Integrating Data and Network Standards into an Interoperable E-Health Solution

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***Abstract*—E-health has raised a great deal of expectations on improving the quality of health services while simultaneously enabling health services cost reductions. To advance towards those visions, it is imperative to gain the trust of the involved stakeholders, doctors and other medical personnel, patients, families, health care providers and regulators. Even though one critical requirement is interoperability among the various systems involved, currently existing solutions are still vertical silos to a large extent. In this paper, we present an E-health solution that results from the integration of components that comply with rising standards at the various levels of the ICT infrastructure: Machine-to-Machine (M2M) communications for interconnecting devices and services, Health Level 7 (HL7) for communicating with health platforms and openEHR for data semantics, storing and making data available. Concretely, we provide an interoperable and extensible e-health service following these three uprising standards and present the architecture design. We map the service to the various components of the infrastructure building blocks, thus demonstrating how the integration can be successfully accomplished. We are currently developing a prototype solution to be used in a pilot project with 15 elders.**

***Index Terms*—Machine-to-machine communications; EHR; HL7; openEHR; system integration**

I. Introduction

The uptake of e-health has not been as expected initially [1]. Its adoption is growing on the several fields that it occupies, user self-monitoring, home monitoring, hospital systems, online consultations or online information, to cite a few [2]. However, these efforts have been too disparate and not concerted [2], [3]. With regards to collection of medical data from patients (at home or in the hospital) and its usage in Electronic Health Records (EHRs) the systems are unrelated and developed to suit a need. To the best of our knowledge there is no framework that enables the integration of different monitoring devices using a scalable infrastructure that connects to a standard EHR system. Our proposal uses the M2M architecture to enable the simple integration of monitoring devices into the system. OpenEHR is the de-facto standard for storing health records. HL7 is the communication and structure standard for conveying medical information. We thus define a framework that interconnects these standard structures to provide a modular, scalable and inter-operating architecture.

We will describe a motivating scenario, before introducing the standards and the proposed framework.

II. E-Health Service

To drive our development and also to better illustrate the application of our service we will describe a storyboard as our working scenario. A very similar scenario is going to be tested with a primary care unit and a selected group of senior citizens.

Mrs. Maria is an elderly woman of 73 years. She lives by herself on the third floor of a building near the town. During her daily life she wears a monitoring system that collects physiologic data related to her health. She has to be monitored as she is at risk of developing Alzheimer and to control her heart condition. The wearable system collects heart rate (variability, R-R interval), breathing rate, posture, activity level, geographical position and steps taken. This is a specific kit related to her health condition.

The monitoring system uploads the data, using a mobile phone, to her primary care unit, where it is stored in her EHR, indexed by her national health identification number. The system analyses the data and searches for patterns that indicate problematic conditions. Today the system detects the occurrence of several mild arrhythmias. An alarm was sent to her primary care unit and the nurses on call followed up by phoning her. It was recommended that she rested the rest of the day and that a doctor would visit her in the afternoon. The visit prompted a change in medication. The doctor advised that she should still rest in the next day, but after that she could resume her daily walks that she so thoroughly had been doing. On the following days the monitored values returned to normal and so did Mrs. Maria's walks, as indicated by the system.

The described scenario raises several requirements on a monitoring system. There are "wear ability" concerns related to the sensors for monitoring the physiologic signals, not only on the ease of use but also on functionality according to the user's normal clothing. Connectivity of the monitoring system to the storage and processing components is also relevant. Depending on the allowed delay for getting the data, this might range from a once in a day upload or to an "always-connected" solution. Privacy of the data is also paramount which adds constraints on data transmission and handling in the system. Reliability and fault tolerance of the system is also extremely important. The connectivity of the different components, the routing of the messages to interested modules, storing the information using standard models, defining the processing components and the system architecture that connects it all are the focus of this paper. Our goal is to ease e-health usage by leveraging known and recognised standards into a framework that provides an effortless and scalable approach to e-health data communication, storage and access.

