Empowering Patients with Cardiac Implantable Electronic Devices across Organizational & National Borders

Stelios Sfakianakis[1], Yildiray Kabak[2], Elif Eryilmaz[2], Yannis Petrakis[1], Gokce Banu Laleci Erturkmen[2], Catherine Chronaki[1], Asuman Dogac[2]

[1]FORTH-Institute of Computer Science, Heraklion, Crete, Greece
[2]SRDC, Ankara, Turkey

Abstract

Remote monitoring and follow-up of cardiac implantable electronic devices (CIEDs) introduces novel patient-focused and information-driven models of care. In this context, iCARDEA employs guideline-driven personalized care plans that use information from personal health records, hospital-based medical records, and CIED reports from remote follow-up or alarms to support clinical decision making. The aim of this paper is to report on extending the iCARDEA Electronic Health Record Interoperability Framework (EHR-IF) to enable use of patient summaries from the epSOS large scale pilot and clinical data from primary care, tovalidate the extensibility of the iCARDEA approach and to analyze the wider technical and organizational interoperability challenges of deploying IHE profiles in telemedicine.

1. Introduction

Recent Cardiac Implantable Electronic Device models have wireless transmission capabilities and clinical trials have confirmed the positive impact of remote monitoring on patient safety and quality care [1,2]. Adaptive care plans in iCARDEA, provide clinical decision support and save time by analyzing health-data from medical records, wellness & lifestyle, and remote monitoring suggesting options for handling alerts (see Fig. 1).

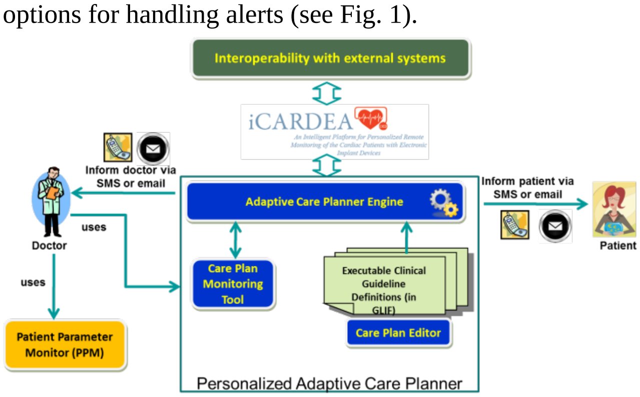

Figure 1: Remote personalized context-aware follow-up.

The adaptive care planner engine is the center-piece of iCARDEA that feeds personalized information to the patient parameter monitor and the adaptive care planner. In the patient parameter monitor, the cardiologist can access a summary of all patient related information irrespective of its source (home, hospital, CIED report, etc.) and save time during the scheduled remote follow-ups of the patient. In the adaptive care planner, the cardiologist may check alternative courses of action in case of incoming alarms or unscheduled remote follow-up based on recent guidelines fordangerous arrhythmias such as Atrial Fibrillation [3].

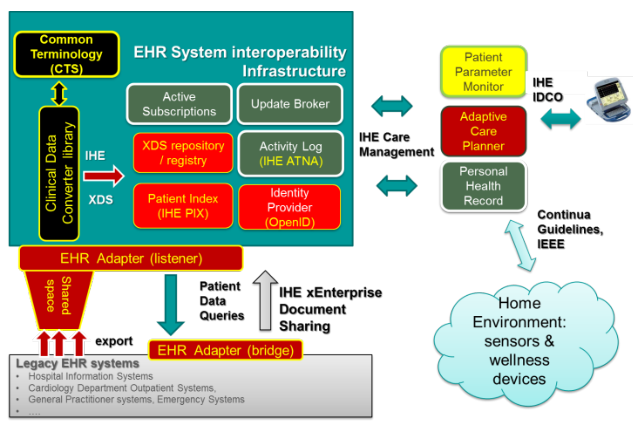

Figure 2. The EHR interoperability Framework.

