Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using IEEE 11073, HL7 & IHE Profiles

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Abstract— For patients with Cardiovascular Implantable Electronic Devices (CIEDs), telemonitoring promises improved quality of life and safety, since events recorded by the device or observed by the patient can alert a health professional. Taking into account the latest clinical guidelines when responding to such alerts, is a topic of active research addressed by the iCARDEA project. A key technical challenge is correlating telemonitoring CIED report data in a vendor-independent format with Electronic Health Record (EHR) data collected in the hospital and Personal Health Record (PHR) data entered by the patient, in guideline-driven care processes. The iCARDEA CIED exposure service component presented in this paper employs standards specifications from ISO/IEEE 11073 (Health Informatics, Point-of-care Medical Device Communication) and HL7v2.x in the context of Integrating the Healthcare Enterprise (IHE) profiles to deliver telemonitoring CIED report data from two different CIED vendors to the adaptive care planner that implements guideline-driven care plans. Experience gained with implementation and initial component testing is discussed, while challenges and expectations for future health information standards to **EHR-integrated** guide-line-driven effectively support telemonitoring services are highlighted.

I. INTRODUCTION

TELEMONITORING of patients with Congestive Heart Failure and other chronic heart diseases is gradually being accepted as a reimbursable medical act as Medicare in the USA has adopted a new reimbursement code for heart failure telemonitoring and insurance agencies in other countries are following. For patients with CIEDs, telemonitoring promises increased quality of life and safety, as events recorded by the device and associated CIED telemonitoring reports may be correlated with objective EHR data and subjective PHR data entered by the patient in guideline-driven care plans.

The technical challenge of designing and implementing an

intelligent architecture supporting interoperability standards that uses evolving clinical guidelines to make sense of EHR data, PHR entries, and CIED telemonitoring reports is addressed by the iCARDEA project. In this paper we focus on delivering CIED telemonitoring reports in a semantically consistent vendor-independent format to the adaptive care planner that implements clinical guidelines and forms the core of the iCARDEA architecture. Clinical guidelines endorsed by cardiology societies as [1],[2],[3] provide the basis on which cardiology departments can develop their care pathways incorporating clinical data from the hospital EHR and lifestyle data from the patient's PHR, with alerts and full telemonitoring reports from the CIED. The iCARDEA project has designed and implemented the framework for capturing and maintaining personalized care plans [4].

Patient data that could enable health professionals to effectively use prior diagnostic information in reaching treatment decisions are currently distributed in a number of disconnected systems. Thus, interoperability challenges in healthcare are important: healthcare systems have to deal with extremely diverse clinical information such as Electrocardiograms (ECG), biochemical examination results, and diagnostic reports, as well as with multiple healthcare specific standards. Moreover, integration profiles and interoperability testing in Healthcare Information Technology (HIT) are rather new. Medical device users, vendors and also healthcare providers have only recently realized that modules and sub-components conforming to IHE profiles can help eHealth developers and engineers to build reliable interoperable systems. In order to ensure interoperability and to conduct testing accordingly, detailed specifications need to be consistently implemented. Medical standards such as the ISO/IEEE 11073 standard for medical devices and HL7 are common data exchange standards used in HIT to ensure interoperability. In this paper, a module that is currently being developed to expose CIED telemonitoring reports through HL7v2.x ORU messages using ISO/IEEE 11073 IDC nomenclature and conforming to the IHE Implantable Device Cardiac Observations (IDCO) profile is presented. In the literature, there are several papers presenting the implementation of ISO/IEEE 11073 Nomenclature and HL7v2.x [5], but none to our knowledge, is using IHE integration profiles to feed data from EHR, PHR, and CIED telemonitoring into guideline-driven care

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plans. This paper presents the message processing infrastructure, the underlying methodology and architecture of the CIED exposure service. A discussion of interoperability testing with practical CIED data from two implantable cardioverter defibrillator (ICD) vendors demonstrates the challenges encountered and demonstrates the functionality for this module.

The paper is organized as follows: section II.A introduces the overall iCARDEA architecture focusing on the CIED exposure component and its interaction with the adaptive care planner and the patient monitor. Section II.B introduces the standards and integration profiles used to deliver vendorindependent reports to the adaptive care planner. Section III presents the results achieved. Section IV discusses the iCARDEA approach in the context of recently developed functional profiles for the EHR in cardiology, laying out common challenges met when building integrated fully functional vendor-independent eHealth systems. Finally, Section IV presents our conclusions.

