

Research Paper ■

Establishing a Personal Electronic Health Record in the Rhine-Neckar Region

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Abstract. We present the underlying vision, the approach, the current status and the gained experiences in the attempt to establish a personal and electronic health record (PEHR) system in the Rhine-Neckar Region. First, an electronic health record (EHR) shall be implemented, which is in a second step expanded by a personal health record (PHR) in order to form a PEHR. Integration between the PEHR and the source systems is achieved with international standards (HL7, DICOM, IHE) and existing technologies. Non-image information (alphanumeric data, e.g. reports, lab results) is replicated; image information is replicated and then referenced after 3 months for capacity reasons. The approach to use off-the-shelf technologies and existing international standards proved successful but current HIS/EPR systems need to improve their support. Major issues could be indentified for the management of access rights and data privacy when using only EHR approaches. PHR is superior for as well ethical as technical reasons. More attention has to be paid to organisational aspects in order to truly empower patients.

Uvajanje osebne elektronskega zdravstvenega zapisa v regiji Rhine-Neckar

Izveček. Prispevek predstavlja vizijo, pristop, trenutno stanje in pridobljene izkušnje glede uvajanja sistema osebne elektronskega zdravstvenega zapisa (OEZZ) v regiji Rhine-Neckar v Nemčiji. Prvi korak je uvedba elektronskega zdravstvenega zapisa, ki v drugem koraku z vključitvijo osebne zdravstnega zapisa postane OEZZ. Integracija poteka po mednarodnih standardih (HL7, DICOM, IHE). Neslikovni podatki so podvojeni, slikovne pa se podvoji in nato nanje sklicuje. Pristop se je pokazal kot uspešen, a potrebno je izboljšanje podpore. Glavni izzivi so povezani z upravljanjem dostopnih pravic in zasebnosti podatkov. V prihodnje bo potrebno več pozornosti posvetiti opolnomočenju pacientov.

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Introduction

In maximum care hospitals like the University Hospital Heidelberg, a substantial and increasing amount of patients is jointly treated with other care providers in the region. This reflects a general trend towards shared care which has taken place in Germany since the year 2000 due to substantial changes in the reimbursement system. An optimised prevention, diagnosis, treatment and rehabilitation strategy for the patient requires a tight and seamless integration of all participating care providers including hospitals, practices, rehabilitation institutes, labs and home care facilities.¹ This cross-institutional communication and the underlying data exchange can not at all or only partially be achieved with the existing hospital based HIS/EPR (Hospital Information System/Electronic Patient Record) or physician practice systems. It requires broadening the current scope to a cross-institutional shared electronic health record (EHR) which provides all required information to all participating care providers.²

This trend is supported by an increasing interest of patients to actively participate in their health care. Hassol et al.³ showed that most patients have a positive attitude towards online access to their patient record. Sprague⁴ indicates that mainly chronically ill patients have a substantial interest in their personal records and even wish to manually add information or remarks. Those desires require a new generation of patient records which is called personal health records (PHR).⁵ PHRs allow in addition to EHRs the manual data entry of information like e.g. wellness, alimentation, pain diaries or the upload of technical measurements from home care devices like weight, blood pressure or even ECGs by the patients themselves. Another main differentiator between PHR and EHR lies in the fact that the patient has full control of his personal record.

The objectives of this paper are to present the ISIS project (InterSectoral Information System), an attempt to establish a personal and electronic

health record system in our region, and to describe the underlying vision, the technical approach and the current status as well as the gained experiences.

Objectives

ISIS aims to improve the overall quality of patient treatment and in addition to demonstrate economic benefits. The co-operation partners shall have access to all relevant information, allowing a quicker, easier and more efficient diagnostic procedure and an optimized therapy. Multiple and duplicate examinations can be avoided and new co-operative treatment schemes supported in an optimal way.

The overall objectives of the ISIS project are the following:

- Empower the patient and maintain his citizen rights;
- Ensure that all participating care providers have access to all treatment relevant information and documents when required in an electronic way;
- Fulfil all data privacy and security regulations;
- Find a technically feasible and pragmatic solution allowing immediate implementation.

