aveiro region and provides information on patients' medical care. RTS integrates any medical information on patients that already exists in electronic format at the healthcare institutions that make up the network. Currently, it is the healthcare professionals who are responsible for registering each patient's medical data in each institution's electronic record. RTS allows healthcare professionals from other institutions to access this information. A portal for patients is currently under development. The Portuguese ministry of health has also defined ambitious e-health objectives and various online services will be launched for RTS when it is rolled out nationally. In particular, these services include applications for patients to monitor certain illnesses themselves, such as diabetes, high blood pressure, addictions, etc. and for treatments to be monitored (electronic prescription). Mobile versions of these applications (for tablets and smartphones) are expected to be released.

4.15   Spain

Several Spanish regions have the Electronic Health Record. Their regional data networks feature patient identification, e-prescription, EHRs and patient management.

4.16 Sweden

In Sweden there are many patient record systems but not an harmonized one. The Uppsala county council has given 250.000 people access to their own electronic health record. So far there have been about 20.000 actual users. The system was developed without consultation with stakeholders in relation to the validity of medical records and the possible risks. The Östergötland county council has around 300 patients who have had access to some parts of their EHRs since 2002. An evaluation in 2006 showed that access to the electronic record contributed to increased patients' interactions with health professionals despite the lack of information. The project highlighted the need to consider with more attention the special needs of vulnerable patients such as children, patients with trustees or victims of domestic violence.

4.17 Switzerland

In Switzerland, a national law is in preparation, containing the regulatory framework for an electronic health record. This electronic health record is based on a distributed architecture and will give the right to the patients to access their own record and to themselves allocate access rights to the attending health professionals.

Along with the national eHealth strategy an electronic patient record is implemented within several pilot projects in different cantons, in particular in Geneva. However, there is no wider experience yet. Difficulties arise from the federalist system, the lack of integration of the physicians, lack of incentives for physicians to invest in the infrastructure, lack of standards, etc.

On a private basis, several systems have been set up to provide patients with personal health data. One is insurance driven. It is run from the insurance company KPT, it is centralized and automatically updated by the insurance company (www.vitaclic.ch). A second one is a centralized system driven by a telecommunication company and it is updated directly by patients (www.evita.ch). And there are two pharmacy driven systems, www.abilis-net.ch and www.my-edossier.com. The latter is not yet operational and there is no central data storage. None of the four systems has really been entirely successful: patients do not seem to be very enthusiastic and health care professionals do not have much confidence in patient data which they did not enter themselves.

In addition there are a series of eHealth projects and implementations, the most important being in the canton Geneva (eToile), linking EHR from a series of healthcare providers (teaching hospital medical doctors, pharmacies, etc.).

4.18 United Kingdom

In January 2013, the UK health secretary launched the project "paperless NHS" in which digital records will be shared between all parts of the health and social care services. The launched was accompanied by a report claiming it could save nearly £5bn a year, after the costs are taken into account. The plan raised concerns about a repeat of the failure over the NHS National Programme for IT, set up by the previous government and scrapped by the coalition in 2011 because concerns over privacy after more than £6bn of public money had been spent. The implementation timetable is very ambitious: in 2014 hospitals and GPs should be able to access and update GP records, by 2015 all patients should be able to see

their own records online, and by 2018 the aim is for every part of the NHS and social care to be connected. Private companies could "potentially" be included.

In the meantime, the NHS in England is introducing Summary Care Records (SCRs) to improve the safety and quality of patient care. As at 03/05/13 more than 27 million records had been created across England. The SCR is intended to support patient care in urgent and emergency care settings. The SCR stores a defined set of key patient data for every patient in England except those who elect not to have one. This data make a summary record created from information held on GP clinical systems. This summary record helps in ensuring continuity of care across a variety of care settings. A patient's SCR contain key health information including details of allergies, current prescriptions and bad reactions to medicines. Following the creation of this initial SCR, a patient and their doctor may add additional information to the patient's SCR. This must only be added with the explicit consent of the patient. As the patient is treated they are asked by staff if they can look at their SCR every time they need to. Not everyone involved in the patient's care will be able to see all of their records. The amount of information staff can see will depend on their job. NHS staff who do not need to see information about the patient's treatment will not be able to view it – for example, non-clinical staff will not have access to clinical information unless it is necessary for them to do their job.

Also NHS Scotland is gradually introducing Emergency Care Summary (ECS) while the NHS Wales is developing a system of Individual Health Record.

5. Recommendations

5.1 Guarantee privacy and data protection and facilitate access
For eHealth solutions to be trusted and accepted by patients and health professionals it is essential to ensure that the system is secure and the data are fully protected.