III. Related Work

Mobile phones have acquired powerful capabilities, in terms of connectivity, battery, memory or processing. Nowadays, mobile phones have achieved a tremendous pervasive presence. Due to their capabilities, mobile phones are becoming an important platform for the proliferation of health-related applications [4]. In recent years, several applications for tracking health-related information (e.g., heart rate, blood pressure or stress levels) or for encouraging physical activity have been developed. Still, healthcare applications continue to use proprietary solutions, in spite that using healthcare or communication standards could speed up the real commercial use of such systems.

The eCAALYX Mobile Application [4], developed under the Enhanced Complete Ambient Assisted Living Experiment EU-project, aims at building remote monitoring for senior citizens with multiple chronic diseases. The mobile applications acts as intermediary between the wearable health sensors and the healthcare facility's Internet site by transmitting the measurements and position or potential alerts. Some other mobile applications like UbiFit [5] enables tracking of cardiovascular exercise or strength training, and users can see daily and weekly views of their data. DiabMemory [6] enables diabetic patients to self-monitor blood glucose levels, insulin use, intake of carbohydrates, and physical activity. The phone application synchronizes with a website where users can chart their data in different ways to better understand how various factors affect their blood glucose levels.

Tracking of health information can also lead to remote coaching interventions where the data collected on mobile phones can be used, after uploaded to a website, for coaching interactions. A mobile phone application for monitoring and coaching of young adults people with type 1 diabetes is presented in [7]. Patients uploaded their blood glucose levels, alongside with the amount of insulin injected, the planned food intake, and the planned physical activity for the next hours. This data would serve as basis for weekly phone calls from nurses to discuss potential issues.

It is clear that information systems are evolving to meet people's needs by implementing regional networks, allowing patient access and integration of ever more items of patient data. Many distinct technological solutions coexist to integrate patient data, using differing standards and data architectures which may make further interoperability difficult [8]. As such, these integrated e-health solutions are, in our view, integrated in a case-by-case approach.

In [9] it is argued that without strong government or cross-border institutional regulations the objectives of obtaining a fully integrated and interoperable healthcare information infrastructure system is not possible. The growing number of patients with chronic diseases and the ageing population world wide will mandate the need to accelerate the progress. The paper discusses the different standards that need to be followed to have interoperable health systems. They show that there are a multitude of these standards and divide them into two blocks: transmission of health data and data structure of EHR. Kreps and Neuhauser [2] in their review of applications' development for health information technologies, also reach a similar conclusion in the challenges they define. Dogac [3], in his summary, acknowledges the same problem regarding EHR standards. However, in our view this is only part of the problem. The interconnection of the devices and the EHR is also something to dwell in and follow standards. In our case we propose the ETSI M2M.

A combination of openEHR archetypes and HL7 standards was proposed in [10]. Their main objective is to centralize the information from medical sensors and the result of clinical decision support systems in a single report, an integrated Personal Health Record. Developed within the MobiGuide project, the focus was on choosing the standards to enable the reception of information from other systems, where although they acknowledge it, the reception of data from devices is not addressed.

Another work that focus in the interoperability between HL7 and EHR is presented in [11]. They propose an Interoperability Mediation System (IMS) that provides interoperability services for exchanging information among Home Healthcare Monitoring Systems and Health Management Information System. They use openEHR enabled systems to provide a standard approach to the information systems. The IMS is proposed and developed by the authors. Although the infrastructure uses standard technologies, the collection of data from the sensors and patients activities follows a case by case solution.

On the other hand we have M2M healthcare solutions that completely abstract health standards, such as in [12] and [13]. In [12] the authors integrate intelligence in wearable sensors, which can sense patients' emergency conditions and notify doctors before severe conditions occur. These sensors are connected, through a communication adapter, to a manager. This entity has policies so that it can make decisions on monitoring information.

The M2M healthcare solution presented in [13] is composed of wearable sensors which measure health parameters and connect, using low-power wireless personal area networks, to a gateway for transmission over the Internet to a server PC. The collected biomedical signals are graphically displayed in real-time on Android mobile devices.

To bridge the gap between M2M and health standards, the manager and the server entities, from above, could be based on openEHR and HL7 for communication. Furthermore, both works settle in rather simple M2M systems as they do not reflect the current envisioned M2M concepts. In our view these examples show that to some extent existing solutions are still vertical silos aiming to solve particular problems.

