Managing the Interoperability and Privacy of e-Health Systems as an Interdisciplinary Challenge

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ABSTRACT

The growing number of patients with chronic diseases, the ageing population worldwide, the rapid increase in hospital costs and in the cost of care personnel as well as the achieving medical objectives "increase the patient quality of life and survival" face Europe with a huge challenge. One of the solutions for reaching these challenges in the future is the deployment of complex eHealth systems in support of all the healthcare aspects on the way between patient home and healthcare provider. In the last decade the European Commission (EC) in cooperation with healthcare associations and standardization institutes announced large frameworks for supporting research and development of various components of the future eHealth systems. This may be considered as an immediate interdisciplinary opportunity for European researchers and developers to create jointly the spine of future healthcare systems.
After a short introduction to eHealth architecture, interoperability, security and privacy the talk refers to the interdisciplinary solutions which approach these healthcare huge overall challenge. Two case studies will be addressed: a) interdisciplinary partnership for conducting jointly European research concerning remote control and management of future wearable dialysis devices, and b) ERASMUS supported international education programs for creating future interdisciplinary expert networks working on developing and implementing a better healthcare system.

Keywords: eHealth, interoperability, electronic health record, health informatics standards, wearable artificial kidney

1. INTRODUCTION

Speaking about interdisciplinary: 500 years ago, the famous all-rounder Leonardo da Vinci (1452-1519) practically incorporated 11 different fields all-in-one person. He was a painter, anatomist, sculptor, architect, botanist, writer scientist, mathematician, engineer, inventor. He could use all his different knowhow and interoperate with them, e.g. for an invention. This type of universal genius appeared at times until the 19th century. Goethe (1749-1832) was the last of its kind. Then, the era of specializations begun. It made knowledge so complex that one person can only focus on specific parts of a field. Thus, interdisciplinary and interoperability have become a daily occurrence for today's interdisciplinary projects. Needless to say, one needs talent to find various outstanding experts worldwide who are willing to interoperate. Creating eHealth systems is the best example of an interdisciplinary cooperation of experts from different fields.
eHealth refers to healthcare practice supported by electronic processes and communication.

A. Reasons for eHealth demand

The healthcare support of the continuing ageing population is expected to change significantly in the future to cope with the dynamic change of the society. Following main demands are to be considered according to the Calliope EU Health Report [1]. Life expectancy is rising and so is the prevalence of chronic conditions. At the moment as much as 80 per cent of national healthcare budgets are spent on chronic disease management. To address these costs, patients should be deinstitutionalized and cared either at home, with their families or in the local community

- Citizens want to be well informed and in a less asymmetrical position vis à vis the professionals when it comes to decision-making about their health situation
- Diagnostic procedures, medical treatment and technologies are increasingly complex and costly, and should be automated and digitized to the extent possible
- Society and patients expect that therapy and care will be optimized to the highest level of quality and cost. Adequate ICT based solutions are needed
- Citizens are increasingly mobile and do not expect that geographical borders, will block their access to adequate care when moving around
- As the demographic shift begins to impact there will inevitably be a shortage of skilled healthcare labor resources and medical expertise.
- With the increased complexity of healthcare delivery and the need for shared information new working procedures and workflows have to be established. Repetitive collection of the same data by different care providers asking in the same period for the same examinations can no longer be afforded.

B. Standard Solution for eHealth Architecture

Patient's health data are usually stored using data structures of type Electronic Health Record (EHR) or Patient Health Record (PHR). EHR and PHR are the cornerstones of the eHealth applications.
EHR represents the digital version of the paper notes written by physicians in their offices for the patients. It is intended to represent patient's overall health, including a broader view of the patient's health history, not only the one provided by a specific physician or care provider. The ISO/TR 20514:2005 standard [2] defines the EHR as "*a repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorized users. It has a commonly agreed logical information model which is independent of EHR systems.*" EHR aggregates electronic records of health-related information for an individual. This information is created and gathered cumulatively by every health care organization the patient had encountered and managed and consulted by licensed clinicians and staff involved in the individual's health and care (see Figure 1)

