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FHIR Based Interoperability of Medical Devices

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Abstract

Although FHIR has been designed to be easy to implement, it requires knowledge that is still hard to find. We aim to evaluate the use of FHIR in Portuguese projects for the integration of medical devices. Two projects were selected, including easyHealth4Covid (EH4C) and Chronic Diseases Management Platform (CDMP). The evolution of each project and the FHIR resources used were analyzed. 11 different sensors of 5 companies were used in the sum of both projects. Previously, none of them used FHIR to integrate and the teams had little to no experience in doing so. The FHIR Observation resource was used for all. There is a general lack of knowledge of the FHIR standard and terminologies of most of the device companies involved in the projects.

Keywords:

Health Information Interoperability, HL7 FHIR, Medical Devices

Introduction

The increase in the aging population is associated with a growing prevalence of chronic diseases and, consequently, an increase in the demand for health care, both in terms of human resources and infrastructure. At the same time, technology has had notable advances in the last years, particularly in the development of devices capable of collecting large volumes of valuable data of different kinds, and also in the ability to manage, store, process and transfer all this data. One of the hot topics of this technological transformation, that is rapidly growing worldwide, and known as the Internet of Things (IoT), consists of a network of physical object-linked devices that are accessible via the Internet [1]. It is enabling the transformation of several domains of our daily lives, being health one of them, through affordable home healthcare solutions capable of improving quality of care while promoting patient-centered care. The adoption of these solutions in healthcare and wellbeing have been increasing in the last years – there was an increase of 63% in the number of remotely monitored patients, between 2013 and 2015 [5]. More recently, the ongoing Covid-19 pandemic has also contributed to the expansion of remote patient monitoring.

These home monitoring solutions include devices and sensors used for continuous observation of patients' physiological parameters (such as temperature, oxygen saturation and heart rate). These are important data to facilitate chronic disease management or diagnosis of acute conditions [6]. This way, domiciliation of care supports the clinician's functions, by communicating regularly and in real-time relevant patient vital signs, to identify and reduce symptoms more quickly, and therefore increasing the patient's quality of life. These benefits are possible in the comfort of the patient's home, which requires less visits to health facilities, and in turn optimizes the availability of the scarce health resources. So, these home health technologies are proving to be the best solution to address the rising demand for healthcare in the years to come, making it easier and more accessible.

At the same time, there are challenges that these technologies face, being integration of data with healthcare information systems one of the main ones. In addition to numerous devices, there are also several different communication protocols and formats that are non-consensually used by device's manufacturers [4]. To allow interoperability between them and clinical information systems or applications, standardization is needed. There are multiple standards and protocols for IoT technology. However, those are not suitable for healthcare, as this is an area with very specific requirements and its standards as well. For this specific purpose of interoperability between medical devices and healthcare information systems, different standard has been used, such as the ISO/IEEE 11073, the Transaction PCD-01 of the IHE (Integrating the Healthcare Enterprise) Patient Care Device (PCD) Technical Framework, and also HL7 Fast Healthcare Interoperability Resources (FHIR) [3]. All of these are capable, having both advantages and disadvantages according to the context of use. As reported by Lee and Do, FHIR is easier to learn and implement, and it allows the exchange of patient and device information [3]. This standard provides transport, structured and some semantic interoperability, as well as health information integrity, while ensuring its ease of implementation. FHIR stores and exchanges data between systems through its XML and/or JSON modular components called "resources", which represent granular clinical concepts [1]. FHIR supports architectures based on representational state transfer (REST), seamless exchange of information using messages or documents, and also service-based architectures [2]. FHIR servers allow storage and retrieval of that healthcare data in the FHIR format. This standard has been widely adopted worldwide and, although it has been designed to be easy to implement, it requires a certain knowledge of the standard and some sensibility of the health industry to be able to use it correctly.

In Portugal, in the last years, there has been an increase in the development of IoT-based smart health projects. For them to be competitive and appealing across borders, they must comply with accepted international standards, such as FHIR. The aim of the present work arose precisely from this need to comply with the FHIR standard. We pretend to evaluate the application of FHIR in Portuguese projects for the integration of medical devices, particularly in terms of compliance with the specification, level of maturity of the Portuguese device's companies and their effort and, finally, the suitability of this specific standard for this type of projects.

Methods

We participated in the development of some projects exploring the concept of healthcare IoT and occurring in Portugal, in particular, easyHealth4Covid (EH4C), Chronic Diseases Management Platform (CDMP). For each project, the sensors and which data to measure were identified, as well as the integration requirements, through storyboards and UML sequence diagrams. Since it was agreed to use the standard FHIR between all entities involved, we selected the FHIR resources more appropriated for each measure of the sensors and helped each sensor partner involved to define and construct the determined FHIR resources correctly. Their work was then monitored along each project in terms of the data integration issues, to evaluate the compliance with the standard.

