Goals and Challenges for the realization of a European wide eHealth infrastructure

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Abstract: A number of Electronic Health Record (EHR) standards and frameworks have been developed to assist with the interoperability and integration of distributed EHR information. Ideally, all EHR systems would adopt common and systematized hierarchies of component names, use multi-lingual clinical coding systems with perfect cross-mappings and use identical reference models for measurements. However, this has not been realized yet. Not only do a number of international health information standards exist, such as CEN EN 13606, HL7 and GEHR, but each country, state, division, hospital and vendor usually has their own "standard clinical data model". Since it is not realistic to expect to have a single universally accepted clinical data model that will be adhered to all over Europe and that the clinical practice, terminology systems and EHR systems are all a long way from such a complete harmonisation. This paper presents some results of the RIDE project; a project that will address the interoperability of eHealth systems with special emphasis on semantic interoperability. The paper describes relevant goals for the development of the eHealth sector in Europe that have been identified in the project as common requirements for many eHealth applications and names the technical and organisational challenges accompanying these goals.

1 Introduction

RIDE is a roadmap project for the interoperability of eHealth systems leading to recommendations for actions and to preparatory actions at the European level. This roadmap will prepare the ground for future actions as envisioned in the action plan of the eHealth Communication COM 356 by coordinating various efforts on eHealth interoperability in member states and the associated states. It is unrealistic to expect that there will in a short or medium-long time span be a single universally accepted clinical data model that will be adhered to by all of these groups. Clinical practice, terminology systems and EHR systems are all, hence, a long way from such a complete

harmonization. Therefore, this problem can better be addressed at the semantic interoperability level. Semantic interoperability is the ability for information shared by systems to be understood at the level of formally defined domain concepts so that the information is computer processable by the receiving system.

2 Methods

In order to create the RIDE Roadmap, first the European best practices in providing semantic interoperability for eHealth domain where assessed and quantified requirements to create a valid roadmap were identified. Based on these requirements, the goals, and the economical, legal, financial and technological challenges of the industry for the 21st century for achieving interoperability in eHealth solutions are elaborated. In the RIDE report on Requirement Analysis [Ride06] we discussed a plenty of scenarios appertaining to the eHealth domain. The following requirements have been identified to be common to many of the eHealth use cases described:

- Network and policy infrastructure enabling a consistent, appropriate, and accurate information exchange,

- Methods to identify patients locally and globally,

- Methods to identify and determine providers of care,

- Security and privacy policies and consent,

- Coding, vocabulary and normalization standards,

- Solutions for the legal and governance issues regarding data access authorizations, data ownership, and data use, and

- Scalable infrastructure and content to start with.

At this time every European country handles these issues differently. Additionally, we provided the current and envisioned situation for all these subjects [Ride07]. Furthermore, in the first RIDE workshop we collected additional input from key persons in the healthcare environment. The input was enriched by a specific questionnaire to active members in healthcare who were asked for comments and reflections about the future development of digital healthcare. Further input was gathered with guided personal interviews which were made with persons and institutions affiliated to the healthcare domain. To deal with the different topics, the RIDE Project worked out nine different goals that should be achieved for a European-wide eHealth system with a highly interoperable functionality [Ride07a].

3 eHealth Goals

Goal 1: Europe-wide secure network

In general, most of the eHealth application scenarios [Ride06] require the presence of a secure health care network that can be used for a secure and reliable transmission of messages and documents. The set of envisioned applications for such a network includes electronic access to patient and healthcare professional identification, patient demographic data, and to information stored in electronic health records (EHRs) or excerpts thereof, patient summaries, and emergency datasets including previous medications, lab results, images etc. The "tele-distribution" service for such content types becomes more and more important for the collaborative care in eHealth scenarios. The structure and content of the different document types mentioned above that might be communicated is not in the scope of this goal. As a result of these considerations, we can define the goal as follows:

> *"Establish a European Health Network IT Infrastructure which connects existing local Member State health IT networks and facilitates secure, reliable, and privacy preserving exchange of emergency datasets, medical summaries as well as electronic health records and excerpts thereof between the (non-)clinical healthcare providers in Europe across Member State boundaries considering authorization, authentication, and patient consent requirements."*