II. METHODOLOGY: CIED EXPOSURE SERVICE

A. iCARDEA Architectural Approach

The iCARDEA project aims to develop and test in practice an intelligent platform to automate and personalize the follow-up of cardiac arrhythmia patients with CIEDs with context-aware, adaptable computer interpretable clinical guideline models using standard device interfaces and integrating patient EHRs and PHRs. The details are described more in [4] and on the official project pages (www.srdc.com.tr/icardea/).

CIED follow-up through telemonitoring that is offered today by most CIED vendors, is gradually being adopted in the practice of cardiovascular medicine. The sharing of updated reports and parameter assessment as offered by the patient care networks implemented by vendors, is helpful for healthcare providers to gain a better understanding of the progress in rehabilitation and the overall effects of medical treatment. Furthermore, emergency alarms and potential problems can be reported and addressed immediately.

In the iCARDEA project, CIED data are exposed through standard interfaces based on international standards such as ISO/IEEE 11073 and HL7v2.x ORU as constrained by the IHE IDCO integration profile and standard transport protocols such as Web Services. The overall process is shown in Fig. 1.

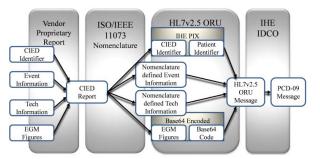


Fig. 1. Standards and profiles implemented in CIED data processing.

Generally, a full CIED telemonitoring report is composed of the following parts: 1) CIED identification such as individual device series number; 2) event information such as number of shocks, recorded arrhythmias, etc.; 3) technical information such as battery status; 4) intracardiac electrogram (EGM) figures. The CIED identifier is mapped with the patient identifier in the hospital-based EHR through a component implementing the IHE Patient Identification Cross-Reference (PIX) profile. Information on events such as shocks or arrhythmia events and technical information on battery status are encapsulated with ISO/IEEE 11073 nomenclature and converted into an HL7v2.5 ORU message. EGM figures in PDF formatted are Base64-encoded and inside the HL7v2.5 ORU message. Finally, an IHE IDCO PCD-09 message is sent to the adaptive care planner.

B. Standards and Integration Profile Aspects

Due to heterogeneous data standards and communication protocols in various eHealth systems, many aspects should be taken into consideration, such as consistent nomenclature, data access, data transmission, data formats and storage. The following standards and profiles will play an essential role in integration of EHR, PHR, and CIED telemonitoring data.

1) ISO/IEEE 11073 Nomenclature

Standardization begins with the vocabulary used for describing the concepts one is talking about. Multiple concepts may correspond to the same observation, but are often labeled differently by different vendors. The ISO/IEEE 11073 nomenclature concerns all aspects of cardiac rhythm disease management measurement devices, aggregators, electronic patient records, electronic health records, etc [6]. The ISO/IEEE 11073 nomenclature was especially developed for remote monitoring [7]. It enables communication between medical, health care and wellness devices and with external computer systems. This increasingly harmonized nomenclature facilitates automatic and detailed electronic data capture of client-related and vital signs information [8], and of device operational data from the ISO/IEEE 11073 domain such as 11073-10102 for annotated ECGs, 11073-10103 for implantable cardiac devices, 11073-91064 for ECG exchange, etc.

2) HL7v2.x Standard

As soon as terms ("words") are found to describe medical findings, a standard for how to combine these words into "sentences" is needed. These aspects are covered by HIT messaging standards. Messages are sent in between all partners of cardiac rhythm disease management [7]. HL7v2.x is the most commonly used HIT messaging standard worldwide. It has the aim to support hospital workflows by enabling different systems to communicate with each another. Early HL7v2.x messages use a textual, non-XML based syntax based on delimiters. Since HL7v2.5, an equivalent XML format is also available.

3) IHE Profiles

Integrating the Healthcare Enterprise (IHE) is an international voluntary collaboration of vendors, healthcare providers, regulatory agencies, and independent experts

working on improving medical data interoperability in a number of subject areas (domains) [6]. The IHE domain concerned with electronic medical devices is the Patient Care Devices domain (PCD). As one of IHE PCD domain integration profiles, IDCO has been defined for an intermediary system to send device data from an implantable device such as ICD to an enterprise system in HL7v2.x messages. The IHE PIX profile has been developed to enable correlation of patient identifiers from different sources, e.g. the hospital information system (HIS), the implant, or the personal health record system.

