Tomorrow's Integrated Care: Interoperability Testing in Guideline-driven Cardiac Telemonitoring

Catherine E. Chronaki[1], Stelios Sfakianakis[1], Yannis Petrakis[1], George Charalambakis[1], Lynne Hinterbuchner[2], Mihai Radulescu[3], Bob Mulrenin[3], Christian Lüpkes[4], Marco Eichelberg[4], Elena Arbelo[5], Yildiray Kabak[6], Gokce Laleci[6], Asuman Dogac[6]
[1]FORTH-ICS, Greece, [3]SALK, Austria, [4]SFRG, Austria, [4]OFFIS, Germany, [5]HCPB, Spain, [6]SRDC, Turkey

Abstract—**Certain types of heart disease such as sudden cardiac death or different stages of heart failure are treated by implanted electrical device. Advances in Information and Communication Technologies (ICT) allow tele-monitoring of implanted devices, event monitoring, and communication of alarms. Electronic Health Records (EHR) and to some extend Personal Health Records (PHRs) along with professional guidelines, expert consensus on evidence based care, provide support for e-visits and remote patient follow-up. For tomorrow's integrated care, empowering cross-organizational care teams assumes technical and organizational interoperability that requires integrated ICT systems for providing the right information, to the right person(s), at the right time. Integration testing of software components to ensure interoperability is one of the challenges addressed by the iCARDEA project. iCARDEA uses IHE profiles to integrate data from the implanted cardiac devices, EHRs, and PHRs and enable decision support based on semi-automated guideline-driven personalized care protocols. This paper presents the iCARDEA component testing and evaluation approach based on off-the-shelf testing tools and reflects on testing for plug-n-play interoperability: the tools and the standards needed to support tomorrow's integrated care.**

Keywords: health information technology standards, integration profiles, interoperability testing, telemonitoring, EHR, PHR.

I. INTRODUCTION

Diseases of the heart and circulatory system (CVD) are among the top causes of death in the industrialized world and Europe (48%) in particular [1]. The estimated cost of CVD in the European Union is estimated to 192 billion a year comprising direct health care costs (57%), productivity losses (21%), and informal care (22%) [2]. Integrated care aims to realize a new model of service delivery with an organizational principle that encompasses continuity of care engaging a team of professionals in different disciplines and possibly organizations working collaboratively on shared care plans to improve the well-being and outcome of chronic patients. Through integrated eHealth services, based on widely accepted and consistently implemented standards, technology has the potential to act as an enabler for integrated care [3].

In the case of patients with Cardiovascular Implantable Electronic Devices (CIEDs) a clear case for benefits, savings, improved care, and potentially lower costs through integrated care that includes tele-monitoring & e-visits, may be identified. Implant tele-monitoring is either event-driven or replaces one of the regular in-hospital visits with a remote one, leading to productivity gains, higher responsiveness in care, and time savings. Moreover, in the iCARDEA project, a guideline-driven integration of EHR, PHR, and telemonitoring data, the clinical profile of the patient is rapidly drawn increasing the productivity of health professionals. A key point is that the tele-monitoring is unobtrusive and used only when needed/planned contributing to a sense of security. This approach can be extended with the appropriate guidelines for all the different disciplines involved in the care of a CIED patient (social workers, nurses, cardiologists, therapists, etc). This naturally requires interoperability support: securing robust interplay of processes, actors, and information flowing through integrated component systems. Achieving this type of plug-n-play interoperability requires streamlining component integration testing, and that is the challenge that has to be faced today, even as the Continua Health Alliance type of design guidelines, testing, and interoperability labeling gain in popularity [4].

II. METHODS

A. iCARDEA

iCARDEA is a three year project that aims to develop and validate an Intelligent Platform for Personalized Remote Monitoring of CEID Patients [5,6]. iCARDEA aims to contribute towards decision support tools based on adaptable computer interpretable clinical guideline models which actively incorporate information available within the hospital (EHR), and the personal/home environment (PHR, implant). The system will be initially validated in SALK, an Austrian hospital that mainstreams tele-monitoring of CIEDs with support of leading cardiac implant manufacturers. However, the overall architectural approach can be used in any CEID clinic that would like to adopt tele-monitoring as part of the medical practice using guideline-driven adaptive care plans.

The integration approach of iCARDEA is based on IHE profiles that employ HL7 v2.x messages as well as HL7 CDA, CCD, and terminology standards (ICD, LOINC, etc). Guidelines are expressed in GLIF. HL7 CTS2 is used to leverage different terminologies. Imaging studies are based on DICOM, and ECG standards from the transfer of the data coming from cardiac implanted devices based on IEEE11073 nomenclature, are provisionally supported. IHE IDCO, IHE XDS, IHE PIX, IHE CM, and IHE xPHR are used respectively in exposing implant report data, converting clinical data from the hospital EHR to standard format, cross referencing of patient identifiers among the participating information systems, supporting active provision of EHR data relevant to specific care protocols or the PHR, and providing initial

information for the PHR to empower patients and encourage regime compliance & achievement of health goals.

