iCARDEA – an Approach to Reducing Human Workload in Cardiovascular Implantable Electronic Device Follow-Ups

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Abstract

The iCARDEA project aims at developing an intelligent platform to semi-automate the follow-up of CIED patients using adaptable computer interpretable clinical guideline models. For this purpose, data from hospitals' electronic health records (EHR), from patient maintained personal health records (PHR) and current generation of CIED devices provided by the remote monitoring services offered by all major vendors are collected and correlated. This article provides an overview of the project that has started in February 2010.

1. Introduction

More than 800,000 patients in Europe have an implanted cardiovascular implantable electronic device (CIED) today, causing 5.8 million follow-up visits for patients per year, and both numbers are quickly rising [1]. This calls for new methods of long-term surveillance with a view to optimizing patient safety and care, alleviating the burden of caregivers, and lowering health care costs through IT support.

One of the key problems in health informatics is the inability to share patient records across enterprises [2]. In the iCARDEA project, an intelligent platform is being developed to automate the follow-up of the CIED patients with adaptable computer interpretable clinical guideline models that seamlessly access data from EHR and PHR data resources as well as CIED data through standard interfaces. The computer interpretable guideline models under development will be adaptable, designed from reusable building blocks to easily personalize the patient follow-up. The guideline models will be converted to executable clinical workflows that will perform the follow-up activities and automate risk assessment via integrative models and hence support medical professionals by automatically assessing the situations and generating alarms.

2. iCARDEA system architecture

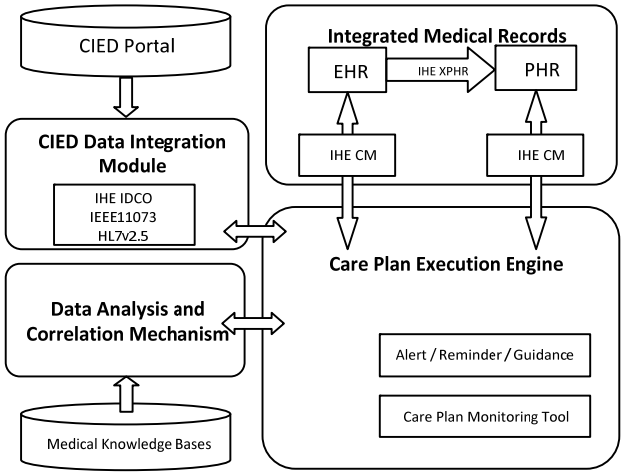

Figure 1. iCARDEA system architecture

Figure 1 gives an overview of the basic iCARDEA components and their interaction:

- CIED data integration module: an interoperability layer that exposes the sensor data and medical information system functionality as semantically harmonized and standardized data to tackle the problem of interoperability between different CIED vendors, medical information systems and the patient empowerment framework.
- Integrated medical records: to make clinical guideline systems more accurate and effective, interoperability with the electronic medical records will be required indispensably. For this purpose electronic health records and personal health records are integrated using the appropriate standards and integration profiles.
- Care plan execution engine: an intelligent personalized adaptive care planner for CIED recipients based

on semantically enriched, computer-interpretable guidelines.

- Data analysis and correlation for context awareness and clinically useful information derivation: a tool to help healthcare professionals to easily identify crucial parameters of a patient, providing suggestions based on data obtained from medical knowledge bases.

2.1. CIED data integration module

Many health care teams and organizations have invested significant effort in data interoperability. Interoperability is a property of a product or system, whose interfaces are completely understood, to work with other products or systems, present or future, without any restricted access or implementation [3]. Data interoperability is facing the challenge of accessing, aggregating and integrating data among multiple systems or external facilities. Unfortunately, most CIED data is made available today in a non-standard, non-structured or even non-coded form, resulting in a lack of interoperability [4].

Currently, CIED read-outs for clinical studies or patient follow-up must often be redundantly collected or the same type of data must be collected using different methods and formats depending on CIED vendors, since there is no standard format and interchange protocol supported by all vendors.