III. RESULTS: IMPLEMENTATION AND TESTING

A. Implementation

As shown Fig. 2, after receiving the telemonitoring report, the CIED data exposure component extracts all information items of interest, and maps them to the ISO/IEEE11073 nomenclature. Then, an HL7v2.5 ORU message is formed and sent to the adaptive care planner using the PCD-09 transaction of the IHE IDCO integration profile. Each of the steps is described below.

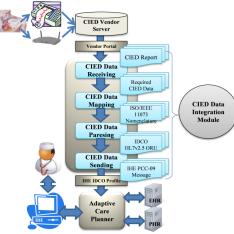


Fig. 2. iCARDEA CIED data exposure module.

CIED data receiving: A CIED telemonitoring report in PDF is transmitted from the vendor's portal based on a predefined telemonitoring schedule or after an alert is triggered by the CIED or the patient. Depending on the configuration in the vendor's server, PDF reports include information on various clinical or technical aspects. The adaptive care planner however, requires only the guidelinerelated information as noted in the definition of the personalized care plan. In the case of ventricular tachycardia (VT) alert [4], the care plan related data mainly refer to patient physiological and cardiologic measurements or device settings, but may also include other data items, such as technical data from the device such as its pacing details (Fig. 3), VT/VF therapy summary (Fig. 4), battery status (Fig. 5) and EGM (Fig. 6). According to the care plan, the essential information is highlighted for increased efficiency, allowing the health professional to retrieve the full CIED telemonitoring report.

Fig. 3 shows the extract of the CIED telemonitoring report that indicates the details of ICD pacing configuration. As this fragment shows, the pacing amplitude for right ventricle (RV) is 2.00 V and the pacing polarity of RV is bipolar information that is used by the adaptive care planner to assess a possible noise case in the VT care plan [4]: If there are other occurrences of such noise cases in the past week, then the adaptive care planner presents the recently retrieved lead impedance alerts, lead impedance trend report, and the value of the amplitude of the signal to the health professional, so that s/he can decide whether there is an abnormality.

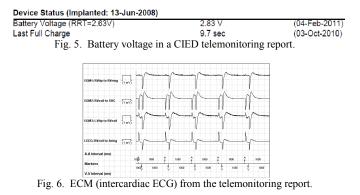
Pacing Details	Atrial	RV
Amplitude	2.00 V	2.00 V
Pulse Width	0.40 ms	1.00 ms
Capture Management	Monitor	Monitor
Acute Phase Remaining	Off	Off
Acute Phase Completed	11-Oct-2008	11-Oct-2008
Sensitivity	0.30 mV	0.45 mV
Pace Polarity	Bipolar	Bipolar
Sense Polarity	Bipolar	Bipolar
Fig. 3. Pacing parameters i	in a CIED telemonit	oring report.

Fig. 4 shows that: 1) the number of shocks applied over the specified time period was 2; and 2) the number of charges aborted over the specified time period was 0. The adaptive care planner by examining the CIED report data above, checks the total number of shocks and aborted shocks. In case of ventricular tachycardia (VT), if there are frequent shocks over a specified time period, the care plan recommends an urgent patient referral to the clinic to check his/her health status and treatment would be optimized [4].

Therapy Summary	VT/VF
Pace-Terminated Episodes	0 of 2
Shock-Terminated Episodes	2 of 2
Total Shocks	2
Aborted Charges	0

Fig. 4. ICD VT/VF therapy summary in a CIED telemonitoring report.

Fig. 5 presents the extract of the CIED telemonitoring report that indicates the measured battery voltage. As this fragment shows, the date and time of the battery measurements was 04-Feb-2011 and the voltage is 2.83 V. This can be used by the care plan to recommend scheduling of the elective replacement of the CIED. Unfortunately, vendors present this information in different ways.



CIED data mapping: During the process of CIED data mapping, the specified terms currently used by vendors are correlated with the terms from the ISO/IEEE 11073

nomenclature. Information from Fig. 3-5 appears on Table I.