Patients should be in charge of their own medical file, they should be able to 'log in' and inspect it. The option to access one's own information is a fundamental right that is embodied in the EU Data Protection legislation.

Patients should be provided with all the information to give truly informed consent, whether it is exchange, analysis, adaptation or removal of medical data. Certain categories of personal health data such as genetic information must be subject to especially strict access controls. A system of data modules or sealed envelopes could help establish a different level of confidentiality and restrict access to some information to some health professionals only. Moreover access to patients' health records should only be permitted to the health professionals directly involved with the patient's condition on a need to know basis.

Patients should be given the possibility to know who accessed their EHR and restrict access if they wish so and are informed about the risks of doing so. In 2010 the Belgian Consumer Organization Test-Achats[21] asked consumers about their expectations of eHealth solutions: 95% of consumers expressed the desire to view their own medical files and 89% believe it is important to see who accessed their medical file.

In cases of a breach of security, leading to the accidental loss, alteration or unauthorised disclosure of personal health data, the individuals concerned and the national data protection supervisory authorities should be promptly informed. It is also important to encourage the deployment of security-enhancing technologies and services to prevent identity theft or other privacy-intrusive attacks.

5.2 Ensure the highest level of quality and safety
The quality and the safety of the technology used, as well as the service associated with them, should be carefully assessed by the competent authorities[22].
The technology should also ensure a reliable identification of the patients and the health professional. eHealth systems should be fully safe from a technical point of view against breaches and crashes (e.g. backup system).
The quality and the safety of eHealth applications also depend on good infrastructures, including broadband internet connections.
EHR should be user-friendly and designed for, with and around their end users[23][24] - who should be involved from the early development of the technology. The information

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[21] Test-Sante, n.99, November 2010

[22] S.Hoffman , A. Podgurski, Finding a cure: the case of regulation and oversight of electronic health record systems, Harvard Journal of Law & Technology, Volume 22, Number 1,2008

[23] T. Greenhalgh et al.,Adoption,not adoption and abandonment of personal health record: case study of health Space, British Medical Journal, 2010. BMJ 2010;341:c5814

[24] C. Pyper et Al, Patients' experiences when accessing their on-line electronic patient records in primary care, British Journal of General Practice, January 2008.

contained in the EHR - and at minimum key information -should be provided in a language and with a layout which is easy to understand, also for people with special needs (e.g. older people, people with disabilities). EHR should be designed using a defined structure or form with predefined terms or coding but this would require significant coordination and adaptation efforts from health professionals.

When implementing an EHR system adequate consideration should be given to the needs of vulnerable groups such as children, migrants or people with mental and other disabilities.

5.3 Inform and involve stakeholders

Providing patients with additional tools to be more actively involved in the decisions regarding their health and increasing awareness of the benefits and the opportunities of eHealth is of vital importance.

Patients are entitled to clear information on the use and processing of their personal data. The implementation of a EHR system should be accompanied with information campaigns and training activities directed at the general public and health professionals.

Patients and health professionals must be educated about the nature and purpose of the equipment, any potential breaches of confidentiality inherent in the technologies deployed. In this respect, knowledge needs to be gained on how to influence cognitive, physical or literacy barriers on workflow and outcomes of using health records.

With the growing introduction of ICT services in all phases of the care process, the health professionals' responsibilities also increase. Therefore, there is a need to educate health professionals to make adequate use of these technological innovations, without affecting the patient health/professional relationship.

5.4 Improve interoperability and data portability

With Europeans becoming more and more mobile within and between EU Member States, developing clear and practicable interoperability standards is essential. It is therefore urgent to enable interoperability between health information shared among different health professionals and among different healthcare settings and systems provided that they guarantee a sufficient level of data protection. An adequate legal framework and networked infrastructures should be built to cover the entire continuum of care.

A change of culture in the healthcare management system and among health professionals' is also needed: the system should not be designed around the physician, the hospital or the insurance system, but rather it should be firmly focused on the patient. Hence, all measures should be put in place to allow the health record to move together with the patient.