EHR provides a comprehensive view on a patient's health and history by pulling information from other systems, providing clinical decision support and alerting providers to health maintenance requirements.
There is a large set of standards that can be interfaced with EHR and PHR (see Figure 1). They are compatible with standard communication protocols, such as HL7, IEEE 11073, DICOM, NCPDP that provide the interface for various eHealth applications with different purposes (i.e. radiology, external medical offices, community pharmacies, personal medical devices, etc.) [20]

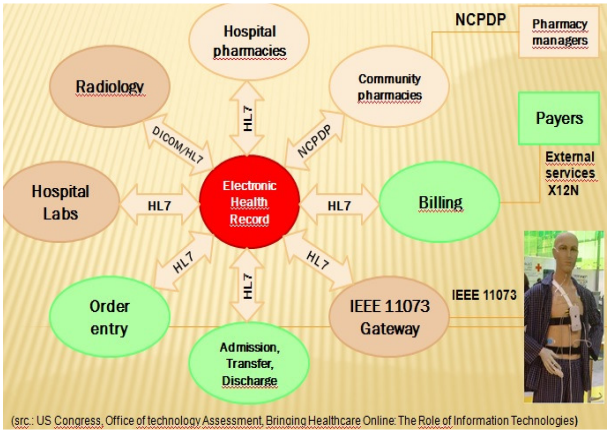

Figure 1. eHealth Interoperability Architecture [21]: Overview

The access categories to these types of data are classified according to the standard ISO EN13606, ISO/TC215 [3]:
1) sensitivity of information
2) functional *role* played by the person accessing the data
3) purposes for accessing EHR data

2. TELEMEDICINE (TELEHEALTH)

Telemedicine is the remote provision of health care services and health education, mediated by technology. There are two primary modes of telemedicine:
• *Real-time (synchronous) telehealth* sessions are live and interactive, and frequently use videoconferencing technologies.
• *Store-and-forward (asynchronous) telehealth*, involves data that are captured locally at the point of care, then temporarily stored for transfer at a later time, via a secure procedure. The consulting provider reviews the stored data and makes diagnosis, treatment, and planning recommendations.
A hybrid approach, utilizing both transmission capabilities is becoming more common. But regardless of the approach, telemedicine requires medical devices that connect to these methods of transmission and allow the patient's effective clinical examination and evaluation for diagnosis and treatment. Multiple products, services, and industries are being developed to serve various telemedicine applications, including information technology vendors, medical device manufacturers, pharmacies, hospitals, and nursing homes.

A. Telemedicine Products

Many medical devices capable of collecting and electronically transmitting information can be digitized for use in telemedicine applications. These include: *blood glucose meters, pulse oximeters, blood pressure cuffs, CT scanners, MRI machines, etc*. Some of these devices are targeted towards home health care and the patients interested in closely monitoring their health status, while others facilitate the exchange of information between hospitals, clinics, and physicians.

B. The challenge

Telehealth care is a tremendous challenge for the industry, because the devices placed at different locations, must have a complex infrastructure which enable them to exchange and process medical information. The tools for in-home care must address the issue of interoperability with diagnostic tools, records tools, and patient information tools.
Specialized application software, data storage devices, database management software, medical devices capable of electronic data collection, storage, and transmission are all key components of the telemedicine infrastructure. All these issues are waiting to be solved through intensive and innovative research and development activities carried out jointly by interdisciplinary experts from all over the world.
Telemedicine market promises an annual growth rate of 18,6%, more precisely: 2010 => $9.8 billion, 2011 => has grown to $11.6 billion, 2016 => expected to continue to expand to $27.3 billion