National cardiology societies have started to provide guidance on the remote follow-up and alarm management for CIED patients [4]. Leveraging the power of information available in the various information systems across the care continuum is a challenge for remote CIED monitoring and follow-up [5]. EHR-IF shown in Fig. 2 aims to capture the information available in legacy EHR systems through customizable adapters and IHE profiles. While the efficacy of iCARDEA is currently being validated in Salzburg Austria, several extensions of iCARDEA have been developed to test its appropriateness in a wider scope. This paper focuses on using epSOS patient summaries from cross-border care[6] and exchanging patient data with general practices.

2. Methodology

The iCARDEA EHR-IF builds on customized EHR adapters along with theIHE Patient Identifier Cross-Referencing (IHE PIX), the IHE Care Management (IHE CM) and the IHE Cross-enterprise Document Sharing (IHE XDS) profiles to retrieve clinical data from legacy EHR systems and make it available through standard interfaces. EHR adaptors address identification, terminology and information exchange. An EHR Adaptor has two main components: the EHR Listener and the Update Broker. The EHR Listener waits for relevant clinical data, converts them into a standard format (HL7 CDAr2), and updates the IHE XDS repository. The Update Broker notifies registered authorised actors on matching IHE XDS updates with IHE PCC-10 messages.Integrating a new clinical information system requires the specialization of an EHR adaptor, leveraging semantics, and initialization including linking identifiers. The EHR Listener connects to the HL7 communication gateway and waits for HL7 ADT/ORU or EDIFACT messages for enrolled iCARDEA patients (see Fig.3). HL7 ADT/ORU messages relate to admission of patients or availability of diagnostic results, whileEDIFACT messages relate to discharge notes prepared for a patient and directed to the General Practitioner (GP).

The EHR Listener is responsible for two main tasks: the mapping of the patient identifiers andthe mapping of coded values in the standard vocabularies supported in iCARDEA. For the first task, it consults the Patient Index through an IHE PIX QBP query and retrieves thepatient's unique identification number in iCARDEA. For the terminology "reconciliation" task, it maps the terms in the messages to UMLS by consulting the Common Terminology Service (CTS) component. This process results in a clinical document in HL7 CDAr2 that is stored in the XDS Registry using the IHE ITI-41 transaction. A separate application, the CDA editor assists when clinical data need to be converted by customized CDA templates in a semi-automated way. Security and privacy is addressed with SSL and the IHE Audit Trail and Node Authentication (IHE ATNA) profile that is used to record (i.e. log) all activities in the EHR-IF.

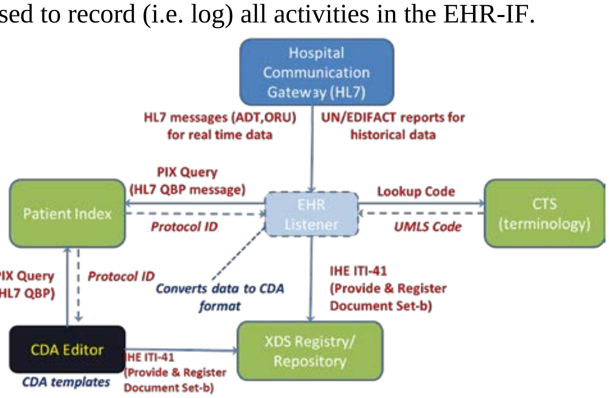

Figure 3. Dealing with Semantic interoperability aspects.

3. Results

3.1. Flows of epSOS patient summaries

epSOS, Smart Open Services for European Patients (www.epsos.eu) is a large-scale pilot engaging European Union member states and several observers in cross-border services for patient summaries and ePrescription (http://www.epsos.eu/epsos-services/eprescription.html). Table 1 shows the content of an epSOS patient summary.