ANNEX I

Available studies and material on EHR

1. European Commission studies and surveys

- "Interoperable eHealth is worth it: securing benefits from electronic health records and ePrescribing", European Commission, March 2010
http://ec.europa.eu/information_society/activities/health/docs/publications/201002ehrimpact_study-final.pdf
- **"**eHealth is worth it – The Economic benefits of implemented eHealth solutions at ten European sites" (2006)
http://ec.europa.eu/information_society/activities/health/docs/publications/ehealthimpactsept2006.pdf
- "eHealth priorities and strategies in European countries" (2007)
http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=3346
- eHealth in action – Good practice in European Countries" (2009)
http://ec.europa.eu/information_society/activities/health/docs/studies/good_ehealth/2009good_eHealth-report.pdf
p. 18 – CZ /IZIP a web based nationwide electronic health record system
p.21 – EE An internation-based digital health record system in Estonia
p.24 – FR two regional experience of electronic medical record (Rhône Alpes and Ardèche)
p.33 – LV/MIS web-based national health services management information system
p.48 – ES/Andalusia – DIRAPYA the electronic health record system of Andalusia
p. 52 CH – Computerised patient record systems at the University Hospitals of Geneva

2. Studies and report from other Institutions

- UK/NHS "Connecting for Health": programme encompassing a shared patient record
- **"**Management of patient information – trends and challenges in the Member States" , WHO 2012: http://apps.who.int/iris/bitstream/10665/76794/1/9789241504645_eng.pdf
- Dossier medical personnel, French Senate(2009)
http://www.ladocumentationfrancaise.fr/var/storage/rapports-publics/074000713/0000.pdf
- "A model for managing medical record information on the Internet for patients", Inera (Link)
- "A model for managing medical record information on the Internet for patients, Inera (Link)
- The Effects of Promoting Patient Access to Medical Records: A Review Stephen E Ross, Chen-Tan Lin, BMJ 2010 (link)

3. Position papers of stakeholders

- EHTEL position paper "eHealth – The Electronic Health Record" (2006)
- The French and the Belgian experience with EHR, COFACE http://www.coface-eu.org/en/Events/eHealth/
- BEUC position the electronic health record (2011).

ANNEX II

EU initiatives and projects linked to the EHR

1. **Digital Agenda for Europe – Key actions linked with eHealth**
-   Action 61: Educate consumers on the new media
-   Action 64: Ensure the accessibility of public sector websites
-   Action 65: Helping disabled people to access content
-   Action 66: Member States to implement digital literacy policies
-   Action 75: Give Europeans secure online access to their medical health data and achieve widespread telemedicine deployment → Data Protection
-   Action 76: Propose a recommendation to define a minimum common set of patient data
-   Action 77: Foster EU-wide standards, interoperability testing and certification of eHealth

2. **Health Action Plan 2012-2020**
-   2013 – Study on legal issues of electronic health records to make recommendations to the eHealth Network (CBHC Directive) – DG SANCO Public Health Programme
-   Support to the eHealth Network (CBHC Directive) in producing guidelines on a dataset for patient summary records to be exchanged across borders.

3. **The European eHealth Governance Initiative**
The eHealth Governance Initiative is working to establish a governance structure for eHealth within Europe in order to ensure continuity of healthcare both at home and across borders. It is achieving this through the development of strategies, priorities, recommendations and guidelines designed to deliver eHealth in Europe in a co-ordinated way. This work involves all stakeholders but especially patients and health professionals. The Initiative seeks a strong coordinated political leadership and the integration of eHealth into national health policies. It achieves this through its links to the Article 14 eHealth Network that brings together national authorities responsible for eHealth on a voluntary basis to work on common orientations in this area and to promote an interoperable and sustainable eHealth implementation across Europe.
The eHealth Network was established by Article 14(2) of Directive 2011/24/EU and it was considered desirable, in order to achieve coordination, coherence and consistency and to avoid duplication, that the eHealth Governance Initiative should operate within the framework of the Network and the objectives assigned to it.
More information is available at http://www.ehgi.eu/default.aspx

4. **Sustains project**
SUSTAINS comprises a rich basket of services based on giving citizens online access to their EHR. The services proposed have been distilled from the experience of regions which have already pioneered such access. The SUSTAINS Consortium is composed of regions in the EU leading in the area of innovation in services for citizens, and a number of user and professional associations all equally committed to the implementation of key

action 13 of the Digital Agenda for Europe. Regions will share their experiences and achievements to speed up the implementation of the SUSTAINS basket of services in a representative cross-section of EU regions. Patient empowerment is high on the agenda of the Consortium, together with great care in addressing the concerns of the professionals in what could be seen as a revolution in the patient-health professional relationship. Legal and ethical issues associated with online access by citizens to their EHR will be thoroughly explored, and lessons will be drawn from 11 pilots in 9 EU countries and disseminated to facilitate the implementation of similar services by other regions. http://sustainsproject.eu/

5. EPSOS

epSOS aims to design, build and evaluate a service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe.
http://www.epsos.eu/home.html

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