C. Continua Telehealth Architecture

Continua Health Alliance [4] is a non-profit, open industry organization of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. With more than 240 member companies around the world, Continua is dedicated to establish a system of interoperable personal connected health solutions. Extending these solutions into the home fosters independence, empowers individuals healthcare-wise and provides the opportunity for truly personalized health and wellness management.
Interfaces are defined based on interoperability. The telehealth interoperability is assured by using standard specifications for the information exchange at each interface level. The interfaces are specified based on the network layer model:
1)PAN-IF => Personal Area Network (PAN) Interface: Measurement exchange around the person using PAN Devices.
PAN-IF supports following standards: *Bluetooth, USB, NFC, IEEE 11073- 20601*
2)LAN-IF => Local Area Network (LAN) Interface: Measurement exchange at a location. The mobile/wearable medical devices that are monitored and controlled over this interface are called: LAN Devices.
3)WAN-IF => Wide Area Network Interface: Measurement exchange across the globe. Device classes used at this tier are application hosting devices: PCs, Smart Phones, etc.
WAN-IF supports standards as i.e.: *HL7 based on IHE Cross – Enterprise Document Reliable Interchange (XDR), XML, HL7 Clinical Document Architecture (CDA) V3*
4)HRN-IF => Health Reporting Network Interface:
Health reporting to other enterprise systems. Device classes used at this tier are: Health reporting devices: Servers, PCs, etc.

3. INTEROPERABILITY FOR HEALTHCARE SYSTEMS

Interoperability [5], [6] is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. This includes:
Technical interoperability (TI) moves data from system A to system B, neutralizing the effects of distance. It is domain independent. It does not care about the meaning of what is exchanged.

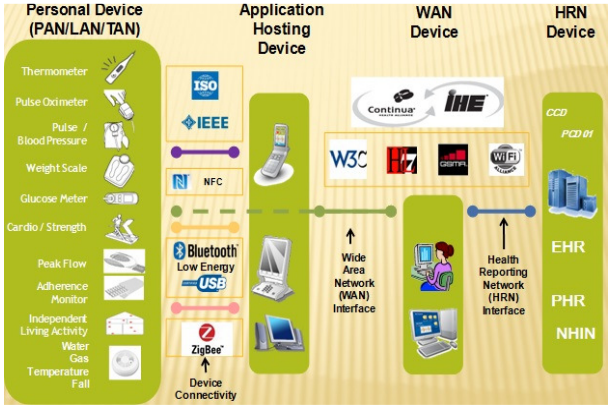

Figure 2. Continua Health Alliance Architecture [4]

Semantic interoperability (SI) ensures that system A and system B understand the data in the same way. It allows computers to understand, interpret and use data without ambiguity. This is specific to domain and context, and usually involves the use of codes and identifiers. SI is at the core of what we usually mean by health care interoperability.
Process interoperability (PI) coordinates work processes, enabling the business processes at the organizations that house system A and system B to work together.

A. Standards requirements for interoperability
The exchange of information based on standards between various health systems allows implementing the process so that is: safe, secure, reliable and cost effective. Health care interoperability is based on the implementation of standards. Examples of functions needing interoperability cover a wide range (see also Figure 1):
• Requests for investigations, i.e.: laboratory tests and radiology
• Prescriptions for medication and other therapy
• Orders for nursing care, equipment, patient transport
• Investigation reports from laboratories, radiology and other diagnostic departments
• Administrative data such as patient registration and identification, clinic appointments, admissions,
• Letters and memos from one clinician to another
• Information for management, audit and monitoring
• Commissioning, billing and accountancy data.
Note: The numbers of transactions in health care systems can be vast. For example, in a single EHR system at one large hospital e.g.: Mayo Clinic in Rochester, Minnesota, 2 million messages are processed every day.

B. Standards Development Organizations (SDOs)
When the European Union was established, it was agreed that the common market required common standards and the *European Standards Organization* (CEN) was established in Brussels, - along the same lines as ISO - as an international member organization. In 1990, CEN set up the first formal international standards organization *in health informatics, CEN TC251*. Each EU country established its own committee;

In the USA, ANSI was established to represent existing SDOs. USA-based standards organizations and ANSI affiliates with an interest in health informatics include: *ANSI X.12* – Claims processing, *ASTM – Continuity* of care record (CCR), *DICOM* – Diagnostic imaging, HL7-Health Level Seven (Clinical and admin information), *IEEE* – Bedside devices, *NCPDC* – Prescriptions
ANSI created the *Health Information Technology Standards Panel (HITSP)*, which was established to make recommendations about *what health informatics standards* should be adopted nationally in the USA.
In 1999, ISO established a committee for *Health Informatics ISO TC215* [3]. The main task of this committee is to *ratify existing standards*. A number of other international organizations also emerged, which do not fit neatly into the traditional ISO pattern. These include:
•*IHTSDO* [22] International Health Terminology Standards Development Organization responsible for SNOMED_CT
•*CDISC*: Clinical Data Interchange Standards Consortium responsible for coordinating data capture for clinical trials
•*IHE* [23]: Integrating the Healthcare Enterprise, which develops profiles for specific use cases
•*Continua* [4]: Continua focuses on home telehealth
•*OpenEHR*: It focuses on elements of EHR architecture
•*OpenHealthTools*: a collaboration to develop tools for developing and implementing Standards