	INDEE I
	ISO/IEEE 11073 NOMENCLATURE SAMPLE SEGMENTS
Pacing amplitude	729985^MDC_DC_SET_LEADCHNL_RV_PACING_AMPLITUDE^MDC
Pacing polarity	730113 [^] MDC_IDC_SET_LEADCHNL_RV_PACING_POLARITY [^] MDC
Shocks delivered	737824^MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT^MDC
Shocks aborted	737856 ^{MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT^{MDC}}
Battery measure time	721216^MDC_IDC_MSMT_BATTERY_DTM^MDC
Battery voltage	721344^MDC_IDC_MSMT_BATTERY_VOLTAGE^MDC

TABLE I

CIED formatting in HL7v2.5 ORU message: During CIED message parsing, ISO/IEEE 11073 data types are mapped to HL7 data types and observation results. Opensource tools are supporting the implementation of data interchange standards. HAPI [9] is an open source, objectoriented HL7 Application Programming Interface (API) that includes a set of Java tools for HL7 parsing and encoding to support connectivity and message handling. The observation results of the ICD pacing amplitude (Table II, row 1), ICD VT/VF therapy summary (Table II, row 2) and ICD battery voltage (Table II, row 3) are shown below encoded as OBX segments, which are the central part of HL7v2.5 ORU message. The EGM figure encoded as Base64 and encapsulated within OBX segment in HL7 message, as presented in Table II, row 4.

TABLE II HL7v2 5 ORU FORMATTED SEGMENTS

	HL/V2.3 ORU FORMATTED SEGMENTS
Pacing amplitude	OBX[1]NM]729985 [^] MDC_IDC_SET_LEADCHNL_RV_PACING_AMPLITUDE [^] MDC[1]2.00[V] F 20110204121708
Pacing polarity	OBX 2 CWE 730113^MDC_IDC_SET_LEADCHNL_RV_PACING_POLARITY^MDC 1 BI^Bip olar Lead F 20110204121708
Shocks delivered	OBX 3 NM 737824^MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT^ MDC 1 2{{shocks}} F 20110204121708
Shocks aborted	OBX 4 NM 737856^MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT^M DC 1 0 {shocks} F 20110204121708
Battery measure time	OBX 5 DTM 721216^MDC_IDC_MSMT_BATTERY_DTM^MDC 1 20110204000000 F 20 110204121708
Battery voltage	OBX 6 NM 721344^MDC_IDC_MSMT_BATTERY_VOLTAGE^MDC 1 2.83 V F 20110204121708
Base64 encoded EGM(pdf)	OBX 7 ED 18750-0^Cardiac Electrophysiology Report^LN^VTVF _EGM Application^PDF^^Base64^JVBERi0xLjVPRgog F 20110204121708

CIED message sending: Finally, the CIED data are sent to the iCARDEA adaptive care planner using the PCD-09 transaction specified in the IHE IDCO integration profile. The iCARDEA adaptive care planner works as a guidelinebased clinical decision support system complemented with a care plan monitoring tool that: 1) enables healthcare teams to define and personalize machine-processable care plans based on clinical guidelines; 2) communicates with healthcare systems i.e. CIED, EHRs and PHRs to access data as required by personalized care plans so that multi-parametric monitoring can be realized; and 3) interacts with responsible healthcare teams transmitting alerts and reminders while supporting personalized guidance services to ICD patients.

B. Demonstration Scenario

In this section we present a case of Mr. Schmidt, a fictitious ICD patient, to illustrate the application of the CIED data exposure module in iCARDEA. Mr. Schmidt, born in 1953, carries an ICD. On 10.02.2011, an alert reporting shock therapy for VT at 01:00 is received. The adaptive care planner receives and parses the HL7v2.5 message, then selects relevant data and EGMs based on the care plan execution for presentation to the health professional. Through adaptive care planner, it is observed that the patient has single episode of non sustained VT: VT in the fast VT zone with 3 ATP failures then a shock with termination of the VT. With the help of the adaptive care planner, the treatment is followed for the case of Real VT with single episode. Since the shock is effective and no inconvenience disturbs patient, the adaptive care planner recommends to the physician that there is no need for patient to come in clinic for further urgent follow-up. Further review of the episode by the physician is suggested because of the 3 ATP failures, but no changes in treatment are proposed. All ICD parameters are checked and observed to be in order, so the patient avoids an urgent follow-up, saving time, costs, and inconvenience.

