I_2A: AN INTEROPERABILITY & INTEGRATION ARCHITECTURE FOR MEDICAL DEVICE SOFTWARE AND eHEALTH SYSTEMS

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***ABSTRACT**: eHealth systems are evolving globally for managing medical data and timely exchanging health information and documents among medical devices and software systems at home, clinics and hospitals. Medical data is an essential part of eHealth systems used for health monitoring and rehabilitation of citizens. Interoperability and integration are huge challenges for communicating health data among diverse medical devices, device software and eHealth systems. In the healthcare scenario, regulatory requirements come on the top of technical interoperability and integration for validation of devices, software, healthcare documents and data based on regulatory authorities and directives. Most of the research considers either technical integration or regulatory requirements in isolation. This paper proposes an I_2A architecture to achieve not only technical interoperability but also validate medical device software and eHealth system against regulatory requirements. In order to cover regional medical device regulations and eHealth systems standards, the I_2A architecture uses more generic approach for transformation of regulatory requirements using available transformation guidelines of regional authorities.*

1. INTRODUCTION

eHealth applications are growing rapidly for handling medical data of citizens relying on interoperable and scalable distributed systems [1]. Medical data is the backbone of eHealth systems. Due to importance of medical data and its social, legal, and organizational requirements; the technical and IT challenges for handling medical data becomes more intensive. Interoperability is a critical issue for communicating and handling different formats of medical data, which includes text, images, and animations. At the same time, various legal and technical standards are involved in handling, processing and communicating the medical data. Interoperability and integration in eHealth system depends on various levels of medical device and eHealth systems connectivity on the underpinning of device communication, network data exchange and business workflows processed by healthcare system application services. It covers a very vast technical and organization scope and poses huge challenges to connect bits and pieces in a regulated and standardized way. Standards such as IEEE 11073 [2], HL7 [3], HIPAA [4], EU Directive [5] are striving hard to define standard requirements to achieve semantic and technical interoperability and also ensure security of data and safety of patients using medical device and software. Medical software manufacturer industry is following the strict regulatory requirements of MDD [6], FDA [7] and ARGMD [8]. At the same time guidelines are provided for development of software using controlled software development lifecycle in ISO/ICE 15504 [9] and ICE 62304 [10] standards. This explains how challenging it is to develop compatible medical device software and eHealth system, so that those comply with both the development process and interoperability and regulatory requirements in parallel for the healthcare system workflows.

During our investigation, we found that the related research either considers interoperability & integration requirements or regulatory requirements in isolation creating huge gap for verification and validation of medical device and eHealth systems. This contribution propose an I_2A architecture to encompass technical, organization and regulatory requirements for development process, data exchange, and storage.

The rest of the article is organized as follows. Section 2 presents the related work in the domain of medical device software and eHealth system interoperability, integration, and regulatory requirements. Section 3 investigates specific challenges faced by different stakeholders for medical data and eHealth systems. Section 4 presents the proposed architecture to meet those challenges using a generic I_2A architecture. Section 5 provides concluding discussion.

2. RELATED WORK

IEEE 11073 aims to establish communication among medical devices, healthcare applications and external systems [2].