IV. ICT Standard Overview

The E-health solution we present below results from the integration of components that comply with rising standards at the various levels of the ICT infrastructure. In this section we provide a concise overview of each level.

A. M2M

M2M communications describe mechanisms, algorithms and technologies that enable networked devices, wireless and/or wired, and services to exchange information or control data seamlessly, without explicit human intervention. Information is originated in machines, usually forwarded to a gateway, and transmitted to a system to be stored or acted upon, with all communications being performed in a networking environment.

To allow a common platform enable interoperability between M2M services and networks, the European Telecommunications Standards Institute (ETSI) developed a standard that defines entities and functions to provide efficient end-to-end delivery of M2M services. Currently, ETSI M2M is the reference architecture for global, end-to-end M2M communications, and is being adopted by the main European telecommunication providers. The system architecture is based on current network and application domain standards, and it is extended with M2M Applications and Service Capabilities Layers (SCLs). SCLs are Service Capabilities (SCs) on the Network domain, M2M Device, or M2M Gateway. SCs provide functions to be shared among different M2M applications.

The key entities in M2M are:

- *M2M Device:* a device that runs application(s) using M2M capabilities and network domain functions;
- *M2M Gateway:* guarantees M2M devices interconnection to the network and their inter-operability;
- *M2M Area Network:* provides connectivity between M2M devices, compliant and non-compliant with ETSI M2M, and M2M gateways (Bluetooth, Zigbee, etc.);
- M2M Applications: applications that run the service logic and use Service Capabilities accessible via open interfaces;
- *M2M Network and Application Domain* provides connectivity between M2M gateways and M2M applications using the access network (WLAN, 3G, 4G, etc.);
- *M2M Network Application (NA):* applications, in the Network and Applications domain, that run the service logic and use SCs accessible via open interfaces;
- *Network SCL (NSCL):* manages the data, including the access control, message routing and notification to other M2M applications and services.

M2M devices can connect directly to the Network and Application domain using the access network if they have an M2M application and a M2M SCL, or, if not, they can connect first to a M2M gateway, which runs a M2M application and a M2M SCL and acts on their behalf.

To exemplify, we consider the scenario presented in section II. Mrs. Maria's mobile phone (M2M gateway) collects information from her physiologic sensors (M2M devices) using a M2M application. The application sends the data to a NSCL that manages it, including access control and notification to other M2M Applications and services. Connections between M2M devices and the M2M gateway use Bluetooth, and between M2M gateway and the NSCL 3G.

In the following sub-sections we will describe the health models and communication protocols. Our proposed architecture to connect them will be discussed on the following section.

B. OpenEHR

OpenEHR [14] is a non-proprietary standard architecture for electronic health records. OpenEHR lets you capture and store clinical knowledge in a structured manner, independent of software, providing interoperability of health information systems, avoiding trapping data in proprietary systems and increasing support for distributed clinical work flows.

OpenEHR allows the standardization of the EHR architecture following a multi-level modelling approach, which separates information from knowledge [15]. The first level (the reference model) specifies a generic model according to which data will be stored and communicated. The second level (the archetype model) defines constraints in the reference model that represent concepts in a specific domain. Through the use of archetypes (structured concepts of clinical knowledge) and templates (combination of archetypes related to a particular clinical task), the semantic meaning and functionality is kept independent of the systems collecting or holding the data (e.g. clinical records, mobile systems).

Archetypes can be developed in any language and later translated to other languages (e.g., Portuguese, English, Chinese) keeping their original meaning. Moreover, terminologies can be associated within archetypes elements supporting their definition.

In our scenario openEHR will enable the definition of clinical relevant documents through templates for assessing the health of Mrs. Maria. As we will describe later, M2M NA components will process the raw data received from the M2M devices and adapt it into the correct archetypes' elements, so that the templates needed to assess Mrs. Maria are populated with the relevant data. Templates are defined by the primary care unit's medical board and the NA is implemented according to the defined archetypes.

C. HL7

HL7 is a well established message-based standard developed by ANSI accredited standards developing organization Health Level 7 Inc. It aims to develop coherent and extensible standards for the exchange, management and integration of electronic information in the clinical and administrative domain [16]. HL7 refers to the application level of the OSI seven layers' model. This level describes how data are exchanged, the timing of the interchange and the handling of communication errors. According to [16], HL7 version 2.x is the most widely implemented standard for health care information worldwide.