Vision

In a first step, an infrastructure for a cross-institutional communication will be installed which will host a physician moderated EHR and integrate a series of co-operating hospitals (Gesundheitszentren Rhein-Neckar GmbH, Universitätsklinikum Heidelberg) and physician practices. Once this is achieved, the focus shall be directed towards citizens and patients and the EHR shall be expanded to a PHR. The latter step empowers citizens and patients by having full

ownership as well as mastery of their personal documents and files allowing them to maintain their citizen rights and act self-determined also in the field of healthcare which in our view is the only appropriate way to deal with eHealth.

ISIS will provide an integrated and unified web-based view to all medical documents without replacing the primary source systems. The ISIS patient record will apart from the required administrative patient data like e.g. patient demographics and ADT information (admission, discharge, transfer) include diagnoses, important reports and discharge letters as well as OR information and images deriving from PACS systems. Technology-wise this will include data formats as ASCII tags, PDF, TIF as well as XML (CDA). Currently existing information systems within hospitals and practices remain untouched and will be interconnected employing standardized interfaces like HL7 and DICOM and web-based protocols. To ensure intra-operability also with future systems all interfacing should be achieved by national and international standards like HL7 and DICOM as well as IHE which will be exploited to a maximum in order to avoid proprietary solutions by all means. Full compliance with the German national telematics infrastructure shall be maintained wherever possible. The access rights and policies will be managed by a particularly granular rights and role based concept.

Methods

The ISIS project consists of three main phases. In phase 1, an EHR will be established between the University Hospital Heidelberg and its four partner hospitals from the Gesundheitszentren Rhein-Neckar gGmbH. In phase 2, the EHR will be expanded to further hospitals in the region and a series of physician practices will be included. Finally, in phase 3, a PHR will be developed and merged with the EHR.

For the implementation of as well the EHR as the PHR products developed by ICW AG (Walldorf, Germany) were chosen. The EHR will be based on the »professional exchange server« (PXS) product which includes a master patient index (MPI) as a basis for cross-institutional patient identification and a so-called virtual patient record (VPR). As PHR the product "LifeSensor" will be used.

For the first phase, it was decided to host the whole server backend for ISIS/PXS in the University Hospital's data centres. They are located in a separate subnet which is physically separated from the hospital's LAN. All access procedures are brokered by a web server positioned in the demilitarised zone (DMZ) of the University Hospital's firewall. All connections to this web server are SSL encrypted and employ https communication. On top of that, all external communications have to be secured via a VPN tunnel (virtual private network).

The overall architecture of ISIS is described in the following (Figure 1). All primary systems in the connected hospitals and physician practices send ADT information using an HL7-ADT message to the ISIS/MPI. For this purpose routine messages deriving from the regular data communication servers are duplicated and routed to ISIS.

After completion of the HL7-ADT message the MPI checks via complex mathematical matching algorithms whether the patient is already available in the MPI. Should this not be the case, a new index reference patient is generated. Alternatively, are matching patient demographics found within the MPI, the above mentioned matching algorithms will calculate »likelihood factors«. Above a certain threshold value, both patients are automatically merged. Beneath this threshold, the patient is put into a worklist which has to be processed manually by a clearing board installed in the University Hospital.

All clinical documents are transferred from the primary systems to ISIS via an HL7-MDM message and stored redundantly in the VPR; hence all clinical documents will exist in two

copies. One in the primary source system and one in the ISIS record. The term VPR is misleading since the documents are not only referenced as “virtual” would indicate but copied. The name was just maintained from the original manufactures’ branding.

Access to the VPR application will be granted via a standard web browser. This can be achieved in two ways. The first one is a manual logon directly to the ISIS platform and the second is a connection with the primary system. In the latter case, the patient and user context from a primary system are used in order to call the web-frontend of the ISIS platform and to jump immediately to the matching patient, removing the need for an additional manual logon for the users. Both approaches do not require any additional client installation on the users' PC.

