HEALTHCARE INFORMATION SYSTEMS IN A NETWORK ENVIRONMENT

An Interoperability Model and a Real Case in a Pathology Network

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Keywords: eHealth, Healthcare Management Systems, Electronic Health Record, Semantic and Syntactic Interoperability, Pathology Networks.

Abstract: Interoperability between Healthcare Management Systems is a fundamental requirement to improve the quality of care, to assure patients continuous assistance and to improve clinical research. Pathology Networks create a common virtual environment which allows to overcome single HIS' borders, by connecting different healthcare organizations adopting common formats to share clinical data and, consequently, knowledge. Syntactic and semantic standards are paramount to enable interoperability in this context, since common document formats ensure efficient communication, while internationally known vocabularies allow the unambiguous interpretation of contents. This paper has the purpose to show a real experience of participation to a Pathology Network, providing a model based on open standards which could be taken as a reference model for similar initiatives in other healthcare environments. Benefits resulting from such an initiative will be presented, in terms of improvement for clinical research and quality of patients' care. The real case we describe is an example of how Pathology Networks can provide scientific features to Electronic Health Records, by adding information not usually reported on standard clinical sheets, but necessary to perform new analysis with the purpose of improving clinical research.

1 INTRODUCTION

Interoperability between clinical information systems represents one among the major opportunities of health informatics. The spreading of many solutions in the field of Electronic Health Records provides a great amount of digital data about patients, potentially available to feed scientific research in order to improve the efficiency of clinical processes (Chauldry et al., 2006). An interoperable infrastructure to enable data sharing is paramount to best exploit the potential represented by digital information: daily activities performed by physicians and nurses are sources of a great amount of data, whose value in terms of clinical and scientific research could be enhanced if handled and stored in a standard formats. In order to allow this interoperability, it is necessary that syntactic and semantic standards are provided: the former are needed in order to assure a common representation to the data which are transferred, while the latter are required to assure unambiguous interpretation of their meaning.

This direction is being followed by initiatives known as "Pathology Networks", whose aim is creating a cross-organizational virtual database for patients affected by a same disease.

This paper analyzes the concept of Pathology Networks, their features and purposes, also by presenting a reference model which could be taken as a basis for such initiatives in different healthcare contexts. The case study we describe is the solution implemented at "Fondazione IRCCS Istituto Neurologico Carlo Besta".

2 A REAL CASE: EPINETWORK, THE EPILEPSY NETWORK OF LOMBARDY REGION

In line with interoperability objectives fixed by Italian Ministry of Health, the Region of Lombardy has laid the foundations for the creation of four Pathology Networks, concerning Rare Diseases, Epilepsy, Haematology and Oncology. These networks enhance contact among clinical and research centres working on the same pathologies, provide a coordinated assistance to patients, helping to ensure the delivery of high quality care processes, empowering clinical research and spreading the outcomes among the different actors.

Among the various initiatives, adherence to Epinetwork, the Epilepsy Regional Network, is being analyzed at Fondazione IRCCS Istituto Neurologico Carlo Besta in a research supported by the Italian Ministry of Health within the project "Web Integrated Information System for the management of clinical and research activities in the field of the neuroscience and the implementation of individual electronic health record", coordinated by the Institute and with the participation of A.O. Ospedale Niguarda Ca' Granda and Fondazione Politecnico di Milano. Istituto Besta is an internationally renowned centre of excellence in the care of neurological diseases and, among them, Epilepsy: physicians and researchers of the Institute worked in a team of experts coordinated by the Region of Lombardy in order to define semantic standards needed to identify an epileptic patient and to provide all information required to follow his care process. A.O. Ospedale Niguarda, together with Fondazione Politecnico di Milano, a research and innovation partner connected to the Politecnico di Milano technical university, is working at a technical solution for the Institute, by exploiting the methodology already followed during previous experiences in the development of a reference solution for the Hematologic and Oncologic Regional Networks.

The solution will exploit the features provided to the Electronic Health Record (EHR) which the three partners are already realizing for the Institute (Locatelli et al., 2009) ; each feature was analyzed and developed trying to produce as much structured data as possible, with the purpose of creating an operative tool aiming at supporting ordinary activities in a complex system able to provide useful information to feed scientific research. Among Besta's scientific pipeline, Epilepsy represents an opportunity to create a structured methodology to collect data, which overcomes the Institute's borders, thanks to Epinetwork regional initiative.