Although version 3.0 of HL7 has been release to address some drawbacks of 2.x, in our scenario we use HL7 v2, as it is the most commonly used. It is used to communicate with the openEHR system, in order for it to receive and update the clinical information regarding the status of Mrs. Maria. As such, NAs in M2M will produce HL7 v2 messages to be consumed by the openEHR repository.

V. Interoperable E-Health Framework

In this section we present our E-Health solution. The framework of our solution is based on M2M communications for interconnecting devices and services, HL7 for communication with health platforms and openEHR for data semantics, storing and making data available.

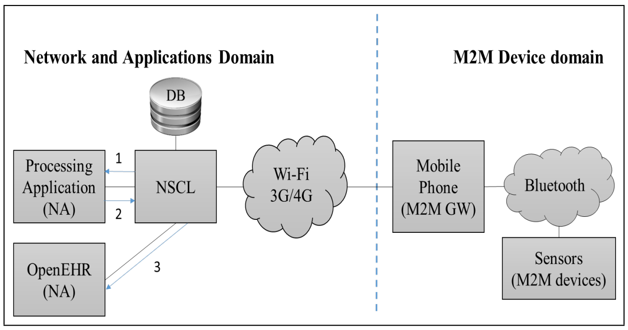

Figure 1. High level view of our solution.

Figure 1 shows the high-level architecture of our solution. Wearable sensors (M2M devices) collect physiologic and geographical information from Mrs. Maria and forward it to a mobile phone (M2M Gateway), using a Bluetooth connection. Mobile phones use Wi-Fi or 3GPP-based connections (3G or 4G) to forward values measured by M2M devices and any other useful information, e.g., the mobile phone identification, to a NSCL whose main function is to manage the data. The NSCL receives raw data from mobile phones, i.e., non-processed data, and sends that content to all entities that are interested in receiving it.

The openEHR system is interested in receiving information from Mrs. Maria in a structured form, Therefore, our framework allows the inclusion of one or several Processing Applications (PAs) as intermediaries that translate information. PAs are NAs that receive raw information (produced by the M2M devices) from the NSCL, process it (in this case into structured HL7 messages) and send it back to the NSCL.

A. Event-based Communications

Our communications will be event-based, i.e., communications are triggered by the occurrence of an event of interest, for example, a drastic change in Mrs. Maria's heart rate. For event-based M2M communications, the publish-subscribe model [17] is the appropriate choice. This model eliminates active requests for content, as such, the number of messages is reduced, which is of extreme importance in scenarios where there are a multitude of devices. In this model, subscribers state their interest(s) to message brokers about specific events produced by publishers. Publishers transmit to message brokers, which deliver the messages only to the interested subscribers. Publishers and subscribers do not need to know about each other. Both can produce and consume events in an asynchronous way.

In our scenario, a PA is a subscriber that will notify the NSCL (the broker), about its interest in being notified of events produced by Mrs. Maria's mobile phone (the publisher). After receiving these events from the NSCL and processing them, the PA will publish the information structured in HL7 in the NSCL. The openEHR system subscribes to these events.

B. Mapping resources

Figure 2 presents the tree structure of how the different resources will be accessible in the NSCL. Figures 3 and 4 show the messages related to the creation of resources and notification of events. Our resource structure follows the approach standardized in ETSI M2M [18]. Our procedures adopt a RESTful [19] architecture style, which controls how the several M2M entities communicate with each others. A RESTful architecture is about the transfer of representations of uniquely addressable resources. The main concepts in REST are the stateless interactions between clients and servers to manipulate data, and the notion that a distributed application is composed of resources, where each resource has a particular state, allowing greater scalability and reliability than other architectures.REST uses CRUD (Create, Read, Update, Delete) operations to manipulate the resources. These operations can manipulate a multitude of resources and, therefore, the same architecture can be used by several applications, avoiding the use of dedicated infrastructures.