On 02.04.2011, an alert reporting shock therapy for VT at 13:00 is received. It is observed that the patient had frequent episodes of non-sustained VT. The patient is disturbed with this shock and goes to the clinic to be checked for further urgent follow up. Treatment is followed for the case of Real VT with frequent episode by adaptive care planner. Since there were frequent episodes, the adaptive care planner recommends to consider decompensating factors after taking into account relevant information from the EHR and PHR.

These examples reveal the role of iCARDEA as traditional in-clinic and remote follow-up procedures are combined to improve the management of CIED patients and contribute to optimal use of healthcare resources. iCARDEA has a positive impact on the efficiency and quality of treatment as patient risk is minimized by prompt processing of alerts and effective decision support.

IV. DISCUSSION

Reflecting on the experience gained from mapping CIED report data from two different CIED vendors into a standard vendor independent format, interesting considerations arise regarding the direction guideline-based telemonitoring should take in the future and the ways that HIT standards and integration profiles should support it. Taking a patient centered approach with guideline-based telemonitoring, an interesting question is: "What are the types of clinical data produced/recorded in the hospital that are relevant to the follow-up of an ICD patient?" The Certification Commission for Healthcare Information Technology has developed comprehensive functional criteria for an EHR in cardiology [10]. Their work is based on the ISO/HL7 EHR system functional model that specifies the functions that should be supported by an EHR system classifying the relevant criteria in three categories: (1) direct care (i.e. care management; clinical decision support; operations management & communication), (2) supportive functions (i.e. clinical support; measurements, analysis, research and reporting; administrative and financial), (3) information infrastructure (EHR Security; EHR information and records management; provision of unique identity, registry, and directory services; support for health informatics and technology standards; interoperability; manage business rules & workflow). The functional model has been profiled for cardiology. The resulting functional criteria that have been endorsed by the American College of Cardiology include besides medical history, active medication list, lab results (INR, Total Cholosterol, LDL, HDL, Triglycerides, HbA1c), a long list of diagnostic reports associated with invasive and noninvasive procedures [11],[12]: ambulatory ECG monitoring, echocardiography, stress test, cardiac catheterization, electrophysiology procedures, and cardiothoracic surgery. Additional data include ejection fraction, etc. Additionally, the implantation procedure needs to be documented [13] and all ECGs diagnostic reports [14], cardiovascular risk factors, and vital sign trends. In the long term, HIT standards and guidelines should be improved to enable the efficient and effective use of all patient data for optimal decision support by patients and care givers.

In iCARDEA all this information should be available to the adaptive care planner as soon as possible, and the IHE Care Management (IHE CM) integration profile provides the appropriate technology based on well established standards such as HL7v3 and HL7 CDA/CCD [15] to actively assemble information from the EHR, and IHE IDCO to collect reports from CIEDs and realize this long term goal. However, the CCD templates supported by various integration profiles and implementation guides are not yet harmonized, and further work needs to be performed by SDOs to develop harmonized and consistent implementation guides that promote plug-and-play interoperability. Furthermore, test data and test suites need to be developed and be widely and consistently used to stimulate the adoption of interoperable systems.

It is also worth noticing that differences encountered in the telemonitoring reports of different CIED vendors require significant adaptation/configuration effort for each vendor, product and version. Not all data delivered by vendors in a proprietary format (e. g. bitmap graphics in PDF document) can be converted to an IHE IDCO compliant standard format. Furthermore, version changes of vendors' proprietary interfaces may render the system interoperable or, at least, require re-adaptation.

V. CONCLUSION

The iCARDEA architecture aims to provide an intelligent platform for guideline-driven telemonitoring and contribute to increased efficiency and quality of care for chronic cardiac patients. The CIED data exposure module streamlines compliance with international electronic data standards such as HL7 and ISO/IEEE 11073, providing access to telemonitoring reports from two CIED vendors. Thus, the efficiency of patient data collection, assessment, and alert processing may be improved. Furthermore, it allows the adaptive care planner to carry out automatic realtime data analysis, thus improving the consistency of patient information and the efficiency of healthcare delivery while reducing the administrative costs and time associated with accessing and analyzing CIED data.

The CIED data exposure component serves the promising world market of telemonitoring CIED patients and may simplify standards compliance for CIED vendors. The main potential challenges are the CIED data diversity and upgrading because of the differences between various CIED vendors. Nevertheless, further effort is necessary to improve the quality (i.e. semantic consistency) and depth of information (e.g. include original EGM waveforms) retrieved from the CIEDs through closer collaboration with all vendors and improved integration profiles.

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