3 A REFERENCE MODEL FOR PATHOLOGY NETWORKS

A Pathology Network is the concretization of an "inter-corporate virtual department" in which operators involved in the same pathologic treatment can profitably contribute to the process of diagnosis and care, even if operating at different geographical sites. This way of cooperation envisages, within a wide domain, that highly specialized medical hubs, qualified for high complexity treatments – as intensive chemotherapy, stem cells transplant and haemorrhage emergency management - and smaller peripheral institutions could not only share and exchange knowledge and opinions but, above all, publish on the Pathology Network all medical reports produced after patient's treatment.

By following well known international standards, it will be possible to study homogeneous data collections, i.e. to analyze a wide range of disease cases monitoring the results of new clinical experimentations, or to compare different treatment schemes with the purpose of defining common care pathways for specific diseases and establishing prevention practices (Tang et al., 1994).

The keystone in a Pathology Network is represented by the implementation of a technological platform linking clinical databases of all hospitals involved in the network and enabling the exchange of clinical data (e.g. patient cases, scientific knowledge, etc.). This platform should be carried out in a flexible way, in order to interconnect the heterogeneous clinical data repository of each nodes, realized with different technologies, various information systems and data management tools.

Data sharing for each clinical episode takes place only at a logical level, not at a physical one: this means that clinical reports are not sent to or received from hospitals but what is really shared is the logical link by means of which each document can be univocally retrieved by a HIS at its physical location.

Italian Region of Lombardy is bringing forward initiatives in this sense, with a centralized structure represented by the extranet SISS (Italian acronym for Social Healthcare Information System) and a central domain embodied by an EHR called FSE, a database collecting data related to the whole clinical history of a citizen registered to the National Healthcare Service (SSN). The cooperative logic

characterizing the FSE structure lets each subject involved in the network act both as supplier and user of clinical documents, at the same time.

FSE database feeding is achieved by publishing clinical electronic documents (called DCE) produced by qualified healthcare organization as PDF files to which physicians' digital signature is applied. In order to give legal value to digitally signed reports, the repository keeps a clear reference of the versioning of the document collected.

Various DCE documents exist, concerning outpatients' examination results, specialized radiology or laboratory reports, accidents and emergency reports, inpatients' discharge letters, evaluation notes, patients' summaries, phone contact reports and tele-consulting results.
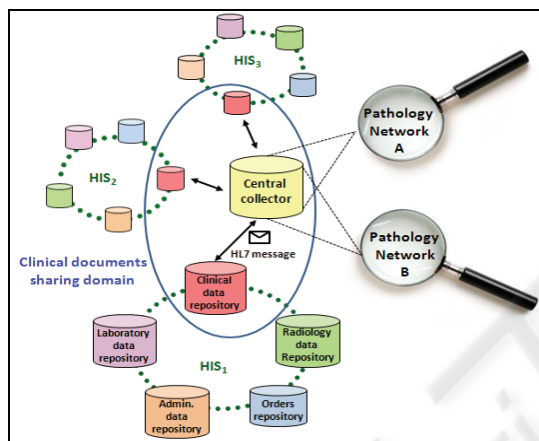

Figure 1: Interoperability model for Pathology Networks.

Based on these assumptions, the Pathology Network database is fed with a DCE subset, made up of predefined sets of data, codified into XML tags, suitable to collect various data formats. Epinetwork solution is based on a syntactical structure defined inside a XML CDA2 (Clinical Document Architecture Rel.2) standard. This standard, besides being the reference solution for exchanging healthcare information at international level, helps us adding efficiency to interoperability: persistence and human-readability assure that all different recipients of the information are able to receive and properly interpret stored information; moreover, CDA specification is so rich and flexible that doesn't place any limitation to future definition of new document typologies (Dolin et al., 2001).

The XML document allows physicians to fill in specific pathology-related fields, such as diagnosis, codified with the international classifications ICD 9 and ILAE (International League Against Epilepsy) (OREp, 1996), causal factor and assessment over

Epilepsy's severity, both semantically codified. Other information are required, especially concerning drugs, EEGs and other exams or demanded performances.

Pathology Networks imply some specific needs in terms of privacy respect and data security: in order to ensure that only authorized subjects can access data, some fundamental concepts regarding report's publication have been introduced, which are DAO, GAN and "consolidated CDA". A DAO - Italian acronym for "Authorization and Obfuscation Document" - defines if the DCE is authorized, i.e. freely and autonomously consultable by the patient and if it must be obfuscated, i.e. not visible by healthcare operators due to a voluntary patient's deny or in case of special legal cases (HIV, voluntary termination of pregnancy, drug addiction, abuse), except in case of emergency assistance.