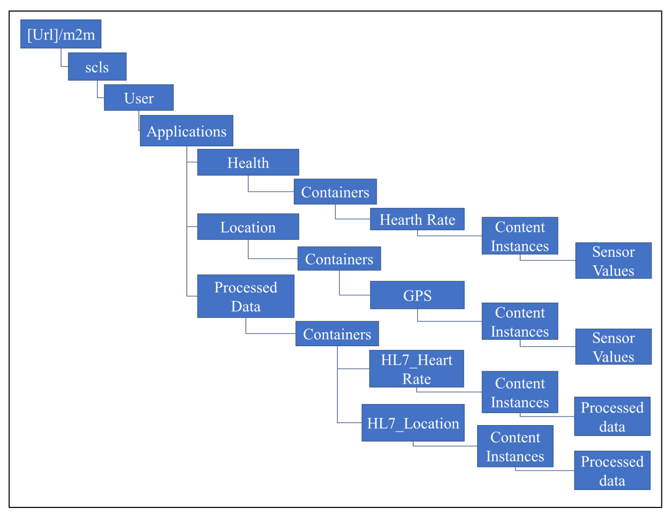

Figure 2. Mapping resources in NSCL, examples from the scenario.

In our framework, as in HTTP, there are four types of requests for the clients:

- `GET` - gets/retrieves the content of an existing resource;
- `POST` - creates a new resource;
- `PUT` - changes/updates the content of an existing resource;
- `DELETE` - deletes/removes an existing resource.

There will be a base URL to which all branches of the tree have to refer to. At start, the NSCL has the resource

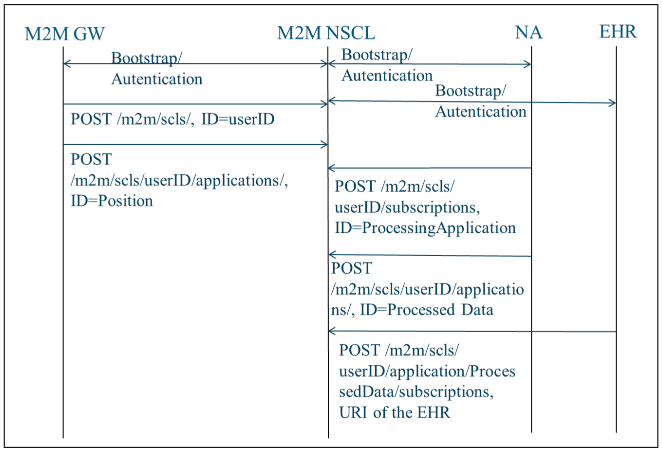

Figure 3. Message exchange to create resource and make subscriptions.

structure empty. The mobile phone will send a `POST` command to the NSCL to create a Service Capability Layer (SCL) resource with Mrs. Maria user identification (national health identification number).For every request from clients, the NSCL replies with an `OK` message, if the requests are correct and possible, or with an `Error` message otherwise. For sake of simplicity we do not include these replies in figure 4. Mrs. Maria's mobile phone sends `POST` commands to create the `Health` and `Location Applications` resources in the target `URL/M2M/scls/USER/Applications`, and their respective resources Containers: `heart rate`, `breathing rate`, `posture`, `steps`, `GPS` and `activity level`. For a matter of visualization, the figure only shows a portion of these containers. These branches of the tree will contain the raw data from the M2M devices in their `Content Instances`.

The PA will subscribe to the applications that produce raw information. It will process the information to produce HL7 structures that the openEHR can receive. There can be different PAs, each one specialized in one or more types of raw data, for increased processing efficiency and modularity. The PA itself creates an Application resource in the tree, termed Processed Data, in which it publishes the data. Its containers are named HL7 followed by their respective raw container names, because they contain the same information but in HL7 format. The openEHR system can subscribe to this application and it will be notified by the NSCL as soon as new HL7 information is created, enabling fast reaction in case of critical conditions.

C. Subscriptions

Every resource in the tree has a Subscription resource child that is used to request subscriptions, e.g., `User` resource has a `Subscription` resource, `Location` Application resource has a `Subscription` resource, and so forth (these are not illustrated in figure 2). All authorized entities can make subscriptions at the different levels of the tree in order to receive different types of information. An application might be interested in receiving only data referring to the location of Mrs. Maria in a raw format, while other might desire to receive all the information concerning Mrs. Maria, raw or processed. An application makes a subscription by sending a `POST` command to the `Subscription` resource child of the resource it wants to be notified about. This `POST` command contains the sender's Uniform Resource Identifier (URI) that permits its identification so that NSCL can communicate with it.