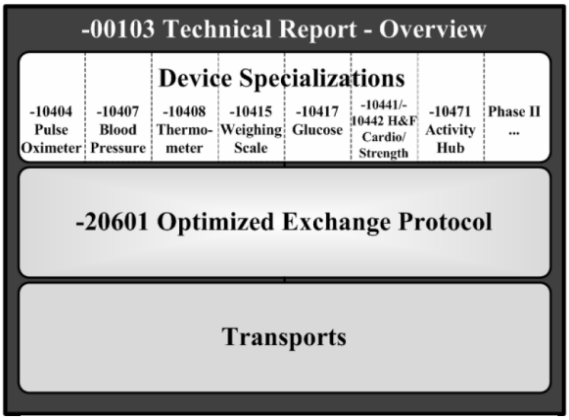

Figure 1: IEEE 11073 architecture

Figure 1 shows the architecture of IEEE 11073 standard which includes base standard i.e., 20601 and device specialization standards i.e., 10404 and others. It provides one level of interoperability among devices and healthcare applications. Few implementations of IEEE 11073 are available. For example, Antidote [11] open source implementation integrates IEEE stack and healthcare applications using transport technologies. Other standards e.g., HL7 focus higher technical and business level to achieve interoperability and integration among applications and systems [3]. HL7 is a family of standards based on a framework for exchanging and accessing medical data. It's a huge challenge to integrate and interoperate systems developed in different software platforms and technologies. HL7 plays extensive role in standardization of medical systems

and data. It's a globally recognized standard also for management and evaluation of healthcare system business workflows and procedures. The technological underpinning of HL7 standard is XML-based used for connecting systems in a platform-independent manner.

Medical data is security-sensitive; it is important to develop reliable and certified eHealth systems involving communication with medical devices. In parallel, the software used by medical devices requires same level of certification as medical devices. In fact it is considered as a medical device, because it processes the medical data more or less the same way as medical devices using proprietary or standard protocols [12]. The related standards encompass established procedures for medical software development, verification and validation. For instance, IEC 62304 addresses development, maintenance, and risk management processes of medical software to ensure safety and effectiveness of medical data and application workflows [10]. ISO/IEC 15504 is one step ahead in the direction of medical software development focusing process improvement within technology organization. The assessment process framework is the key of ISO/IEC 15504, which takes into account pre-process assessment and process rating activities along with data validation and verification. Other standards discussed in [13] focus more aspects of medical devices and medical device software.

Healthcare standards are not the only basis for medical device and eHealth system. Additionally, technical standards used for communication are the backbone for connecting devices with applications and applications with systems in a seamless interoperable way. Wireless communication technologies used for personal area networks (PAN) such as Bluetooth and Zigbee are the key technologies used in this arena. Medical devices used for measurement of blood pressure, weight, oxygen saturation, and other vital signs, supporting sensors and wireless transport allow efficient and reliable data integration through Bluetooth network [14]. On the top of Bluetooth stack, health device profile (HDP) is specifically developed application protocol for medical devices to ensure secure and reliable transmission. The HDP profile provides strong application level interoperability with connection-oriented multiple data channels [15]. Correspondingly, ZigBee standards provides interoperability and integration among medical devices and applications using ultra low power devices [16]. ZigBee offers enhanced security level using AES 128 encryption and connects wide range of personal and clinical health monitoring devices and home automation solutions. ZigBee technologies are aligned with Continua Health Alliance [17], which have broader scope of interoperability for eHealth systems.

RRID technology and applications are extensively used in hospitals to monitor patients and enforce authorization for accessing eHealth system services. CareStore project [18] uses RFID tags for user and device authentication in the cloud-based healthcare store for medical devices and applications. The same is also used for seamless and automatic integration of devices and applications with the homecare platform.

3. EHEALTH SYSTEMS CHALLENGES

eHealth systems have evolved many challenges at every stage starting from requirement specifications to implementation and operation. Some of the key challenges within the scope of this article are discussed below:

Business and IT alignment for eHealth Systems:

At the system requirement phase the huge challenge is to translate business policies into software requirements. Plenty of gap exists among the knowledge and semantics of business and technical vocabulary. The domain experts and software engineers have different perspective of the eHealth systems. It's hard to find common set of procedures to align the business with IT for eHealth solutions. At the same time, more requirements coming from legislation and administrative bodies enforce an additional burden on business and technical alignment of eHealth systems. For example, the privileges of a physician to access the medical data of a citizen may varies in different regional or national regulations.

