Interoperability Challenges in the Health Management of Patients with Implantable Defibrillators

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Abstract

Patient empowerment frameworks engage citizens in their healthcare. Heart patients undergo implantation of Cardiovascular Implantable Electronic Devices (CIEDs) that support remote monitoring hoping to live a longer healthier life. Electronic Health Records (EHR), remote device monitoring, and lifestyle data can supply patient context to computerized guidelines so that health events are timely assessed and effectively treated, before they become life-threatening. In this way, lives may be saved, health care resources be optimized, and hospital visits be reduced saving time, hassle, and money. iCARDEA aims to provide health professionals with such an adaptive care planner offering decision support through semi-automated clinical guidelines integrating data from CIEDs, EHRs and Personal Health Records (PHRs). The enabling standards and interoperability initiatives are presented underlining barriers that need to be overcome, before such eHealth innovations become widely adopted.

1. Introduction

An increasing number of patients choose to accept implantation of a Cardiovascular Implantable Electronic Device (CIEDs) to alleviate the risk of life-threatening conditions such as dangerous arrhythmias, sudden death, and heart failure. Technology empowered patients and their families access online educational resources, maintain PHRs, engage in social networking relating to their condition, using activity and lifestyle monitoring devices. Hospital records and decision support tools assist cardiologists in follow-up of CIED patients typically three times per year based on current clinical guidelines [1,2]. Recent CIED models support remote monitoring and preliminary results from clinical trials show reduction of in-office visits and improved quality of care [3,4]. Typically, the CIED transfers via GSM or through a dedicated home gateway, data on the status of the device and cardiac events of the patient to the data center of the implant manufacturer on a preset schedule or on patient request. Attending cardiologists may sign up to receive alerts and can remotely access the portal of the implant manufacturer to review relevant reports. When an event is reported for a patient, the attending cardiologist needs to evaluate the condition of the patient and decide whether to reschedule the next patient visit, call the patient's home, or just make a note for future reference. However, the relevant patient data are not readily available. In the hospital, patient information is typically distributed in heterogeneous legacy systems, even paper. Data on lifestyle, medication compliance, emotions, stress, physical activity, etc. may be part of a health journal or PHR, but no access to that information is available, even if the nurse calls the patient's home.

iCARDEA [5] aims to change this situation. Health professionals will be able to use an adaptive care planner, a decision support tool that will semi-automatically execute computerized clinical guidelines rapidly assessing all the relevant clinical information for the patient available in the EHR, the PHR or provided by the implant through remote monitoring. The guideline for Atrial Fibrillation has already been defined based on available clinical guidelines and in collaboration with leading cardiology centers [2, 6]. Besides the challenge of turning hundreds of guideline pages into a computer-interpretable form, a significant challenge for iCARDEA is retrieving health and lifestyle data of the patient from disparate sources and converting them into a semantically interoperable format usable to the adaptive care planner without violating the security policy of the hospital, or the privacy of patients and health professionals (see Fig. 1).

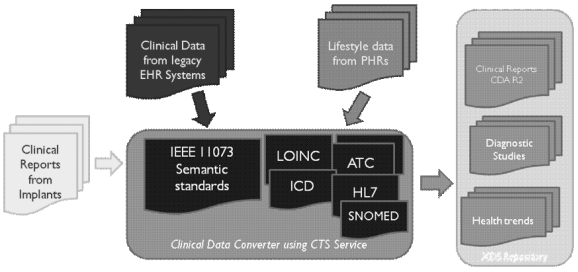

Figure 1: The challenge of semantic interoperability.

In this paper we report on the current status of global interoperability initiatives that facilitate the incorporation of clinical, personal health, and device data into computer processable guidelines, in a scalable way that preserves consistency cultivating trust through appropriate security, privacy, and consent policies. The iCARDEA interoperability layer aims to leverage widely adopted reporting standards such as HL7 CDA R2 constrained with "Integrating the Healthcare Enterprise" (IHE) content profiles. At the same time, the technical framework developed by IHE is used to create an infrastructure that is scalable and secure. In the context of patient empowerment, iCARDEA can also benefit from the work of Continua Health Alliance on design guidelines and certification processes that enable vendors to build interoperable devices and monitoring platforms for wellness and disease management at home.

As for the rest of the paper, the next section "Methods" presents enabling standards, interoperability initiatives, and functionality criteria for EHRs and PHRs. In the "Results" section, the basic principles of the iCARDEA interoperability layer are presented in association with well-known barriers to wide adoption. The "Discussion" section focuses on the ways iCARDEA aims to address technical and organizational challenges in the deployment of its architecture, while conclusions summarize our contribution and future plans.