This goal is relevant to medical care providers who need to access emergency datasets, patient summaries, and/or EHRs or excerpts thereof –below simply referred to as medical documents– electronically pertaining to patients they are currently providing care to and that are available from Member States within the EU. The technical descriptions are dedicated to cross Member State communications and access to medical documents. [CEN00] [SSA06]

Goal 2: Emergency Dataset

Sometimes a patient is not able to provide any form of medical history, and immediate medical aid is necessary for the maintenance of life functions, for example in cases of accidents. Once the immediacies of resuscitation are taken, the emergency dataset can be used to identify the patient, establish access to the most relevant information about known health problems or past medical history and at last to contact the husband, wife or other kin. Some aspects of the dataset may assume major importance in the second phases of resuscitation once life processes are controlled.

Even if the patient is accessible he might not know exactly the major information about his current medications, his allergies, blood type and normal vital status. The patient may not able to provide an adequate medical history to aid the actual process of care.

For such situation there is a need of an emergency dataset containing these essential clinical information and some administrative data. These data have to be carried by the patient at all times and must be accessible even without special devices.

In the real world, emergency care is so complicated and diversified that we have to consider the scenario for the utility of emergency data set in advance. [CEN04]

Goal 3: Patient Summaries

The documentation of all observations made and procedures performed during the provision of care is considered an integral part of medical practice. The documentation of prior episodes of care is an important input to the medical decision making process. Today, a patient most often receives medical treatment from different health professionals in different organizations over his/her lifetime – a family doctor, specialists, and hospitals to just name a few. In this situation it is of significant importance that the healthcare professionals involved in the care delivery of a patient communicate, exchange clinical documentation. Such clinical documentation may range from condensed abstracts of prior episodes of care (medical summaries, access to prior lab results etc.) to a complete, cross-institutional longitudinal electronic health record (EHR) that covers the complete lifetime of a patient. Since the medical documentation takes place in digital form in many healthcare enterprises today, an electronic exchange of such documents and data is an obvious application scenario for any eHealth infrastructure, since a digital exchange of digital documents and data avoids error-prone conversions between digital format and hardcopy, accelerates the transfer and allows for a re-use of machine-readable (coded) information when available.

Such summaries are used for different purposes, to comply with shared medical pathways or to make information available for unexpected contacts. Summaries may include identification data on the patient and on the next of kin, the clinician and the insurance in the dataset header. The summary body can be divided into sections about medical history, allergies, current problems, lab results and medications. Further information and links to external data like images or waveforms may be included in the summary. [TAB+06] [Rec06]

Goal 4: Electronic Health Record

The Overall or Virtual EHR represents the full collection of electronically "available" patient related information. Each instance of an EHR has to be considered as separate operational entity. Each instance of an EHR generates original and specific health and care related data. Each instance of an EHR forms an application enabling appropriate management of a patient's condition. An optimal management needs to involve all the information regarding the patient.

The ultimate goal of the Interoperable EHR should be the full availability to any authorized care giver of the appropriate patient related information, considering the legitimate preferences, consents and/or refusal of the patient. The full bi-directional connectivity not only to devices of any kind but also between the different components of the Overall EHR and even the Personal EHR (also called Personal Consumer Health Record, PCHR) of that patient. The full/maximal use of health and/or care related decision support and monitoring tools provided anywhere by any service provider. [EAR+05][CEN04]

Goal 5: Clinical Guidelines, Evidence Based Medicine

The idea behind this goal is to have an IT infrastructure that supports the execution of clinical guidelines to consult and assist physicians treating patients. Such systems should be able to propose individual evidence based treatment paths to the physician tailored to the patient's disease symptoms. These treatment paths should be changeable and adaptable.

The information cycle concerning patient diagnostics and treatment as well as aftercare is of growing velocity. Individual physicians can barely follow every development in science and biomedical development and structure their delivery of care along the best possible practice for the patients. Clinical Guideline systems should be able to react on newest developments in scientific research taking into account the most recent studies, performed in the sense of evidence based medicine. The interface to clinical organization systems should accept easy queries and present understandable and easy to interpret results, tailored to the patient's disease or symptoms.

