# iCARDEA: Practical Data Integration for the Follow-up of Cardiovascular Implantable Electronic Device Patients in Cardiology Departments

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## Abstract

*In cardiology departments supporting implantation and follow-up of Cardiovascular Implantable Electronic Devices (CIED), relevant clinical data reside in autonomous healthcare information systems that support different health information technology (HIT) standards and proprietary data formats. Each organization chooses the Electronic Health Record (EHR) integration solutions, underlying technologies, and HIT standards based on their needs, experience and budget. However, without efficient data integration, significant gaps in workflow will continue to hinder immediate availability of critical medical information and limit optimal utilization of clinical and human resources. This paper presents iCARDEA cross-healthcare platform from the view of the cardiology department, driven by the story of fictitious patient with remote CIED monitoring and own Personal Health Record (PHR), supported by personalized care plan and cutting-edge eHealth innovation.*

## 1. Introduction

One of the main challenges facing current healthcare industry is enabling of timely and efficient access to information, which could greatly improve both the quality and cost-effectiveness of care [1]. Adapting treatment and follow-up to the needs and lifestyle of specific CIED patients would benefit from patient data available in information systems in and out of the hospital such as EHRs, PHRs and CIED vendor remote monitoring services. In other words, more and more, healthcare systems need to work in a coordinated manner to support health professionals in their work, thus increasing the demand for information exchange. The quality and safety of cardiology treatment can be deeply impacted by the availability of patient data, improving its timeliness and effectiveness.

In the iCARDEA project, a healthcare integration platform shown in Figure 1, applies clinical guidelines and data analysis mechanisms on the data retrieved from various healthcare systems to integrate patient information residing in and out of hospital, e.g. laboratories, outpatient clinics, vendor portals, thus facilitating prompt decision making.

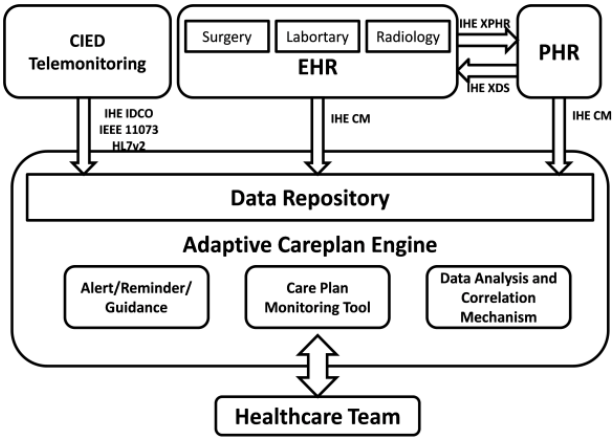


Figure 1. iCARDEA system architecture

## 2. Data integration methodology

### 2.1. Motivation for data integration

Currently, there are various types and brands of CIEDs implanted in patients. Different models of CIEDs are associated with dedicated sometimes different software tools and proprietary data standards. CIED patients' health data are also maintained in different healthcare systems within and across hospitals. The lack of data standardization results in limited interoperability even within a single institution [1]: there exist incompatible

systems, disconnected islands of information unable to communicate with each other and support integrated medical workflows in an efficient manner. Recognizing this problem, Integrating the Healthcare Enterprise (IHE) profiles have been defined to address systems and data integration issues and support the industry in developing standards based integration for specific workflows such as Care Management (CM) and Implantable Device Cardiac Observation (IDCO) [2].

iCARDEA proposes guideline-based follow-up of CIED patients, including clinical indications, contraindications, reminders as well as alerts based on the evaluation of all available related clinical data i. e. vendor reports from remote CIED monitoring, personal patient information from EHR/PHR based on personalized care plan templates proposed by the iCARDEA healthcare team, etc. Table 1 shows a general view of relevant data.