C. Standardization for Coding and Classification
Coding is the *allocation of identifiers*, which can apply to anything (including classes in classifications). A code is just a *sequence of symbols*, usually digits or letters, which designate an object or concept for identification or selection purposes. It is just an alternative name for something, an identifier, designed for computer processing.

Classification allocates things into groups or classes.
Statistical analysis requires patients to be classified into a relatively small number of discrete and mutually exclusive groups. Classification is the *basis for most statistical analysis*, quantitative management, accountancy and research.
SNOMED CT [5] is the most comprehensive, *multilingual clinical terminology in the world*. In 2009 it contained over 310,000 active concepts, 990,000 English descriptions around 1.4 million relationships. SNOMED CT was acquired by IHTSDO [22] which aims to achieve interoperability and harmonization between its terminology products and other standards.
SNOMED CT Numeric codes (SCTID): identify every instance of the three core building blocks: concepts, descriptions and relationships.

4. E-HEALTH EUROPEAN INTEROPERABILITY FRAMEWORK

Today's lack of interoperability between eHealth solutions developed and implemented by various healthcare provider lead to a reaction of EC which set the objective to develop, an eHealth European Interoperable Framework (EIF) [19]. As a result, the EC announced a set of proposals oriented towards creating an EIF as i.e.: a high-level structure and conceptual eHealth EIF and an initial population of the technical level of the framework by assessing 10 technical specifications from two consortia: 1) IHE [23] and 2) CHA [4]
The EC intends to provide substantial support for further populating the eHealth EIF with interoperability specifications at the technical, semantic and organizational levels. The EC also announced additional, research funding programmes for e-Health projects: 1) *Horizon 2020 Work Programme*, 2) *3rd EU Health programme*, 3) *Active and Assisted Living Programme (AAL)*. These commitments represent a great challenge for multidisciplinary experts to get involved in EC-supported projects.

5. MANAGING ACCESS CONTROL TO PATIENT CLINICAL DATA

Managing the secure transfer and storage of patient's health data (Security) as well as protecting the access to personal data (Privacy) are very complex issues. Such a complex ICT task is carried out by implementing a series of procedures governed by algorithms and standards.

The worldwide "Privacy" guidelines issued by the Organization of the Economic Cooperation and Development (OECD) [7] specify the privacy rules which apply to personal data (PD) in the public or private sector. Among the basic OECD rules, the following ones are the most relevant in case of eHealth data:
• Collection limitation: collection of PD should be limited
• Purpose specification: the purposes for which PD are collected should be specified
• Use limitation principle: PD should not be disclosed, made available or otherwise used
• Security safeguards principle: PD should be protected by reasonable security
• Individual participation principle.
The European Council adopted in 1995 the Data Protection Directive, 95/46/EC "on the protection of individuals with regard to the processing of personal data and on the free movement of such data" [8]. Similar guidelines containing rules for protecting personal eHealth information were also specified in the USA under the document "Protection Act" in 2004 [9].
According to Benson [5] the general procedures applied for assuring privacy on eHealth patient's data are mainly based on the management of the following components:

1) Authentication (AUTH) of the subject accessing data
AUTH is the process of verifying the identity of a subject in order to check/prove if someone or something is, indeed, who or what it claims to be. "Authentication is the binding of identity to a subject." [10]. The authentication process has a set of authentication parameters:
a) Assertion (AS): data which guarantee the authentication of any user or of an entity at a particular time using a particular authentication method. A simple abstract definition: AS was issued at time "T", by issuer "IS", concerning subject "S", under the provision that condition "C" is valid.
b) User Credentials (UC): represents the required input to the authentication process that must be present in order to perform authentication. The frequent forms are: user password/PIN, hash password, salting password, shared keys, one-time password, digital certificate, biometrics credentials, etc. In case of entity authentication, one party proves its identity to the other party. In case of eHealth applications, entity authentication is relevant and has to be implemented [18].