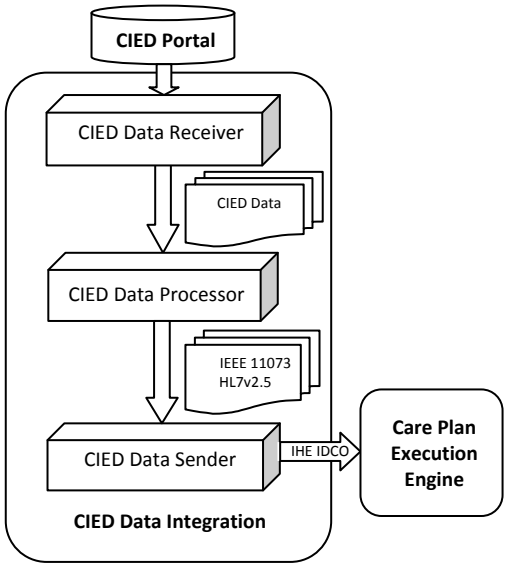

Figure 2. CIED data integration module

The CIED data integration module shown in Figure 2 enables the act of combining sources of CIED data residing in multiple, distributed locations to present a single, central collection of the data. For this purpose, the CIED data from various individual CIED vendors would be received, converted into a standard format and forwarded through a standard interface, which is defined by HL7, ISO/IEEE 11073 and the IHE Implantable Device Cardiac Observation (IDCO) Profile. The CIED data integration module will be composed of three main components:

- CIED data receiver: through various vendor-specific interfaces, CIED data will be captured with automatic login-in to the CIED vendors' data centers. This enables a regular receipt of up-to-date information with minimal manual interference.
- CIED data processor: the data provided by the CIED vendor's message will be extracted according to the requirements of the clinical guidelines used in iCARDEA. The CIED data will be encoded using IEEE 11073 Nomenclature into an HL7v2.5 message.
- CIED data sender: transmits the final IHE IDCO compliant HL7v2.5 message to the central receiver, in the case of iCARDEA to the care plan execution engine.

The CIED data integration module allows CIED data to be used in further applications (including, but not limited to the iCARDEA care plan execution engine), to be processed regardless of origin, and to be aggregated and compared across location and time.

2.2. Integrated medical records

An electronic health record is an evolving concept defined as a systematic collection of electronic health information about individual patients or populations [5]. The EHR includes information such as observations, laboratory tests, diagnostic imaging reports, treatments, therapies, drugs administered, patient identifying information, legal permissions, and allergies [6].

This information can be used to control the flow of computer interpretable clinical guideline models to be followed in the care plan. This, however, required EHR data to be available through a standard interface in a structured and machine-readable manner. The iCARDEA project aims at using the HL7 Clinical Document Architecture (CDA) as standardized format for the exchange of EHR content and the HL7 Web Services Profile as transport protocol, well knowing that existing HIS and EHR systems are rather unlikely to already support these today. Furthermore the IHE Care Management (CM) profile is studied as another (although technically related) standard interface that may well suit this use case.

Patient-maintained PHR systems contain additional useful information for the guideline execution such as diet logs and current medication and dosage of the patient. Therefore, a PHR component is also foreseen as part of the iCARDEA system. It will also be possible to update the PHR by new EHR data, e.g. relevant CIED data of patients or HL7 Continuity of Care Document (CCD) subset data, thus supporting the empowerment of the patients to be better informed about and involved in

their own healthcare.

2.3. Care plan execution engine

Healthcare professionals will be involved in iCARDEA effectively through the personalized adaptive care planner engine exposing multi-parameter data through various standard interfaces. For this purpose it seamlessly integrates the data of CIEDs, EHR and PHR without further effort from the user.

In order to support the management of complex clinical problems, the adaptive care planner engine offers the appropriate clinical guideline to be executed for each patient based on the selected pathway by reasoning on the patient's context. Through interaction with the existing healthcare IT systems for operations like scheduling in-clinic follow-up with the responsible physician and checking the existing healthcare records from EHR systems, the appropriate clinical guideline will be chosen to execute. The system will also provide specific reminders and personalized guidance services to the patient, via the PHR component, to enable improved compliance with the follow-up. Outcome parameters will be evaluated by the system as inputs to the control flow as a feedback mechanism, so that the care process can be adapted automatically, hence a closed-loop system will be achieved.

The engine will be supported with a monitoring tool as well, from which the execution of the care plan as a whole can be followed in detail. The monitoring process will be based upon a comprehensive auditing mechanism, where the detailed history of care plan will be maintained.

2.4. Data analysis and correlation mechanism

The Data analysis component is responsible for providing a visualization of the correlated patient's data from all sources to the healthcare professionals, in order to help them to determine the crucial parameters of the patient for personalizing the follow up. The data presented is enriched by automatically generated patient-specific warnings and suggestions based on statistically valid patterns. The patterns are extracted using state-of-the-art data analysis techniques applied to reference case knowledge bases.