Table 1. Information required by a personalized care plan.

| PARAMETER | EXPLANATION | SOURCE |
|---|---|---|
| PATIENT INFORMATION | | |
| Name | Name of the patient | CIED/EHR |
| ID | Hospitals ID number | EHR |
| Age | Age of the patient | EHR |
| Diagnosis | Main diagnosis of patient | CIED/EHR |
| CIED model | Medtronic / SJM | CIED/EHR |
| PATIENTS CLINICAL STATUS | | |
| Hsp admissions | Hospital admissions since last visit | EHR/PHR |
| Medical history | Recent & prior medical conditions | EHR/PHR |
| Lab results | Recent lab results | EHR/PHR |
| Medications | Current medical treatment | EHR/PHR |
| ARRHYTHMIA EPISODES | | |
| ATAF | Number AT/AF episodes | CIED |
| SVT | Number SVT episodes | CIED |
| VT/VF | Number VT/VF episodes | CIED |
| SVT treated | Number SVT treated episodes | CIED |
| VT/VF treated | Number VT/VF treated episodes | CIED |
| ALERTS | | |
| Safety alerts | Safety alerts detected by device | CIED |

## 2.2. Methodology of data integration

**Exposing CIED-data from proprietary CIED-telemonitoring Service:** CIED follow-up through telemonitoring as developed, marketed and operated by CIED vendors, is being increasingly adopted in cardiology departments. For example, with Medtronic and St Jude Medical CIED-Patient Care Network, by sharing up-to-date CIED reports and parameters assessment, healthcare providers may gain better understanding of the progress in rehabilitation and the overall effects of medical treatment. Furthermore, emergency alarms and potential device problems will be immediately reported. In the iCARDEA project, (CIED) data will be exposed through standard interfaces based on international standards such as HL7, ISO/IEEE 11073 (Point of Care Medical Device Communication Standards); standard profiles such as the IHE IDCO Profile [3] and standard transport protocols such as Web Services.

**Interoperability infrastructure for EHRs:** The objective of the EHR interoperability infrastructure component is to identify and retrieve the clinical data of relevance to CIED patients and then convert them as appropriate HL7 Clinical Document Architecture (CDA) and its constrained version Continuity of Care Document (CCD) entries as dictated by the IHE CM profile. CDA and CCD comprise a human readable and a structured entry based on the HL7 Reference Information Model (RIM) providing the framework to refer to concepts and codes from coding systems such as SNOMED and LOINC. An HL7 Common Terminology Services (CTS2) component will be used to convert terms from value lists used in the health care systems to widely accepted terminologies such as LOINC, SNOMED, etc.

**Interoperability infrastructure for PHRs:** The iCARDEA project provides a framework for patient empowerment in the form of PHR system, which enables patients to take an active role in the management of their own healthcare, and benefits from the availability of their healthcare records in an easily accessible and shareable format. The PHR component will allow patients to track their activities, monitor their progress and request/receive feedback even assistance when necessary. Increased patient interaction with their health records and interoperability among health information systems can support healthcare delivery processes with timely and accurate patient information. iCARDEA platform enables hospital-based EHRs to be updated with care plan compliance data from PHRs and patient-based PHRs to be updated with up-to-date information from healthcare facilities. For this purpose, the IHE Exchange of Personal Health Record Content (xPHR) profile [5] and Cross-enterprise Document Sharing (XDS) [6] profile are implemented and configured.

**Data analysis and correlation mechanism:** Building a patient data-based decision support system requires substantial modeling work to define which clinical and patient data are relevant to a certain guideline. The data analysis component is responsible for presenting correlated patient data from all sources to healthcare professionals, in order to assist them in identifying the crucial patient parameters for personalizing their follow up [6]. Patient data from CIED, EHR and PHR, such as history of illness, surgeries, and medications are intuitively and graphically presented by interrelating the data from various sources. To obtain suitable suggestions for the healthcare teams, the data analysis component will not only use the data obtained from iCARDEA patients, but also data-mining results from previous cases.