Goal 6: Decision Support Systems

The idea for decision support systems is to assist physicians making diagnostic or therapeutic decisions. Assistance should be given regarding possible or most likely problems that might occur, e. g. in case of specific therapeutic decision. In the latter case the system should also warn the physician in case of a potentially wrong or risky decision. Possible applications of decision support systems are for example computer assisted diagnosis/detection and ePrescription.

In times of increasing workload in hospitals, as well as in private healthcare sectors an additional support of the care deliverers is urgently necessary. This support has to take newest developments into account, should comprise encyclopedic knowledge and should be able to react on changes in the patient's status immediately. The point of start will be EHR systems. These systems have to monitor the patient's health status and should have internal functions available to draw conclusions from different input. Decision support has to be a rule based system, which may be supported by Clinical Guidelines and results from Evidence Based Medicine.

The main two differences to clinical guidelines are that decision support systems do not necessarily need to be integrated into an electronic workflow and that they are based also on simple rules that may only depend on institutional decisions and policies.

Goal 7: Semantic Interoperability, Classification Standards, and Coding Schemes

Clinical data and information are still largely collected and disseminated on the basis of terminologies and coding systems devised by diverse disciplinary communities in ad hoc and inconsistent ways. The result is that data generated for one purpose are very hard to reuse for other purposes, and the results gained from analyzing these data do not contribute towards an evolving comprehensive picture of human well being and disease. Europe's long-term vision in these matters must be one in which the data generated in the course of biomedical research and practice will form a single, consistent and

cumulatively expanding algorithmically processable whole. The envisioned long-term benefits of this will be a better understanding of the complex multi-dimensional processes underlying human disease, an enhancement of our ability to reuse data, an improved organization of research, and opportunities for new kinds of information-based research cooperation and clinical care. The aim must be to have semantic interoperability on different levels, EHRs and excerpts like emergency datasets and patient summaries up to system interoperability. A basic requirement is that classification standards and coding schemes must be harmonized or need to be made interoperable, i. e. basically mappable. Ideally an emergency dataset, patient summary or complete EHR can be read and interpreted from different medical information systems, ideally including decision support systems, clinical guideline systems and workflow systems. [CHJ+89] [BKB+06]

Goal 8: Unique Identifiers

A cross enterprise or even cross country border electronic provision, retrieval, and access to patient centric medical information is rarely seen nowadays. This has several reasons and one is related to the multiplicity of medical documentation and communication standards and proprietary solutions between which interoperability is not possible or limited. Another reason is that in most countries no nation-wide systems for patient identification like unique national patient identifiers and identifiers for healthcare professionals and healthcare providers are available. Methods to enable cross organization identification of patients, healthcare professionals, and providers are necessary to allow for localization of medical records pertaining to a patient in question at hospitals or practices. Such mechanisms are required to enable access to distributed patient centric data for example to gather information about previous treatment episodes without the necessity that a patient needs to remember all healthcare professionals and providers where s/he has been treated. Marking documents digitally with identifiers for healthcare professionals and providers is mandatory for legal transfer and use of medical documents and would allow for documenting their origin. Furthermore an exchange of medical data requires that sender and recipient of a document can be identified and identity details including the current concrete profession and authorization can be queried from any trustworthy site. This holds for medical professionals as well as for providers. Besides the technical practicability on all levels mentioned above, legal aspects such as patient consent and access rights must be considered. [AHAI04]

The goal can be formulated:

> *"Establish within an European Healthcare Network an infrastructure for unique patient, healthcare professional and healthcare institution identifier creation, maintenance and application, considering data privacy, patient consent and further legal aspects in order to facilitate medical record localization and communication across country borders of the member states as well as healthcare professional identification.."*

Goal 9: Business Process Interoperability

The cooperation between different partners in healthcare makes it inevitable that the complete business structures will have to adapt to the information exchange processes and have to offer a sustainable environment.

eHealth interoperability will not occur without a shared policy and a process framework that supports appropriate business collaboration models and provides a sustainable environment in which interoperable solutions can be created, deployed, and managed. Coordinated business interactions require a common understanding of business function even though alternative delivery mechanisms and channels may be employed. A patient may visit various organizations or units within organizations to get proper diagnoses and treatment. The role of *healthcare workflow management by use of IT* is to adjust the contributions of those organizations or units in terms of timing, quality, and functionality. [SWE06]

Workflow management technology can play an important role, because it helps to organize, automate and improve business processes. Supporting clinical processes with information technology requires workflow specification (i. e., the identification of tasks, procedural steps, input and output information, people and departments involved, and the management of information flow according to this specification).