In the iCARDEA modular setting, different software components contribute specific functionality as follows: patient monitor, adaptive care planner, EHR interoperability framework, patient empowerment framework, consent manager, and CIED data exposure service. The pressing need for practical integration testing in view of the high number of components and integration profiles in use, combined with concrete usability needs both from the perspective of the healthcare provider, but also from the perspective of the patient and informal care givers, called for a standardized testing approach.

B. Testing and Evaluation Approach

The iCARDEA evaluation and testing framework will follow the standard process defined on the evaluation reference model and guide ISO/IEC CD 25040 of the SQuaRE series of standards [7]. This standard details the activities and tasks providing their purposes, outcomes and complementary information that can be used to guide a software product quality evaluation.

The outcomes of applying a standard process approach for the evaluation activities in iCARDEA were repeatability, reproducibility, impartiality and objectivity of the full process. Several evaluation modules where employed to achieve this objective namely functionality testing at level of units, and use cases, along with along with reliability, usability, efficiency, maintainability, and portability. An evaluation team comprising developers, testing experts, as well as end users was set in iCARDEA to support this effort. Given that IHE profiles are used extensively in the iCARDEA system, it was decided to rely upon already developed off-the-shelf testing suites by IHE, NIST and others.

III. RESULTS

The overall integration testing process is based on unit and functional testing using off-the-shelf tools where available. Although the testing process outlined in figure 1, is still at an early stage, working in parallel to the actual development, a wide survey of testing tools for IHE profiles has been carried out. There are several IHE tools based mainly on the MESA tools supporting the IHE preconnectathon testing[1,2,3] these cover the XDS (Cross-enterprise Document Sharing), ATNA (Audit Trail and Node Authentication), PIX (Patient Identifier Cross-Reference), PDQ (Patient Demographics Query), IDCO (Implantable Device Cardiac Observation), and XPHR (Exchange of Personal Health Record Content) profiles.

The main observation was that availability and comprehensiveness of tools is uneven across profiles. While for some profiles extensive testing tools are available, for other profiles testing is nascent. Furthermore, we noted the lack of testing data suites, and benchmarks, as well as testing tools addressing complex use cases that involve multiple profiles. In that direction, using available IHE XDS and PIX testing tools, functional testing for the EHR interoperability framework was developed to support its main use cases as follows:

Subscribe to a clinical content profile & Provide updates. These use cases represent the subscription and the proactive delivery of matching EHR contents to the interested parties. The relevant software interfaces are defined by the IHE Patient Care Coordination (PCC) Technical Framework Care Management supplement as two transactions: Care Management Data Query (PCC-9) and Care Management Update (PCC-10). Both of these transactions are supported by the iCARDEA EHR Interoperability Framework that acts as a Clinical Data Source. For this functionality custom testing will be performed, as appropriate testing tools were not identified.

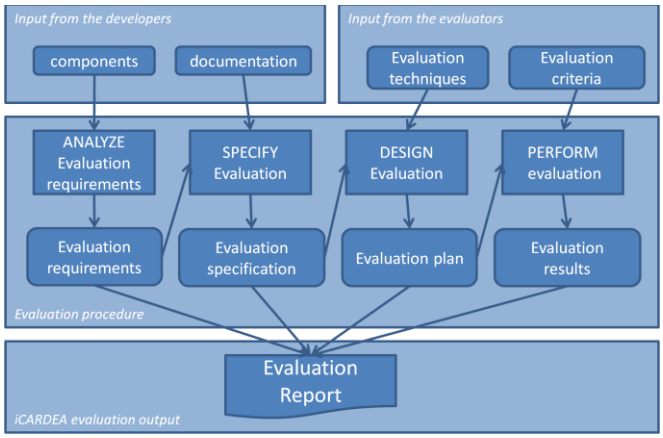

Figure 1: Information flow and activities of the iCARDEA evaluation

Export EHR data to PHR: The retrieval of EHR content from the iCARDEA EHR Interoperability Framework is based on the XDS Repository functionality. The EHR Interoperability Framework acts as a combined Document Registry and Repository and the supported transactions to be tested are the Stored Query and the Retrieve Document Set. The XDS Toolkit (http://ihexds.nist.gov/) by the National Institute of Standards and Technology (NIST) will be used as the testing software for these transactions.