Information/dataset	Contains
Patient Identification	Unique patient identification in a country
Patient Personal information	Full name. Date of birth Gender
Allergies	Allergy description and agent
Medical Alerts	Other alerts not in allergies
List of current problems	Problems/diagnosis that need treatment and/or follow up by a Health Professional
Medication Summary	Current medications
Country	Name of Country of origin of the patient (country A)
Date of Creation	Date that Patient Summary was generated
Date of last update	Data on which PS was updated
Author organization	At least an author organization (HCPO-Health Care Provider Organization) shall be listed. In case that no HCPO is identified a HCP shall be listed.

Table 1. Patient summaries in epSOS.

A specialized EHR adapter, the epSOS adaptor, was created and used to retrieve the patient summary produced abroad using the national identifier of the patient in the target country. Upon patient registration activation of the epSOS adapter initiates the process to retrieve his/her patient summary from abroad(see Fig. 4). The epSOS adapter uses the IHE Cross Gateway Query/Response (IHE XCA), an IHE profile developed specifically for epSOS to query and retrieve the patient summary of the patient. Using the CTS service, the terms used in the patient summary are converted into UMLS. Then, the adapted patient summary in HL7 CDAr2 is registered to the IHE XDS repository. Finally, the Update Broker notifies the adaptive care planner and other actors that are registered authorised recipients of updates when new patient data is available in the IHE XDS repository.

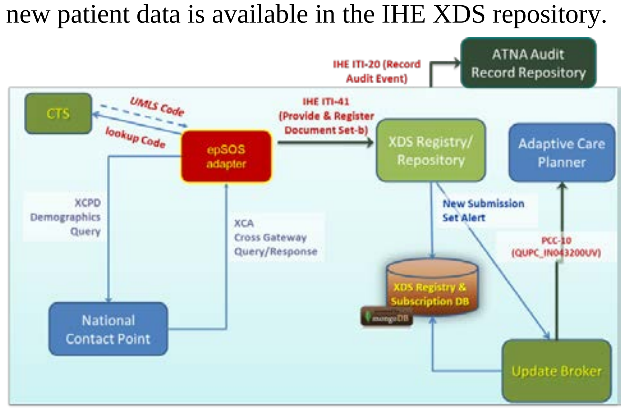

Figure 4. epSOS integration and supported processes.

3.2. Primary care information flow

A specialization of the EHR adaptor was created for ICS-P, a primary care EHR system that is currently used in several primary care centers throughout Greece. Collaboration between the hospitaland the GP of the patient can be quite extensive, involving sharing of medical history, problems, medications, lab and imaging exams, ECGs, and other interventions. As a proof of concept, this implementation was limited to medication and medical history problems. Two alternatives were considered for the initial registration of identifiers. According to the first option, upon hospital discharge after CIED implantation, the GP of the patient is notified in a secure email that his/her patient has decided to accept remote CIED monitoring and follow-up and is provided a URL. By activating this URL, the patient's EHR in the local system will be linked to that in the hospital enablingthe exchange of clinical data. Alternatively, the patient may receive a card with his/her iCARDEA id and will provide it to the GP to enable exchange of clinical data with the hospital.The ICS-P primary care system was extended with a specialized EHR adapter, the ICS-P iCARDEA Bridge. Following exchange of identifiers and establishment of the connection, the end points become producers and consumers (i.e. observers) of clinical information for iCARDEA patients in accordance to the IHE CM profile (see Fig. 5). Specifically, two flows of information were implemented:medication and problems. When the initial connection is established, ICS-P receives the current medication list as prescribed to the patient at the hospital. In the next visit, if the GP updates the medication list, the list will be forwarded to the hospital to be used by the adaptive care planner during the next scheduled or unscheduled remote or in-person follow-up.