## 2.3 Adaptive careplan engine

In iCARDEA, adaptive careplan engine, operates as a guideline-based clinical decision support system together with the care plan monitoring tool to: 1) communicate with dedicated healthcare systems i.e. CIED, EHRs and PHRs to receive and store relevant data as specified in personalized care plans, so that multi-parametric monitoring will be realized; 2) define and personalize machine processable care plans based on clinical guidelines to interact with responsible healthcare teams and transmit alerts, reminders and support personalized guidance services to CIED-Patients.

# 3. iCARDEA in action

## 3.1. Illustrative demonstration scenario

Below we refer to the disease trajectory of Mr. Schmidt, a fictitious CIED patient, to illustrate the iCARDEA cross-healthcare platform focusing on the perspective of the cardiology department, at different stages of a atrial fibrillation case: first admission to the hospital, surgery, rehabilitation, daily living with the implant, and assessment of events reported through telemonitoring to the healthcare team at the cardiology department:

- *[14 November 2009, 5pm]: Andreas Schmidt, born in 1953, experienced a sudden death when he was jogging in a sport center. He was reanimated on the road to hospital and was resuscitated approximately five minutes later and then defibrillated for ventricular fibrillation in the ambulance.*
- *[14 November 2009, later]: He was admitted to the Coronary Care Unit, his medical history was recorded in the hospital information system and he underwent several laboratory and diagnostic examinations: ECG, Echo, Digital Angiography, etc. Given his medical history of sudden death and the results of the diagnostic examinations, he was recommended for CIED implantation.*
- *[20 November 2009]: The CIED implantation procedure was successfully performed in the heart surgery department. The diagnostic report of the X-ray taken after the CIED placement showed good placement of the electrodes.*
- *[21 November 2009]: Mr. Schmidt was informed about the telemonitoring capabilities of his CIED implant and his option to maintain a PHR that would help him follow his health progress, and better coordinate better with his cardiologist, Dr. Jones and his team. Mr. Schmidt opted in.*
- *[24 November 2010]: Mr. Schmidt's was discharged from the hospital and the next two tentative appointments were set up for February 24, 2011 and May 24, 2011. Since Mr. Schmidt opted in for tele-monitoring, while the 1st appointment will be in the clinic, the 2nd one will be carried out remotely. In the meantime, his health progress, and any cardiac events would be reported via telemonitoring and someone in Dr. Jones's team would call him at home.*
- *[24 November 2010]: when Mr. Schmidt opted in for telemonitoring, clinical data including medical history, lab results diagnostic reports, etc, were processed in the iCARDEA EHR interoperability framework. Based on his clinical profile, a care plan was selected by his healthcare team and personalized. Based on this personalized care plan, adaptive careplan engine subscribed to clinical data updates in his PHR and EHR using IHE CM profile. Adaptive careplan engine is also configured to receive data from the CIED using the IHE IDCO profile. From that point on, adaptive careplan engine received updates from EHR and PHR.*
- *[Back home] Mr. Schmidt with the help of his young daughter started using his PHR where he kept a diary of his daily life activities, his blood pressure (BP) values and medications intake. He consented to releasing his daily activity levels, BP values, and medication intake to his cardiologist at the hospital.*
- *[February 24, 2011] Mr. Schmidt came to the clinic for his scheduled follow-up. He seemed well-adjusted to his new lifestyle. Dr. Jones adjusted his medicine dose and suggested that Mr. Schmidt resumes exercising.*

## 3.2. iCARDEA under the hood

On March 22, 2011, Nurse Allan logged in the CIED portal and documented an alert in Mr. Schmidt's folder and she exported data related to the event to notify the attending physician. Then Dr Jones stated execution of Mr. Schmidt's personalized atrial fibrillation care plan in adaptive careplan engine. The care plan suggested the presence of an atrial fibrillation event and corresponding EGM was presented to Dr. Jones, who confirmed this diagnosis. Current CHADS score was automatically evaluated at 3 based on recent data from EHR and PHR, and presented to Dr. Jones. Then the recommendation to consider anticoagulation therapy was appeared. From Mr. Schmidt's medication list as retrieved from EHR, along with the medication compliance information from PHR, any possible contraindication was highlighted.