Interoperability:

Interoperability is defined as the property of an application, device or system to be able to exchange business data in meaningful way. Interoperability has different levels such as semantic and technical interoperability. The former relates to the organization policies, whereas the latter is concerned with technical implementation of the systems including the technologies and protocols used to develop systems components. HIMSS [19] defines interoperability as the ability to exchange healthcare data across eHealth systems, which are running across organizational boundaries.

Integration:

Integration in the domain of eHealth data and systems is the ability to connect scattered applications and devices efficiently and effectively. The HL7 standard provides interoperability and integration for interfacing using common technical language. The organizational scope of HL7 integration is very broad and its technical documents cover protocols for clinics, national healthcare record, medical imaging, and insurance.

Medical Device Software Processes:

Development process of eHealth systems is a crucial factor, which leads the stakeholders to evolve such systems, which do not only provide the required functionality but also ensure quality of service. The quality of service is evaluated based on the standards and legal frameworks formulated for medical devices or medical device software. The life cycle requirements of the medical software are defined in IEC-62304 standard [10]. Medical device software has to get through the additional regulatory requirements, besides technical software development lifecycle processes. The challenging part of regulatory requirements is that the validation standards are different in different global regions. For example, FDA has defined validation requirements of medical software used in USA, which covers the medical software used as the embedded software installed on the device or a software component attached to the execution of embedded software in an external computing environment such as PC or smartphone. Figure 2 shows a typical medical device software development process. The evaluation and programming standard checking are typical activities specific to medical device software.

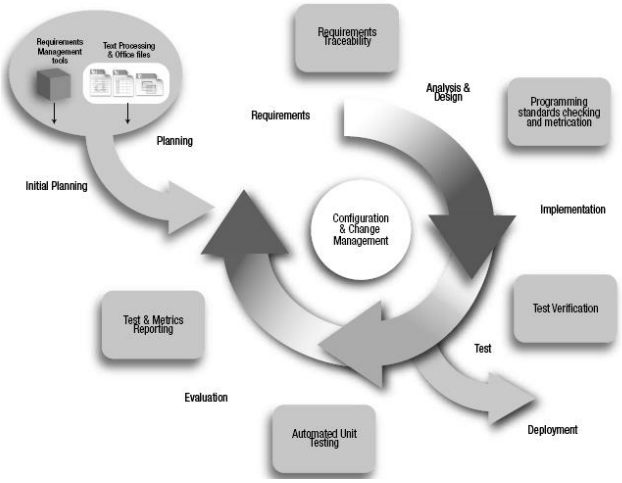

Figure 2: Medical Device Software Development Process

The European Medical Device Directive (MDD) requires medical device and software companies to meet the requirements defined in MDD for integration, standards, interoperability, safety and marketing. Likewise, the Therapeutic Goods Administration (TGA) in Australia regulates the medical devices and its software before the devices is supplied in the Australian market [8]. The Australian Register for Therapeutic Goods (ARTG) covers all the aspects of medical device and software development from concept to obsolescence.

Security and Privacy:

Security and privacy of medical data is an inherent property of eHealth system. People and healthcare organizations are extremely concerned about the technical security and privacy of medical records. Unfortunately, there has been plenty of global incidents of intentional and accidental breach of privacy, which has increased an awareness among the masses on one hand and also enhanced the responsibilities of medical device and software manufacturers to consider the privacy issues more seriously [20]. The eHealth systems offer services of access medical information and create/update medical documents such as diagnosis reports, medical images, and referral documents. Security is required at both service level and document level in communication and storage. HIPAA security rule [4] adopts cutting-edge technologies for improvement of eHealth service efficiency for patient care. However, the personal identification information of individuals should be secured through anonymization techniques, if medical data is used for secondary purpose such as research, marketing or governmental reports.