The effort required to extend ICS-P with the iCARDEA Bridge was not significant but required some knowledge of theunderlying database schema. ICS-P uses well established terminologies such as ICD-9 for procedures/diseases and ICPC-2 for symptoms. The terms are translated to UMLS by the ICS-P Bridge, using the CTS component. The major issue was with the medication lists and active substances as the relevant terms in Austria and Greece present significant differences and frequently no correspondence exists.

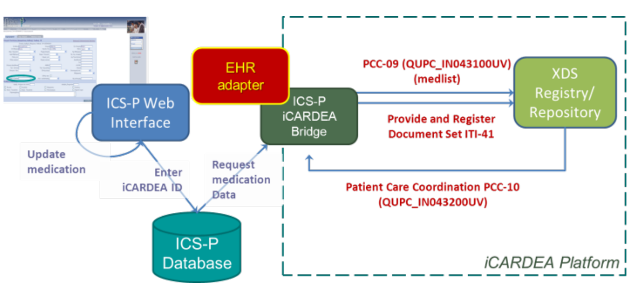

Figure 5. Primary care EHR integration and flows.

4. Discussion

The exponential growth in the number of CIEDs encourages development of new models of care enabled by Information and Communication Technologies (ICT) that focus on participatory care, remote follow-up, long-term monitoring, and alert management. Remote monitoring and follow-up has been associated with improved clinical outcomes, early detection cardiac events, as well as targeted optimized use of health care resources and indirect cost savings. Suggested improved clinical outcomes include reduced risk of catastrophic cardiac events, reduction of inappropriate shocks & battery drain, higher patient adherence and satisfaction, enhanced patient safety and security. Remote monitoring and follow-up may also contribute to early detection of cardiac events through proactive management of disease exacerbations as in the case of heart failure,and more timely medical interventions. Assuming effective reorganization of health services, it may also result in targeted optimized use of healthcare resources byfocusing on event-based follow-ups scheduled according to patient need, fewer or shorter hospital stays and in-person visits, shorter waiting times and increased productivity. The patients and informal care givers are also expected to benefit from less travel and shorter hospital waiting times.

The challenge for ICT is to collect and analyze patient information based on adaptable personalized care plans to reduce the data burden of caregivers and increase the quality of care leading to flexible care pathways, using professional guidelines, and developing trust in remote monitoring and follow-up. Personalized care through adaptive care plans takes into account the particular needs of the patients combining activity and lifestyle data along with clinical data, contributing to the development empowered patients actively participating in their care.

A patient-centered approach remote monitoring has to take into account all points of care. ICARDEA-compliantEHR adapters can be used to support care coordination with legacy EHR systems. Implementation of the Primary Care EHR and epSOS adaptors has been completed, thoroughly tested and reviewed with physicians. This work demonstrated that it is technically feasible to exchange medication and examination results among healthcare institutions managing patient data.Identification, terminology and clinical data exchange are addressed using standards and integration profiles implemented by shared iCARDEA components part of the EHR-IF, namely IHE PIX, HL7 CTS, and IHE CM.As a result, following primary care patient encounters, clinical data updates,can assist remote follow-up. In this way, the iCARDEA adaptive care planner has readily available the information needed for effective decision making.However, as clinical data crossinstitutional borders questions on organizational interoperability arise:

(a) How to treat incoming data? Should the EHR be automatically updated with the new data or should the GP update the EHR of the patient manually with incoming information?
(b) Data security: once organizational barriers are crossed who is responsible for the data accuracy and quality? Should the data source be noted?
(c) Interoperability testing: when is a solution adequately tested to be considered operational? What happens when one of the organizational systems is updated?

These questions need to be answered in the context of specific organizations and health systems as we move forward to operationalize integrated health services; an imperative for patient safety, efficiency, and effectiveness oftelemedicine.