Import EHR data from HIS/PHR: This use case refers to the uploading of new clinical data into the patient's health records maintained by the EHR Interoperability Framework. The core of this functionality is implemented though the XDS "Provide and Register Document Set.b" transaction and therefore the XDS Toolkit (http://ihexds.nist.gov/) by the National Institute of Standards and Technology (NIST) is an obvious choice for conducting the testing and evaluation. Additional testing will involve the iCARDEA "bridge" to the HIS, i.e. the EHR HL7Listener component, and the subsequent upload of the clinical content to the iCARDEA XDS Repository. For this testing special test HL7 v2 messages will be constructed to convey test clinical data and will test the transformation to CDA documents and the import to the XDS. An alternative is AHML, the Australian HL7 testing lab (www.ahml.com.au/)

[1] http://ihewiki.wustl.edu/wiki/index.php/Index_to_Preconnectathon_Test_Software
[2] http://ihewiki.wustl.edu/wiki/index.php/Pre-Connectathon/MESA_Software
[3] http://ihewiki.wustl.edu/wiki/index.php/NA-2011-Technical-Training

Manage Patient IDs: This use case concerns the enrollment of new protocol ids associated with patients that accept tele-monitoring as part of their follow-up and involves management of relevant patient identifiers. The managed IDs are associated with patient demographics and include the ID of the Implanted Device, hospital IDs, as well as the PHR ID of the patient. Alternative use case flows involve the search, retrieval, and cross referencing of these identifiers. The implementation is based on the IHE PIX and PDQ profiles and relevant interfaces and, therefore, the testing of this use case and the constituent scenarios will be based on the IHE compliant testing software. In particular the National Institute of Standards and Technology (NIST) Patient Identity Cross Reference (PIX) and Patient Discovery Query (PDQ) Test Tool will be used to test the ITI-8 ("Patient Identity Feed"), ITI-9 ("PIX Query"), and ITI-21 "Patient Demographics Query") transactions. This tool is accessible over the web at http://pixpdqtests.nist.gov:8080/.

However, for other components and particularly the IHE CM profile, there aren't any off-the-self tools and samples. For the more complex parts of guidelines and CIED exposure, there are no ready to use test applications and customized testing will be performed. The associated complexity increases further when considering use cases that involve multiple integration profiles across organizational boundaries in the absence of comprehensive test suites. Significant steps need to be taken to create robust testing tools and benchmarking tools that can be lead us towards plug-n-play interoperability.

We would like to use the TestBATN tool (Testing Business Process, Application, Transport and Network Layers) [8,9] as a framework to create complex business process tests that includes more than one integration profile by making use of the available test applications in a plug and play manner. The TestBATN framework with its computer interpretable test description language provides the necessary functionalities for the set-up and execution of test cases. By offering a choice of messaging adaptors to be plugged into a test case, the TestBATN framework gives the flexibility to tailor test scenarios that meet the varying transport and network layer needs of different systems. Its messaging framework enables the underlying intra-system communication to be intercepted without interference, hence making plug-n-play interoperability testing possible.

The intent of the iCARDEA is to share its testing tools and data sets to further enrich enrich prior efforts such as those of openECG (www.openecg.net) for testing samples of the IEEE11073 ECG standard and those of IHE-Europe in the frame of HITCH[4], Gazelle[5], and ePSOS (www.epsos.eu)[6] projects.

IV. Discussion

Today integration testing relies mainly on custom tools for this kind of software application. This situation needs improvement for plug-n-play interoperability to be realized leading to robust & reliable systems supporting integrated care. Streamlined interoperability testing is important for component based systems enabling integrated care. The case of guideline-driven tele-monitoring is an interesting one as it dictates an unobtrusive case of e-visits and remote alerts being integrated in the health care process. Although iCARDEA does not address the full spectrum of integrated care of CEID patients, it has designed an integrated system based on complex interoperable components to support different stages and actors in the overall care process. Naturally, a robust testing and evaluation process is necessary to create systems that serves its purpose improving care and saving money.

For the future, we expect that the creation of benchmarks, and robust testing tools for all profiles and their combinations in the context of use cases that could support component certification and pave the way towards plug-n-play interoperability.

[4] http://www.hitch-project.eu

[5] http://gazelle.ihe.net

[6] http://jumbo.irisa.fr:8080/SchematronValidator-prod-SchematronValidator-ejb/GazelleObjectValidatorWS?wsdl

V. Conclusions

In this paper the topic of integrated testing and evaluation of component systems was discussed that allow coordination of processes, people and information in the context of integrated care. Taking as an example the iCARDEA project, which aims to enable guideline-driven tele-monitoring of CEID patients, seamlessly integrating data from implanted devices, hospital patient records, and personal health records. Although this process is by no means complete, it gives us the opportunity to search for available tools, and reflect on future of shared resources and infrastructures for interoperability testing.

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