In the light of the above considerations, one goal should be to automate and simplify the management of critical, complex healthcare transaction processes that span multiple systems, multiple formats and multiple trading partners, thus transforming Core Business Processes while Enabling Health Information Exchange (HIE) and Electronic Health Record (EHR) Interoperability. Business Process management will facilitate intelligent interoperability with various trading partners; healthcare providers, intermediaries, third-party administrators (TPAs), Pharmacy Benefit Management (PBMs), financial services, care management partners, etc. [Wag+04]

Consequently, the following goal can be derived:

> *"To define the models, methods and systems of workflow management for achieving business process interoperability (BPI), internally and across healthcare domains in the European Member States".*
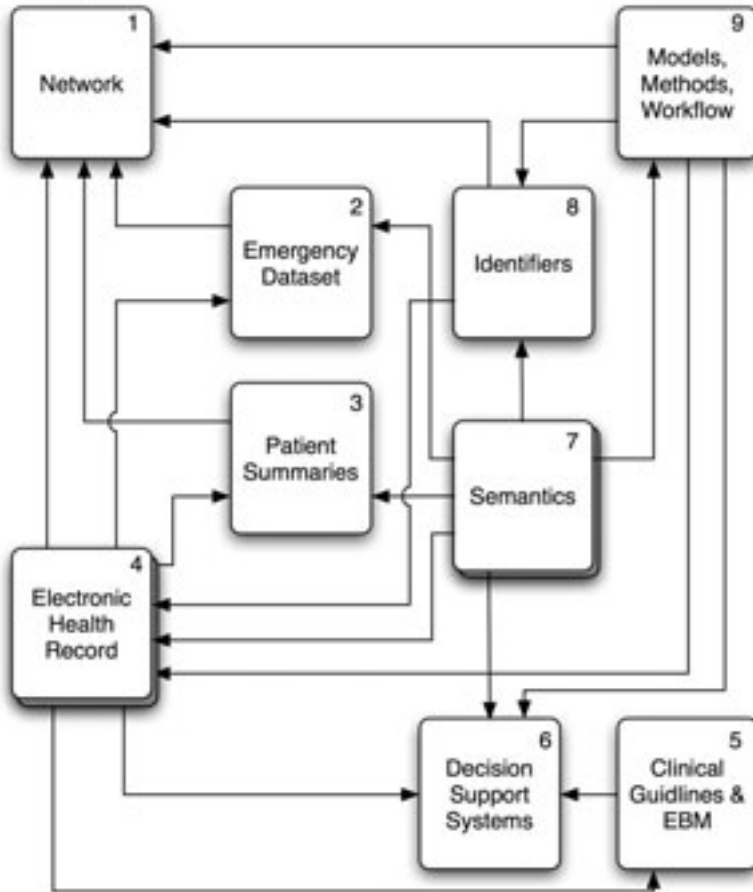
Figure 1: Dependencies between the Goals

Figure 1 shows the dependencies between the goals identified in [Ride07a].

4 eHealth Challenges

In previous chapter, nine different goals have been defined and as a result of the Roadmap process in the RIDE Project we identified five global challenges associated with these goals.

Identifiers: All well-defined systems need specific, unambiguous identifiers for subjects (e. g. health professionals, patients, and organizations), objects (e. g. documents, roles) and transactions. Those identifiers have to be retrieved from authorities that will create, hand out and maintain them. The law in different Member States of the EU does not

allow for the use of a single ID number for every purpose, therefore, different IDs have to be organized and managed. To avoid complications, matching algorithms and clearing authorities have to be established that are able to completely identify a person or institution based on demographic information. Even if distributed, those services have to observe a centrally defined structure and way of information propagation. Combined with the identifiers, roles and activities have to be defined. Especially the roles of the healthcare providers have to be clarified. This information will decide whether access to specific medical and personal information of the patient is allowed or denied. Roles (as well as the patient's preferences) also decide about the rights of entering data into medical records. [CS06] [WHO04]