5. Conclusions

iCARDEA aims to reduce the data burden of cardiologists by providing clinical decision support through semi-automated context-aware care plans. With the active support of clinical partners, semi-automated guidelines for Atrial Fibrillation and Ventricular Tachycardia, have been developed.Building on standards and IHE profiles, iCARDEA aims to remedy fragmented healthcare processes treating CIED patients by:

- Exposing CIED data through IHE profiles
- Semi-automating the follow-up of the CIED patients with context-aware, adaptable computer interpretable clinical guideline models
- Fostering EHR interoperability by exposing legacy EHR systems through HL7 CDAr2, IEEE11073
- Creating a Patient Empowerment platform to provide feedback on lifestyle educating patients for better living, sharing activity & problems.

This work shows that iCARDEA can be extended beyond the hospital to employ data created cross-border or in the primary care setting to support adaptive care plans. Today's standards can support the design of an intelligent interoperable platform fit for integrated care. However, deploying and testing integrated solutions is not straightforward and requires tackling technical and organizational issues. Better testing tools and data sets should be developed. Moreover, it would take a change in culture as well in the role of interoperability standards to enable contributions to clinical decision support, patient safety, and overall health system productivity.

Escalating care costs and novel care pathways challenge the traditional way of healthcare delivery calling for collaboration and sharing of information. Technical and organizational interoperability are keys in cultivating synergy and trust to support intuitive, simple, but also effective decision-support systems.

Acknowledgements

This work has been supported by the European Commission, iCARDEA Project "An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices". The authors would like to thank all members of the iCARDEA consortium for their contributions.

References

[1] Wilkoff B, Auricchio A, Brugada J, et al. HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations, in: Europace 2008 10(6):707-725; doi:10.1093/europace/eun122
[2] Dubner S, Auricchio A, Steinberg JS, Vardas P, et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). Europace. 2012 ;14(2):278-93.
[3] Erturkmen, GL, Dogac A, Yuksel, et al. The Personalized Remote Monitoring of the Atrial Fibrillation Patients with Electronic Implant Devices.Journal of Health Engineering. 2 (2), 2011
[4] de Cock CC, Elders J, van Hemel NN,. Expert consensus report on remote monitoring of implantable devices: the Dutch experience. Neth Heart J 2012; 20:51–52. http://www.cardiologie.nl/wp-content/uploads/nhj_2012_02_051.pdf
[5] van der Velde ET, FoekenH, WittemanTA, et al. Integration of data from remote monitoring systems and programmers into the hospital electronic health record system based on international standards http://www.cardiologie.nl/wp-content/uploads/nhj_2012_02_066.pdf
[6] Smart Open Services for European Patients, D3.8.2 Final National Pilot Set up and Deployment Guide, Sep 17, 2010, http://www.epsos.eu/uploads/tx_epsosfileshare/D3.8.2_National_Pilot_Set-up_and_Deployment_Guide_01.pdf
[7] Yang M, Chronaki CE, Lüpkes C, et al. An Hein. Guideline-DrivenTelemonitoring& Follow-up of CIEDs using IEEE 11073, HL7 & IHE Profiles, In Proceedings of EMBC2011, Boston
[8] CE Chronaki, S Sfakianakis, Y Petrakis, et al. Tomorrow's Integrated Care: Interoperability Testing in Guideline-driven Cardiac Telemonitoring, In Proceedings of IHIC2011, Orlando Florida, May 2011
[9] M Yang, CE. Chronaki, C Lüpkes, et all. iCARDEA: Practical Data Integration for the Follow-up of Cardiovascular Implantable Electronic Device Patients in Cardiological Departments, CiC2011, Hangzhou, China
[10] CE Chronaki, M Plößnig, F Tuncer, et all. Interoperability challenges in the health management of patients with implantable defibrillators, in CiC2011, Belfast, Ireland.

Address for correspondence.

Catherine E. Chronaki
FORTH-Institute of Computer Science
Science and Technology Park of Crete
N Plastira 100, 70013 Heraklion, Crete, Greece
tel: +302810391691, fax: +302810391428
email: chronaki@ics.forth.gr