2. Methods

The iCARDEA interoperability layer implements IHE integration and content profiles to enable productive use of CIED, EHR, and PHR data mainly by the adaptive care planner. IHE profiles prescribe the constrained use of standards such as DICOM and HL7 through integration profiles based on actors and transactions for specific clinical domains as those relating to iCARDEA: Patient Care Devices (IHE PCD), Patient Care Coordination (IHE PCC), and IT Infrastructure (IHE ITI).

IHE PCD addresses interoperability issues with regulated medical devices such as CIEDs. The Implantable Device Cardiac Observation (IDCO) profile [7] uses HL7 v2.5/6 and ISO/IEEE11073 standards including the Rosetta Terminology mapping to facilitate interoperability at the device level. Adoption of IDCO will alleviate the problem of attending cardiologists having to use a different system to follow-up the devices of each implant manufacturers and enable storage of clinical information to the Hospital Information System (HIS) or the EHR.

Part of IHE PCC, the IHE Care Management (CM) profile [8] enables subscriptions to specific types of clinical data that conform to HL7 CDA R2 [9], HL7 CCD, ASTM CCR and are constrained by specific IHE clinical content profiles [10]. Thus, the adaptive care planner may subscribe to EHR and PHR updates of CIED patients in the hospital and receive new reports or results when available. However, it is unlikely that HIS will fully support IHE CM, largely due to the number of subsystems that co-exist and carry part the patient's fragmented EHR.

IHE ITI offers IHE profiles that address EHR interoperability issues aiming to leverage provider data (e.g. diagnostic examinations, lab results, progress reports) through cross-enterprise sharing of clinical data in an XDS repository. These include patient identification (IHE PIX), cross enterprise sharing of clinical documents (IHE XDS), and security (IHE ATNA).

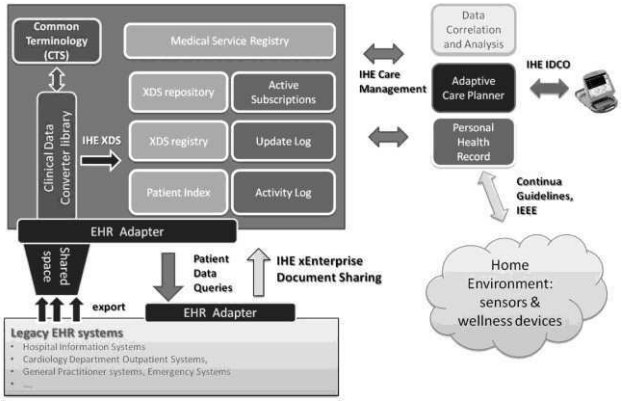

Figure 2: Overall EHR interoperability infrastructure.

iCARDEA analyzed the state of the art in standards, technologies, and architectures and selected the most promising approaches for the design of its interoperability layer. Designing and implementing these components engages a multi-disciplinary team. Achieving deployment of this architecture in a hospital on an efficient workflow that conforms to the local security policy that redefines CIED patient followup is certainly a challenge. Moreover, since no two hospitals are alike, the design of the interoperability layer has to be flexible and adaptable to different modes of information exchange that range from human mediated to automatic updates based on a subscriber/observer pattern (IHE CM). In addition, different hospitals adopt different clinical documents (forms or templates) to document the care procedures. This requires the creation of converters that translate local forms into standardized content templates with the help of a Common Terminology service (Fig. 2).

Importing data from different types of legacy information systems is not easy. So far, three different ways have been considered: (a) maintaining a shared space where clinical data will be exported in the format that has been agreed upon by a human agent following the security policy of the healthcare facility, (b) extending the legacy EHR system to support cross enterprise document sharing, effectively actively exporting data in CDA R2, (c) periodically using the native DB interface of the legacy EHR system to query subscribed patients.

EHR data, personal health and lifestyle data are

increasingly relevant in the emerging Internet of Things and smart home environments that aim to provide unobtrusive care for elderly people. So, while the above IHE domains concentrate on the extended hospital environment, the Continua Health Alliance develops design guidelines to foster the development of interoperable personal health solutions for the extended home environment. Here the focus is on disease management, wellness and independence integrating devices like weighting scales, thermometers, exercise monitoring, etc. to PHRs [11]. The focus of Continua's design guidelines includes PAN-IF (Interface to Personal Area Network health devices) and xHR-IF (Interface to export personal health data from Disease Management, as for example transmission to an EHR). By June 2010, 15 products were certified including oximeters, glucose meters, weighing scales, blood pressure monitors, pedometers, along with collectors of that information. It is through the PHR that iCARDEA can provide the adaptive care planner lifestyle data from homecare devices or sensors if so dictated by the guideline.

The power of iCARDEA is that it takes a collaborative evolutionary approach where technological innovation goes hand in hand with developments in evidence based medicine. As additional lifestyle data become available from the home of the patient, these data can be readily used in an automated guideline, assuming the patient consents. A consent management architecture is needed to enable patients to grant or revoke permission to access selected PHR data. In line with this requirement, in iCARDEA an XACML and SAML based patient consent management methodology is being implemented.