Copying data does only partially apply to imaging objects deriving from PACS systems within the project partners' sites. A full duplication of all PACS systems would mean a tremendous data amount resulting in a substantial financial investment which did not appear as a preferable approach. Hence instead of replicating all images they will only be stored temporarily and then referenced after erasure. This image integration will be conducted via a CHILI web server (CHILI GmbH, Heidelberg, Germany). Imaging data to be interconnected with the ISIS record will be forwarded via DICOM from the PACS source system to the CHILI web server which is located in the ISIS subnet and stored here temporarily. Upon image arrival, the CHILI web server will generate an HL7-MDM message filled with demographics and study related information derived from the DICOM header of the incoming images and forward this to PXS. PXS will then generate an entry in the patient document list in the VPR. When this entry is selected by the user the images are requested and displayed in the web-frontend of the CHILI web server. This web server cache shall be configured in order to hold approximately three months of imaging data from the co-operation partners and works with the »first-in first-out« principle. When the requested

images derive from the above mentioned 3-month time interval they will immediately be displayed. When the images are older and hence erased from the cache, they will be requested automatically by the CHILI web server via DICOM from the primary PACS system and then delivered for display.

All requirements resulting from data privacy and protection regulations will be considered and fulfilled according to the currently existing legal frameworks. This includes patient approval for data storage within ISIS in general in a very granular way. Each user, as well as the primary systems, are authenticated to the platform in order to get access. A role-based access concept allows a highly sophisticated and differentiated access to the patient data only when a treatment context is present and can be proven based on the ADT messages. In the case of referrals which are not associated to ADT messages, access rights can also be provided manually for a limited time period which may be applicable in cases of second opinion or advice. In addition to the above mentioned methods, the system provides an emergency button, which allows a quick and effective access to the patient core information. In all cases including the emergency scenario, all user actions and accesses to documents are logged in detail.

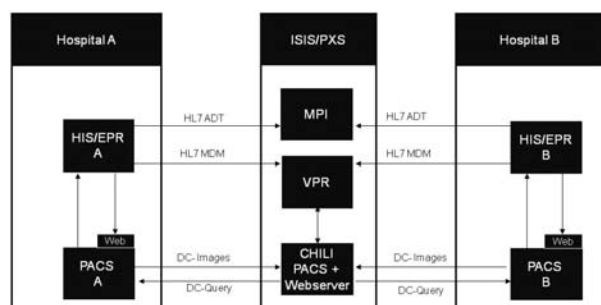


Figure 1 System architecture of ISIS (InterSectoral Information System). PXS = Professional Exchange Server; MPI = Master Patient Index; HIS/EPR = Hospital Information System/Electronic Patient Record; DC = DICOM.

Results

The conceptual stage of ISIS has been concluded and phase 1 is in implementation. On the technical side all hard and software installations of PXS including the MPI and VPR as well as the network configurations of the ISIS servers and subnets have successfully been accomplished and tested. On the university hospital side all required changes to the message-based communication have been implemented. This includes the HL7-ADT messages which were extended by the information whether the patient has approved data storage in ISIS. An additional HL7 messaging path was created in cases where the patient would initially approve but at a later point in time withdraw his approval. For the patient information a workflow procedure has been established together with the patient administration department and the treatment contracts have been modified to inform the patients about the features of ISIS and their rights in this context. For the MDM messages special mimics have been developed in-house for the hospital's EPR in order to enable document exports. This task required a thorough analysis of documents to be exported and the point in time for the export. It was decided to export only finally approved documents. However, even then amendments or revisions may occur which had to be considered in an updating mechanism throughout the data flow chain. According implementations and tests are currently being conducted for the partner hospitals.

The experiences within the project as so far have clearly indicated that there exist two main areas of problems for the implementation of an EHR. Whilst the technical issues were difficult but solvable by sticking to pragmatic approaches and established standards, we faced substantial problems with the data privacy aspects. The essential experience from our project is that despite the information which is currently communicated within the community that eHealth was safe, we could not find a solution satisfying all requirements of all involved

stakeholders: the patients, the care providers in particular physicians and the IT. An in-depth analysis revealed that the requirements of each group were comprehensible but, and this is the crucial point, contradictory. Fulfilling all needs and requirements of one party would automatically lead to a breach of desires of another group of stakeholders and vice versa.