2) Authorization (AUTZ) of the access to the eHealth data
AUTZ performs so called "Access Control Decisions" (ACD) based on access control policies. ACD has to be always performed when access to a restricted resource is requested. Intuitively, AUTZ can be represented using a simple abstract model: AUTZ (S, R, O) → (False, True): AUTZ evaluates if "S (subject performing the access)" is allowed to access the resource "R" using the operation "O" to be performed on the resource. AUTZ also verifies the Assertion generated by AUTH in a prior step. There are several models that handle the specification and evaluation of access control policies:
a) *Role-Based Access Control (RBAC) [11]*: maps permissions to access resources to roles instead of users. Users are then mapped to different roles. Users therefore acquire access permissions through role assignments.
b) *Attribute-Based Access Control (ABAC) [12]*: controls access to objects by evaluating rules against the attributes of entities, operations and the environment relevant to a request. Compared to RBAC, ABAC provides more flexibility in creation of access rules.

3) Patient Consent for eHealth data
Patients would like to have more control over who is allowed to access their health information, when, where and for what purpose (e.g. read, write). In order to manage the patient consent for the health data, some services should be supported:
a) Delegated consent: patients transfer the control of their healthcare data to a trusted entity (e.g. trusted doctor).
b) Shared decision-making: patients contribute actively to their own care. This is best expressed as "no decision about me without me".

6. E-HEALTH RESEARCH PROJECT AS CASE STUDY

This section presents briefly some aspects of one research project conducted jointly by an international multidisciplinary European team in the area of eHealth:
„Remote Monitoring-Control System for Future Wearable-Portable Dialysis Devices"

A. Introduction
Moving the dialysis treatment from the nephrology clinic to the patient's point of need, instead of moving patients to the nephrology clinic, is a great challenge today. The main objective of research work is the development of a universal prototype system, suitable for European environment, for the management, control and monitoring of wearable and portable dialysis devices. The research focused on design of the main components of an experimental Artificial Wearable Kidney, emphasizing also the main advantages of using such approach. The proposed system is created based on collaboration among 12 European institutions: 3xHospitals, 3xManufacturer, 3xUniversities, 3xSoftware companies out of 6 EU countries: Germany, UK, Italy, Romania, Finnland, France. The project united multidisciplinary experts in: cellular biology, bio-engineering, applied-physics, machinery development and testing, drugs kinetics, pharmacokinetic analysis, pharmacodynamics, health informatics, healthcare economy. Research results were presented at various conferences and journals [13], [17].

The long-standing dream of dialysis patients, to have access to the treatment when they need it and where they are, can now be realized due to cutting-edge technological progress in the area of water purification, component miniaturization and secure ICT remote monitoring and control of wearable devices.

A group of medical experts has demonstrated the possibility of carrying out dialysis treatment using wearable [14], [15] or portable devices [16].This revolutionary, avenue of research has been complemented by innovations in the area of wearable, non-invasive vital sign monitoring devices such as, Oxygen saturation by Pulse oximetry, ECG (up to 3 channels), Pulse rate (via ECG or pulse wave), Plethysmogram wave, Blood pressure (wrist or upper arm cuff), Motion sensor, Sensor shirt with ECG, etc.

B. System Architecture of Artificial Kidney

The architecture of the experimental Artificial Kidney System can be explained with reference to the following schematic diagram (see Figure 3).

At the patient site the system includes:
1) the dialysis device (wearable or portable)
2) dialysis device embedded control and interface
3) set of vital signs monitoring devices
4) audio-video communication device
5) the Portable Universal Terminal for Monitoring and Control (PUTMC) device

The first three items can be commercial devices provided by different manufacturers, or downsized devices specifically for dialysis platforms. The last two items are designed to be independent of the specific dialysis equipment, with the exception of a software module within the PUTMC that is conceived to be customized to interface specific equipment.