In the course of guideline execution, health professionals may need to review diagnostic exams, or prior ECG traces. The OpenECG network started in 2002 [12], to provide its community with tools for the integration of resting ECGs in the EHRs according to the ISO/IEEE 11073-91064 standard (SCP-ECG). SCP-ECG focuses on the diagnostic ECG and was quite successful in primary care and telecardiology. Unfortunately to this date, Continua does not address diagnostic ECG and some existing IHE profiles do not support SCP-ECG, selecting DICOM instead. For the future, data from clinical documents will be correlated with vital signs, ECG and diagnostic imaging to provide a more accurate status of a patient's health.

Recent advances in the area of functional specification/ certification of information systems provide a broader view on the full potential of the iCARDEA approach as they take note of all the different kinds of clinical data that can be made available to the adaptive care planner as clinical guidelines become more complex. The functional criteria defined by CCHIT based on the EHR functional model of HL7 [13] provide a standardized description of the functions available in a given clinical setting as in a cardiology department [14].

3. Results

The core of the EHR system interoperability infrastructure presented in Fig. 3 aims to leverage recent IHE integration and content profiles in a scalable and flexible way that permits deployment in any hospital.

The infrastructure for clinical documents/diagnostic imaging/laboratory results sharing across organizations (XDS) forms the core of the component. A medical services registry maintains a list of clinical data sources along with the preferred way to retrieve clinical data. Active subscriptions refer to active requests for specific content profiles as requested by:

- adaptive care planner to meet the needs of personalized medical care plans of the patient,
- personal health record of the patient to receive reports or examination results,
- correlation and analysis component for knowledge discovery.

Through the so called IHE PCC9 and PCC10 transactions an EHR interoperability infrastructure can provide the adaptive care planner, the PHR, and the data correlation and analysis component (i.e. an evolving knowledge database) with dynamic updates on clinical data of enrolled CIED patients. An IHE XDS repository can act as an EHR server for CIED patients aggregating data from different sources within the hospital (Fig. 3). Relevant ITI transactions are used to register a new clinical document set and query or retrieve other.

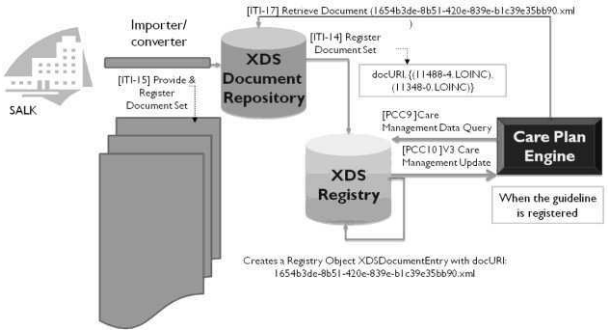

Figure 3: XDS repository acting as a buffer to enable interoperability with legacy EHR systems.

Empowered individuals would like to assemble all his medical data in their Personal Health Records. For our system the PHR is another entity that once authenticated may subscribe to receive updates on clinical data registered in the XDS repository using the IHE XPHR content profile. Beyond iCARDEA, the patient empowerment framework should be able to interface personal health devices, and environmental sensors that provide the contextual awareness relevant to interpret lifestyle trends.

4. Discussion

Huge amounts of data can be collected at the different

stages of the health care delivery process and when combined with data on lifestyle, activity, nutrition the value of decision support is evident. Building a sustainable interoperability framework for computerized clinical guidelines to execute seamlessly using quality data from different sources within and out of the hospital, would certainly improve quality of care, reduce errors and increase productivity.

Although there is significant activity on standards development and interoperability frameworks that aim to constraint standards so as to achieve higher levels of interoperability providing implementation guidance, adoption rates remain low. This is probably due to gaps in the maintenance and promotion of standards but maybe more importantly to the lack of organizational support and a clear legal and regulatory framework.

iCARDEA portrays a different way of work for the attending health care professionals, possibly also a different model of care. Healthcare professionals will no longer passively wait for patients to come on their appointments. They reach out proactively through the graphical interfaces provided by the adaptive care planner to check the status of patients in response to remotely reported patient events. Wide acceptance of decision support tools such as those developed by iCARDEA will certainly contribute a sense of aptitude to health professionals and convey feelings of confidence in technology, safety and trust to patients that have to live with an implant.

5. Conclusions

The iCARDEA (An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices) project has engaged a multidisciplinary group in addressing this challenge offering automated computer interpretable personalized guidelines based on PHR, EHR, and CIED data. The resulting Adaptive Care Planner aims to become a valuable Decision Support tool for attending physicians hoping to improve quality of life of CIED patients in a secure, unobtrusive and transparent way.

Acknowledgements

The research leading to these results has received funding from the European Commission's 7th Framework Programme (FP7/2007-2013) under grant agreement no ICT-248240, iCARDEA Project.

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