Based on the information retrieved from EHR and PHR, Dr. Jones documented that Mr. Schmidt had a drug-eluting stent implanted 3 years earlier and was taking simvastatin and aspirin. No contraindication for anticoagulation was found. Therefore, the care plan recommended the medical professional to start anticoagulation and reevaluated the necessity of aspirin.

On the other hand, the atrial fibrillation care plan evaluated the degree of rate control of the arrhythmia. As the heart rate was >100 bpm, it suggested the presence of tachycardia to the doctor, who then confirmed it after reviewing the EGM. Therefore, adaptive careplan engine recommended considering an immediate referral to clinic with a subsequent evaluation of rate control drug prescription. In this step, based on the previously PHR message, adaptive careplan engine first checked whether Mr. Schmidt has an active life style.

Then adaptive careplan engine also checked the EHR and discovered that the patient has history of hypertension. Therefore, adaptive careplan engine recommended prescribing beta-blocker, calcium channel-blockers or digitalis. It also reported currently he was in fact using beta-blocker (nebivolol). The doctor might consider up scaling the dose or changing the rate control medication.

In the next step, with the help of adaptive careplan

engine the medical professional evaluated the need to perform rhythm control. For this purpose, adaptive careplan engine presented the updated EGM of the patient to Dr. Smith. The doctor confirmed the persistence of the arrhythmia and adaptive careplan engine suggested an "Urgent in Personal Follow-up".

## 4. Data integration benefits

The demonstration scenario described above, illustrates several important advantages of the iCARDEA approach: (a) the healthcare team is immediately notified of any cardiac events that Mr. Schmidt experiences and is able to respond promptly to Mr. Schmidt's problems. (b) iCARDEA assembles and processes all pertinent health information, so that the healthcare team saves time and effort. (c) in-patient appointments can be scheduled flexibly. Thus, this demonstration scenario provides preliminary evidence that iCARDEA has the potential to support increased effectiveness of medical treatment and positive economic benefit for patients and the cardiology department by enabling responsiveness, timeliness, flexibility, and quality in CIED follow-up.

At the same time, automating monitoring of data from different data sources and providing role-specific display of patient data for the next decision step reduce the workload of healthcare team. Healthcare teams are released from the complexity and the diversity of clinical guidelines. The personalized care plan of the CIED patient and device follow-up are facilitated by adaptive careplan engine. This approach is likely to promote and assist decision making based on guidelines and advance safety in treatment cultivating a sense of security for CIED patients.

Furthermore, through EHR/PHR integration and self-management, CIED patients are actively involved in their health care. Finally, through the exchange and sharing of information in decision-making, CIED patients and healthcare teams become significantly more empowered.

## 5. Conclusion

iCARDEA facilitates data integration between various healthcare systems through the provision of an intelligent platform to ensure secure and reliable communication of health data. Great benefit will be gained from integration of medical information that makes data much more accurate and medical information more conveniently accessible to both healthcare providers and their patients. At the same time, iCARDEA can facilitate and assist healthcare providers to promote collaboration with CIED-Patients and empower the efficiency and quality of cardiology departments when dealing with chronic, complex heart diseases such as life threatening arrhythmias. Furthermore, iCARDEA is well placed to build on and benefit from several important trends. One is the rapid growth in the amount and complexity of data captured by various healthcare devices and systems that provide the raw data expressing clinical situations in a form that should be interpreted for personalized care plan. Another is the increasing number of cardiology departments adopting remote CIED telemonitoring. As the patient case is presented to the healthcare team promptly and in an organized way that facilitates prompt evaluation and response, the trust relationship with CIED patients will be cultivated at no cost for the healthcare system. Thus, iCARDEA is expected to have a positive impact on health care quality for CIED Patients and a disruptive innovation for healthcare systems and vendors.

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