GAN document - whose acronym stands for "Authorization and Designation Management" - compiled by the patient at his first contact with the hospital and then digitally signed by a clinical responsible, specifies who inside the Pathology Network is authorized to consult the DCE, with the understanding that access to patient's data are restricted to clinical information correlated to the specific pathology treated.

A "consolidated CDA", the real entity shared by healthcare organizations, is made up of the digitally signed DCE (P7M format), the clinical report in XML-CDA2 format, and the XSL file containing presentation rules; this set is then compressed into a ZIP archive, encoded with Base64 system and finally inserted as a field of an HL7 message, which will then be shipped over the network through a manager.

The procedure applied for feeding the Pathology Network is carried out in a semi-automatic way from structured clinical documents contained in the Health Information System's local repository, following the guidelines "Integration Profile" defined by IHE (IHE International, 2003).

When requesting storage of a Pathology Network document, such as an Epilepsy report, a form is opened soliciting the physician's digital signature, realized with a card identifying the user as an operator enabled to publish documents over the SISS platform: signature enables the creation of the Epilepsy structured report. Then, a first transaction "Provide & Register Document Set" takes place towards the clinical organization's repository producing the document; due to platform's

constraints in terms of control over documents' formal correctness, an employee owning a SISS card

with super-user rights is assigned to collect all reports stored into local database and not yet published, control that related DAO documents are authorized and not obfuscated, and finally mark them with a timestamp. At this point, the "Register Document Set Document Registry" transaction can be processed, which effectively publishes the report into FSE database.
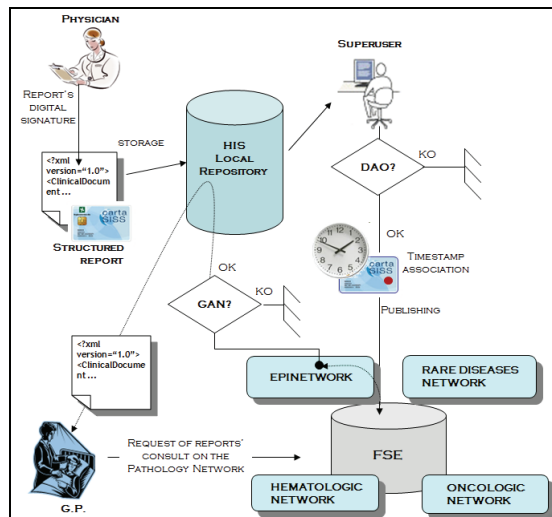

Figure 2: Feeding and retrieval process of a Pathology Network.

In case an Epinetwork member asks for patient's clinical documents consultation, a Query Registry is invoked over FSE Document Registry: services offered by SISS infrastructure control if requester is allowed by the GAN and, if so, generate a Retrieve Document transaction to show the epilepsy report to the final user through his local visualization tool.

4 DISCUSSION

The aim of this paper is to show a real solution adopted to participate in a pathology network and to show the positive effects it could have inside a healthcare environment. The solution realized at Besta represents a particular implementation of a general model already applied to the Hematologic, Oncologic and Epileptic Pathology Networks in the Region of Lombardy, and it could be taken as a reference methodology for similar initiatives in different environments. Generality and reusability of the solution are ensured by technological choices: first of all, the interoperable platform is supplied by a unique provider (in this case the Region), which takes care of all aspects concerning data security and

communication between repositories; moreover, the adoption of international syntactic standards ensures correct interpretation of all data published by various participating systems.

Advantages experienced in taking part in a Pathology Network can be felt both at clinical and scientific level, since clinical researchers are provided with a great amount of high reliable data, on which more efficient analysis can be performed, contributing to support clinical decisions, providing a general improvement in diseases' care processes and a better service level to patients.

Pathology Networks could be seen as a revolutionary concept in healthcare, since it moves the focus from Health Information Systems to Web integrated Healthcare Information Systems. Networks allow to overcome single organizations' borders, enabling extended co-operation via Web between healthcare professionals working in different structures: this represents an opportunity to share experiences and to join together different approaches towards the care of diseases, with undeniable benefits for scientific progress and the quality of assistance delivered to patients.

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