4. INTEROPERABILITY AND INTEGRATION ARCHITECTURE (I_2A) FOR EHEALTH SYSTEMS

The discussion in previous sections highlights the most critical integration and interoperability requirements of eHealth systems. Though the research in this direction is extensive but divided in terms of covering all the critical requirements of eHealth systems. A reference architecture that covers the most critical requirements of eHealth systems starting from business modeling to validation of medical device software and eHealth together as a complete solution is still missing. To continue research in this direction, we propose a reference architecture that encompasses eHealth systems requirements comprehensively with extended and specialized needs of business integration, technical interoperability, data security and regulatory based validation. The reference architecture shown in Figure 3 has following layers:

User Application Interface (UAI):

The User Application Interface layer covers the requirements and standards applicable for development of client-side applications within eHealth Systems. Currently, the most commonly used user-interfaces rely on web applications and mobile applications. At the backend, service interfaces connect applications with eHealth systems for sending medical data to central database. The UAI is integrated with medical devices within the wireless personal area network (PAN) via Bluetooth or Zigbee protocols.

Personal Area Network (PAN):

Web and mobile client applications are locally connected with devices producing medical data for health monitoring and clinical observations such as blood pressure, pulse rate and weight. Medical devices create these vital signs and transfer the data using PAN via Bluetooth or Zigbee. Additionally, RFID is used for device identification to initiate connectivity at transport layer. PAN provides a secure and reliable medial data transfer using certified devices medical device software over wireless network.

eHealth Systems Services (eHSS):

eHealth systems services are the core business or functional services required by healthcare professionals and patients. Example of such services are: creating a patient profile, creating an electronic health record (EHR), viewing periodical health reports of patients, creating and views X-Ray, ultrasound or other medical images. The embedded medical device software transfers the vital signs through services to the eHealth systems. The eHealth system also stores the data into database of electronic health records.

Interoperability & Integration Architecture (I_2A):

I2A layer solves interoperability problems by transforming the medical data into the standard format. The interoperability standards such as IEEE 11073 play a vital role in this part of integration for connecting devices with local applications. To achieve further integration with the central hospital systems, the I2A layer transforms the data into HL7 format as shown in Figure 3. The I2A layers is also responsible to store the data into central database including the information of patients' personal profile and healthcare data such as clinical observations and health monitoring reports. The medical data is stored in the standard format in electronic healthcare record (EHR) database. The data can be accessed by eHSS services by the healthcare professionals and patients with proper authorization.