D. Payload

Data communicated from Mrs. Maria mobile phone to NSCL contains values related to the time, heart rate, geographical information, and sensor identification. In our framework, after the Processing Application converts it to HL7, the openEHR system will receive from NSCL an $ADT\hat{}A08$ HL7 message to update the information related to Mrs. Maria. The openEHR archetypes and templates used are already known so when this system receives the message, it is mapped, associating the values from HL7 fields to openEHR elements' unique paths. The values are then stored, in openEHR format, and can then be visualized, edited, or complemented, if clinically relevant in the EHR interface.

E. OpenEHR to M2M devices

It is also possible to have the flow of information in the other direction, i.e., to allow the openEHR system to add, delete, or update information in the NSCL, using HL7 v2 messages. For example, the health system might want to inform Mrs. Maria that she should rest given the alarm detected. For that, the health system has to register itself as an Application resource and another PA has to subscribe to this resource. For every openEHR system's request, the PA makes the necessary translations, and publishes it into the NSCL, and the latter makes the necessary proceedings. This allows health systems to interact as the other devices in M2M and we are able to remove further complexities.

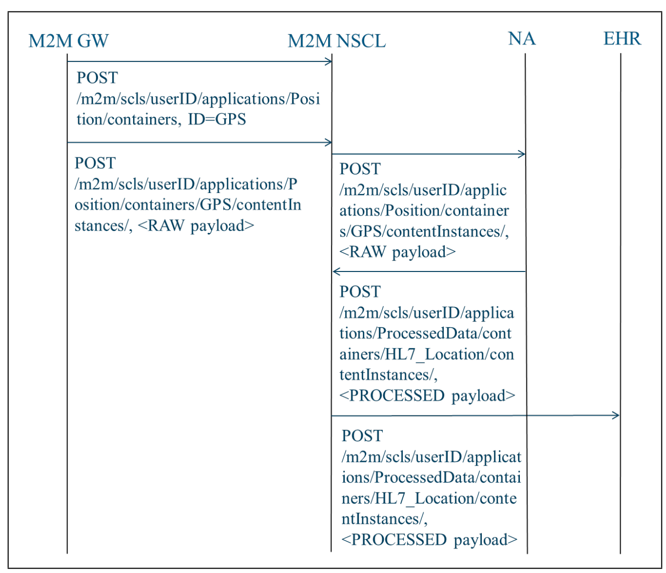

Figure 4. Message exchange to create a resource and event notification.

VI. Conclusions

In this paper, we present an E-health solution that makes use of M2M standards to distribute information collected from physiologic sensors and integrate it in a de-facto standard for EHR, openEHR. This is done using the health communication and structure standard HL7. Our goal is to utilize defined standards thus building on advances already done and to allow easier interconnectivity and inter-usage by different components from different systems. We present a working scenario to illustrate the application of our service.

The main advantage of our approach is bringing the scalability and reliability that is the hallmark of M2M systems. The increase of devices that collect medical data mandates such approaches. This provides fast reaction in case of critical conditions due to our notification mechanism. Also, providing the inter-relation of M2M and openEHR using HL7 is another advantage. Our architecture defines a component where this translation is done, thus reducing complexity.

A point that needs further development is data redundancy. The collected raw data and the processed data will be both stored within the system. This is a normal scenario where the raw data that produced a specific result is kept for further analysis. Nevertheless, the M2M cannot maintain a relationship between the two, as it treats the data transparently without understanding its contents. A possible solution would be to collect the raw and processed data in openEHR maintaining the relationship. However, openEHR's objectives are to deal with the treated data only.

Although an expected increase in delay might be experienced in notifications from NSCL to the openEHR system due to the use of intermediaries to translate data from and to HL7, the use of publish-subscribe provides, in terms of reaction, better performance than other mechanisms, such as polling models, and should minimize or eliminate this problem.

We will implement the system with a primary care unit and a selected group of senior citizens in a pilot project with 15 elders. The scenario will be similar to the one presented in section 1. This will be the evaluation of the proposal to test and verify our goals.

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