To obtain suitable suggestions for the healthcare provider, the data analysis component will not only use the data obtained from iCARDEA patients, but also from previous cases. Therefore, the component will provide facilities to harmonize data changing over time. The analysis process will follow the "CRoss Industry Standard Process for Data Mining" (CRISP-DM) [7] and be performed regularly. Both parts of the data analysis component will ensure the necessary security and privacy of the patient's data by restricting the access and following the privacy preferences of the patient obtained from the PHR system.

3. Benefit of application iCARDEA system

The iCARDEA project provides an intelligent platform to semi-automate the follow-up of CIED patients using adaptable computer interpretable clinical guideline models. This is achieved by combining structured data from different sources with computer interpretable guidelines provided by iCARDEA as the foundation for the semi-automated personalized CIED follow-up and in support of the healthcare professionals.

3.1. Executable personalized CIED follow-up

iCARDEA aims to reduce the workload of healthcare professionals by releasing them from routine workflows. The intended process is as follows: The healthcare professional uses the data analysis component to see all accessible data from CIED, EHR and PHR for the current patient. The visualization (patient parameters displayed) can be parameterized to the different kinds of follow-up visits. Inconsistencies within data originating from different sources will be marked. Based on the values of the specific patient, personalized suggestions for suitable guidelines or patient specific warnings are presented. Because the healthcare professionals remain always in charge, they decide and select the appropriate guidelines and parameters for the follow up. After this, the physician is released from regular checks of patient data: The guidelines assigned to the patient are monitored automatically, that means, if new patient data is available, either from the patient through the PHR, from the EHR or through a remote readout of the CIED, the guideline is executed and in case of problems, the healthcare professional is informed. If there is a complication, the healthcare professional can call the patient for an in-person treatment. If there is a problem with the guideline execution or wrong parameters, the healthcare professional can adjust the settings for the patient. All this is implemented at a single system, so the healthcare professional doesn't have to deal with different CIED vendor specific tools and access many systems.

By obtaining CIED data through remote facilities and other current patient data from the PHR, the healthcare provider can also decide if an in-person consultation is needed by checking the latest patient data whenever he wants.

To obtain suitable suggestions, iCARDEA also provides data analysis on past cases based on the assumption that similar patients receive a similar treatment. There is also a component to add new computer interpretable

guidelines.

The data analysis component together with the care plan engine releases the healthcare professional from routine workflow, enables visiting time independent diagnostics and reduces the in-person follow-up to the unavoidable amount.

3.2. Prospect and opportunities

Due to the rising number of patients with implanted CIED devices causing nowadays already 5.8 millions follow-up visits a year, the need for IT systems to reduce the health professionals' workload such as iCARDEA is certainly increasing [8]. The expected benefits obtained from using iCARDEA are:

- The component based architecture connected by well established standards makes it easy to integrate additional components like other PHR or EHR systems.
- The CIED integration module can simplify the provision of standard compliant interfaces for CIED vendors.
- Healthcare professionals only use one system for monitoring the patient's data and don't have to be trained for every vendor.
- The healthcare provider's workload is reduced by automating and supporting routine workflows without lowering the quality of treatment.
- The patients using iCARDEA will hopefully less often require in-person follow-up and still know that their parameters are monitored all the time.

With respect to all these benefits we assume that iCARDEA will be a very interesting platform for healthcare providers and CIED vendors. Due to the standardized data interchange, the system can easily be adapted to be used with further devices providing structured patient data.

4. Conclusion

The iCARDEA system enables an intelligent semi-automatic follow-up for patients with CIED devices and improves the efficiency of healthcare delivery while reducing the administrative costs and time associated with accessing and analyzing CIED information.

By streamlined compliance with international standards such as HL7, CDA, IEEE 11073, the performance and efficiency for data collecting and processing will be improved.

iCARDEA is implemented as a common platform for CIED vendors and EHR/PHR systems. Due to the medical environment handling sensible patient data, the platform will provide sophisticated security and privacy mechanisms for all components and interconnections. The component based implementation using communication and data interchange standards for interaction makes it possible to easily add new CIED vendors or other data sources providing patient data using these standards. The prototype of iCARDEA will be evaluated at an Austrian clinic with CIED data integration of two major vendors.

We expect the successful implementation to encourage further structured data exchange between CIED vendors and EHR/PHR-systems by providing a platform to build on.

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