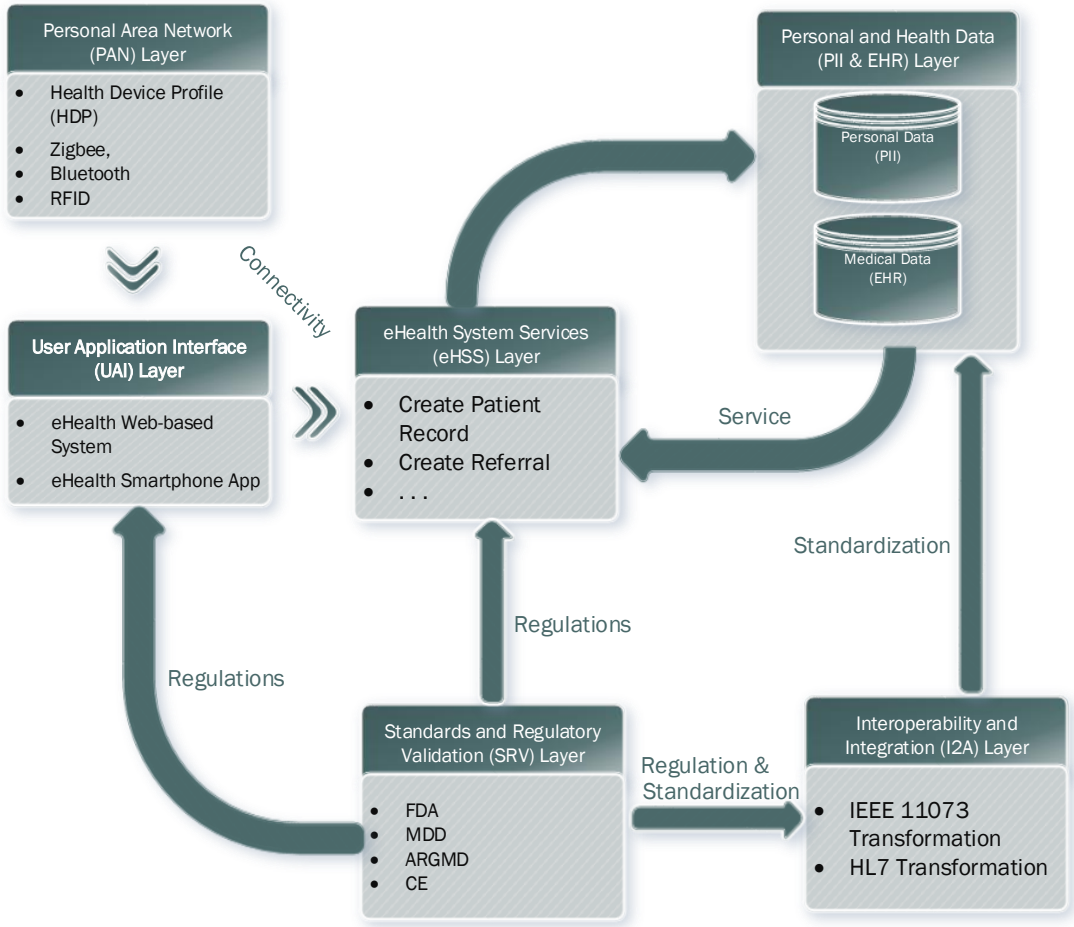

Figure 3: I_2A **architectural components, interfaces and workflows**

Standards & Regulatory Validation (SRV):
Throughout the process of creating, communicating and storing the medical data, the standards and regulatory validation (SRV) layer checks at any stage if the regulatory requirement applicable to development, operation and communication process and data formats are achieved. SRV layer is most powerful feature of the proposed I_2A architecture. Most of the related solutions discussed in *Section 2* consider either communication and data format standards or regulatory standards. The proposed architecture consists of both so that the medical device software quality is verified throughout the development and operation phases of eHealth systems. The SRV layers is central in I_2A architecture to achieve interoperability and integration but not at the cost of producing unauthoritative medical device software and eHealth system. On the contrary, it interfaces every phase to check regulatory requirement in a controlled environment. I_2A is a generic solution, which considers the regulatory requirements depending upon the region or country. For example, FDA for USA, EC and MDD for Europe and ARGMD for Australia. There exists a semantic interoperability gap among these standards, but it is the responsibility of the regulation authorities to provide transformation rules among the regulations as also discussed in [8], which compares ARGMD and CE requirements for medical device manufacturing. The I_2A architecture does not provide such transformations but instead relies on the transformations provided by the authoritative bodies.

5. CONCLUSION AND DISCUSSION

The development and validation of medical device software and eHealth system is an 'Easier said than done' task. The challenges are huge and the regulations are very complex. Also, regulation have local scope in manufacturing but global scope in marketing and sales, which creates a gap in understanding and authorization. Practically, it is near to impossible to create an organizational and technical homogeneity of standards and protocols. The encouraging fact is that the regulatory authorities and governments are aware of the problem and putting all effort resolve technical and semantic gap to produce verifiable medical device software and eHealth systems. In coming years more emphasis is required to produce equivalent standards and regulations, so that the device manufacturers and software development lifecycle have guidelines within the regional reach. The technical contribution for developing tools will follows the strategic steps taken by the authorities. Today the technologies

are stablished, but what is missing the business alignment of technical solutions in the medical domain. The applicable technical solution with focus on different standard and regulatory aspects will bring the business and technology together to achieve satisfaction both from an end user and business stakeholders.

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