Discussion

Our experiences indicated that HIS and EPR software manufacturers are facing new requirements. Until so far the capabilities of the systems were concentrated on receiving data from various hospital internal subsystems. However, cross-institutional data exchange requires in addition the export of all documents and in addition of structured information like diagnoses or procedures and other elements like e.g. medication data in a standardized way. We could not solve those requirements with the functionality natively provided by the HIS/EPR systems involved in our project and hence had to develop it in-house, which is obviously an unsatisfactory situation since by far not all hospitals and regions will have the capabilities and knowledge to do that. Since the request for cross-institutional data exchange is tremendously increasing we believe that the pressure on the software manufactures will rise and hopefully in the near future lead to an extended support of the applicable IHE-XDS profiles (Integrating the Healthcare Enterprise - Cross-enterprise document sharing). This trend would certainly be supported by more and more hospitals requesting this functionality as a substantial criterion for a HIS/EPR selection. But also another message can be derived from this situation. With the evolving HIS/EPR market we see companies becoming more international and offering Pan-European products. They will not be able to implement and maintain integration with a variety of national or even regional EHR solutions or "standards". A fragmented market would only lead to a lack in quality and seriously jeopardize the sustainability.

Hence we strongly recommend abstaining from trying to foster national standards in favour of using international standards wherever possible.

It was evident that conventional data privacy and access policies do not at all suit the needs and requirements for cross-institutional communication via EHRs. Since it is impossible to simultaneously fulfil all needs of all participating stakeholders (patients, care providers, IT) the particular interests obviously have to be weighted against each other. We believe that priority should be given to the citizens and patients. It is in all our interest that traditionally established in-house concepts are substituted or completely replaced in order to achieve proper privacy and not violate the citizen's rights. We conclude that in particular the nationwide implementation of EHRs requires much more thoroughly conceptualized and implemented data privacy approaches unless citizen maturity and self determination is abandoned to a high extent as can be observed in an astonishingly high amount of EHR projects across Europe. This carries a substantial risk for abuse and the inherent jeopardy can hardly be underestimated considering the upcoming of personalised medicine and the increasing amount of genetic information prospectively to be found in EHRs.

We believe that PHRs offer the only possible solution to address and solve the described privacy issues. In PHR scenarios, the focus is on the patient and citizen who are the exclusive owners and only actors in granting and taking access rights to cross-institutional information. In our eyes PHRs are the only way to ensure citizen-centred eHealth and maintain full citizen self-determination in the long run, unless a breach of the civil rights is accepted. But apart from the ethical justification we also consider PHRs technology-wise an easier approach to establish cross-institutional data exchange. Both aspects together laid the conceptual foundation for our project. In addition a PHR-based eHealth concept will also be capable of easily integrating home care and ambient assistant living systems in order to establish a fully integrated clinical documentation.

Since we believe that elements classically considered being either only EHR or PHR have to be merged we call it Personal Electronic Health Record (PEHR).

In general astonishingly little attention is paid to the organisational aspects surrounding eHealth and the importance appears under-estimated. Although the concept of "empowering" the citizen is universally present in eHealth discussions, and often mentioned as one of the big advantages, the degree of concreteness is very low and the visions are quite blurry when compared to the elaborate level of technological proposals and solutions. There is a lot of work to do including a general definition of ethical principles for eHealth, putting the citizen in the centre, and a revision of the existing legal frameworks, in particular in order to strengthen the patients' rights and to establish substantial fines for violations of data privacy. Evidently, the citizen can also not be left alone with the task to appropriately manage access rights to clinical documentation in a PHR context. Similar to seeking a lawyer's advice in legal matters we imagine a neutral supporting structure in the medical domain.

Conclusion

Our experiences in the ISIS project show that the concept of using technologies and international standards existing today in combination with a pragmatic system architecture approach is valid and demonstrates quick results. However, HIS and EPR vendors have to extend their capabilities in order to better support cross-institutional data exchange. But the most important experience is that a major revision and re-thinking of data access and privacy concepts has to take place in the eHealth domain. Especially considering the trend towards personalised medicine and the upcoming inclusion of genetic information into cross-institutional patient records, emerging from the evolving integration of bio- and medical informatics, demands an appropriate solution.

We believe that PHRs are a strong asset in order to avoid abuse and allow full data privacy and patient empowerment. Other than today the patient has to be put in the middle of the ongoing eHealth discussion in order to maintain his rights and decide which institution and which physician has access to which information, if any. In order to achieve this degree of patient empowerment ethical guidelines have to be provided, the legal framework has to be adjusted and especially designed support structures have to be established which have to be neutral and provide full trust to the citizen.

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