Semantics and ontology: Nearly all goals described in this document require a precise representation of the "world". To guarantee interoperability, all systems involved have to understand the same content by even if using different wording or language. Problems will arise if ethnological understanding will differ from each other, causing slightly different meanings of standard understanding. Those information needs to be set up for single items, metadata descriptions, and process understanding. Interfaces – even between devices and EHR – will be easier to be built and the overall information transport would be facilitated. However, the obstacle is that not only one coding system is available, but many – for example, the Unified Medical Language System (UMLS) of the US National Library of Medicine provides cross-references for more than 100 controlled vocabularies. Since this is a main problem, most of the new efforts should be brought into this definition. However, it should be possible to tailor the work to the first need of dedicated areas. That would help to start in specific areas of the healthcare system earlier. Standards will be less important if definition of semantics will be sufficient on a higher level. [Rec+99] [Smi+06]

Chain of trust: Security is a complex issue and contains a lot of facets. For the specific and very sensitive data of the patient and the attending physicians no risk is allowed, that might impede their work or disclose data of neither of the partners in healthcare at the wrong place and time. Starting with encryption of medical data, information has to stay in a trusted "infoway" all over the time. Logistics to support this process, i. e. secure identification processes, audit trails for understanding and tracking the flow of information, signal encryption and digital signatures are necessary. Overall, an electronic patient's consent (explicitly stated or implicit to the specified topic) has to control these information pathways. Digital certificates, authorized by trust centers should accompany the transfer and activation of other cryptographic means. [SSA06] [Mar04]

Technical challenges: The information society sets up new challenges for the technical solutions. Besides a mostly permanent access to the central database servers of the trust centers there has to be a device that allows for an offline verification and access to medical data that are stored in the emergency dataset. The new introduction of semantics and/or ontologies require applications that have the possibility to draw conclusions from a multiple-entry database, reflecting all necessary meta information on the ontology. The main server has to react on short notice to guarantee seamless information flow without handicap. A synchronization between offline media and the

more centralized EHR or decentralized practice information systems has to be realized. The network has not only to be secure in terms of cryptology, but also in terms of functionality. Second loops of pathways should be available. From a technical perspective also matching algorithms have to be developed that might cover the needs of fuzzy but definite matching personal information with stored information.

Personal and society issues: One of the most difficult challenges is located in this category. These issues cannot be solved technically alone, but have social and educational components that take a longer time of consistent and complex changement efforts. Education is a main topic. This combines education of the actors like healthcare professionals, but also of the patients, that have both to accommodate to the digital means and policies to digital actions. They will have to practice and adjust to digitally organized work and business models. To deal with a hybrid paper and digital based health record will cause additional efforts. Politicians have to adapt existing rules and laws to meet the needs of the digital area. All have to perceive the new way of thinking and acting. [TAB+06]

Business model: The driving force will be the cycle of healthcare delivery and reimbursement. New models of incentives have to accompany the introduction of the digital means. The new systems to be introduced must be refinanced; both additional gains through higher efficiency of work and improved care have to return on the investment of new systems. [Wag+04]

5 Conclusion and Outlook

Within the scope of the RIDE roadmapping process we had the opportunity to examine the requirements and envisioned situations for specific parts of eHealth interoperability in detail. As it has become clear from these analyses, some of the issues identified have very similar or even identical requirements which can possibly be harmonized and grouped. In this document we presented nine major goals that have been derived from these requirements, each encapsulating one or more of the requirements. Dependencies between these goals, respectively requirements on which the goals are based, demand a prioritization of the goals regarding their implementation, i. e. some issues are more critical and should be considered before others. The goals identified delineate more general views and might be adapted to more specific use cases.

Based on the presented work, the next steps in the project will be

- The analysis of the gaps that exist between the "state of the art" ongoing in the eHealth domain (as-is situation) and the desired future description identified in the RIDE vision statement for achieving semantic interoperability in eHealth (to-be situation).

- The documentation and an analysis of the current trends and opportunities in health care IT interoperability with special emphasis on those trends and opportunities which affect semantic aspects of interoperability.

- The development of an implementation guide for member states to reach the vision defined for European eHealth system.

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