At the Remote Care Center site, the system includes:
1) Care Center Management Platform for Teledialysis Treatment (CCMPTT).
2) supervisor console for healthcare professionals to interact with the system and with patients
3) HL7-IHE standard communication channel to other Hospital Information Systems (HIS)

The experimental system provides three levels of closed loop control paths:
1) dialysis device level: inside the local control device
2) local wearable/portable level: inside the PUTMC device

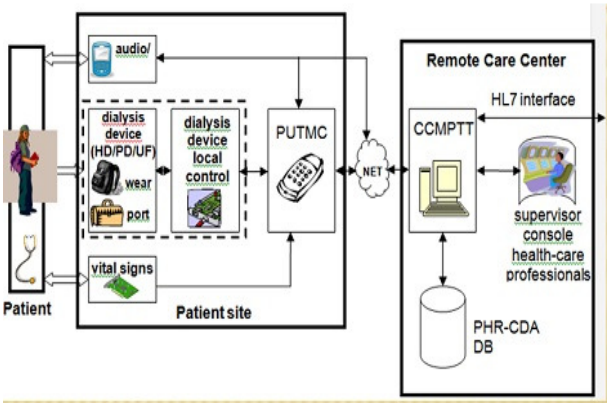

Figure 3. Prototype Architecture of the Artificial Kidney

3) remote supervision level: at the Care Center, with the intervention of health care professionals.

C. Remote monitoring, remote control and accuracy of monitored data

The experimental system is conceived to provide an efficient and reliable communication link to allow both patients and their dialysis devices to exchange information with the remote care center. The monitoring data is stored in ISO/IEEE 11073 format. All locally monitored data are transmitted via secure protocols to the care center. Control of the local devices may be performed remotely by medical personnel at the care center. All data delivered by the dialysis devices, vital sign sensors, etc., are conceived to be intensively verified in order to certify that the measured values are accurate and reliable.

An audio/video communication subsystem will allow a form of personal interaction between the remote patient and the medical personnel at the care center, so that the patient may feel that someone is taking care of him/her, as if he/she was performing treatment at the medical care center.

7. ERASMUS INTENSIVE PROGRAM AS CASE STUDY

Title: *Healthcare Support Using Domotics & IT (HESUDI).*
Target Group: Interdisciplinary students of different fields of study from 6 EU universities: Healthcare, Robotics, Domotics, ICT, Mechanics, Engineering, Aeronautical Engineering, Business Informatics, Business Economics.
Level of students: 4th year Bachelor and 1st year Master.

Six EU participating universities:
Finland (*host*): *Metropolia Univ. of Applied Sci., Helsinki*
Germany: *Munich University of Applied Science*
United Kingdom: *Birmingham City University*
The Netherlands: *Inholland University, Amsterdam*
Austria: *University of Applied Sciences, Graz*
Slovenia: *University of Ljubljana*

Learning Outcomes: Students will get a better insight in the possibilities to enhance healthcare by the effort of ICT. Multidisciplinary projects provide benefits examples to the students offered by involving different fields into their own fields of study.

Expected Outputs: Students will be capable of calculating the impact of ICT and Domotics on healthcare from financial, legal, health, ethical, technical and international point of view. Multidisciplinary exchange of knowledge between students, lecturers, healthcare institutions, and business

Duration: 3-month project preparation + 2 weeks intensive program: lectures, labs, project presentations, guest lectures by companies.

Project examples:
1) Monitoring health vital signs via Telemedicine application system: *Munich University of Applied Sciences, Germany*
2) Design and develop a WEB appl. for elderly people to overcome loneliness: *Helsinki Metropolia University, Finnland*
3) Find my staff application to support daily life of Alzheimer persons: *Inholland University, Amsterdam, Holland*
4) Medcation reminder using pill detection applic. with connectivity to an EHR: *University of Ljubliana, Slovenia*
5) Save care: privacy and security in video conferences in telemedicine applications: *University of Birmingham, UK*
6) Generic monitoring application for people with coronary artery disease: *JOANNEUM University of Applied Sciences, Graz, Austria*

8. CONCLUSIONS

A journalist once asked Leonardo da Vinci: „Do you think you could still add 2 more fields to your vast expertise: IT and medicine and go global?“ - „IT and Medicine? No problem! However, go global? I wonder with all my duties whether I find the time for travelling: carriage, boat, carriage, boat, …!“

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