CDMP

The CDMP is a solution developed by a set of companies of the Health Cluster Portugal (HCP), with the ambition of integrating the best features and know-how of each one around Chronic Obstructive Pulmonary Disease (COPD). It resulted in a set of devices (oxygen saturation, respiratory rate, respiratory capacity, heart rate, hand grip strength and daily physical activity) and products (cognitive assessment online platform), listed in Table 1, integrated within a data centralization and treatment platform, that in turn integrates with a support web interface. This interface was created by VirtualCare and it displays the data in a dashboard to the doctor, for monitoring the disease. COPD is particularly interesting to perform remote monitoring given that it can be controlled with treatment, and at the same time it can cause threatening health problems if it is not well monitored.

The online platform to perform a self-administered longitudinal cognitive test, called Brain on Track, has been developed by Neuroinova. The assessment can be repeated periodically, and each session is composed of several tests, from which a total score is obtained, accompanied by a percentile corresponding to the number of correct answers, according to the normative sample [6]. This can be useful for diagnosis and follow-up of cognitive disorders like Alzheimer's disease, but also useful for COPD, as it can also be associated with cognitive impairment. The physical activity sensor responsible for the steps, distance and calories count per day is FitBit, provided by Fraunhofer. This is a wearable that is continuously used by the patient tracking its day-to-day activity. Plux is responsible for its product biosignalsplux, which comprises the respiratory and SpO2 sensors. Also, they are responsible for other third-party sensors of respiratory capacity. Gripwise is a small device developed by Wisify that measures the strength profile of different muscular groups of the hand, therefore assessing the frailty of the patient, which can be a useful indicator for COPD.

EH4C

The EH4C project aims to develop a digital health solution for remote monitoring of elderly people living in nursing homes, in the context of the covid-19 pandemic. The monitoring of vital signs associated with covid-19 in this population at higher risk will serve to complement the assistance capacity of the National Health Service during the pandemic. These vital signs are measured through sensors provided by Plux, listed in Table 1, and sent to an Electronic Health Record (EHR) developed by Future Healthcare and to a dashboard implemented by VoH.Colab.

Results

For each project, the sensors and corresponding measures are represented in Table 1, as well as the FHIR resources used. For the COPD part of the CDMP, seven sensors were used, belonging to different partners, while for the EH4C project seven sensors were used as well, despite being different. Prior to being involved in this project, all entities concerned used their own format to describe and communicate the variables resulting from their sensors, which means that none of them previously used FHIR. As so, the work done with each entity to construct the JSON FHIR resources had to be more thorough.

As indicated in Table 1, all measures were translated in an Observation resource – only one FHIR resource was used to convey all the sensors data. We defined the subset of elements that the resources should contain to be complete and understandable to the receiver, which are:

- resourceType - always "Observation"
- status - always "final"
- category.coding.system/code/display - fulfilled according to the type of measurement, either "activity" or "vital-signs"
- code.coding.system/code/display - corresponds to the identification of the measurement, according to one terminology system such as LOINC or SNOMED
- subject.identifier.value - value used to identify the patient in the resource

Table 1– Devices used in each project and FHIR resources adopted for each sensor

Device	Measure	Project	FHIR resource
FitBit	Physical activity	CDMP	Observation
Gripwise	Grip strength	CDMP	Observation
Brain On Track	Cognitive assessment	CDMP	Observation
Bewell's spirometer	Respiratory capacity	CDMP	Observation
Biosignalsplux respiration sensor	Respiratory rate	CDMP, EH4C	Observation
Biosignalsplux ECG sensor	Heart rate	CDMP, EH4C	Observation
Biosignalsplux pulse oximeter	Oxygen saturation	CDMP, EH4C	Observation
Bewell's blood pressure monitor	Systolic and diastolic blood pressure and heart rate	EH4C	Observation
Bewell's pulse oximeter	Oxygen saturation and heart rate	EH4C	Observation
Bewell's thermometer	Temperature	EH4C	Observation
Bewell's glucometer	Glycemia	EH4C	Observation

- subject.identifier.assigner.display - entity that issued the patient identification value provided
- effectiveDateTime - date and time of measurement
- performer.display - name of the entity responsible for the measurement
- valueQuantity.value - actual numerical value of measurement
- valueQuantity.unit - unit representation of measurement
- valueQuantity.system/code - coded form of the unit and respective system
- device.identifier.type.text - the type of identifier of the device
- device.identifier.value - value used to identify the device in the resource
- device.identifier.assigner.display - entity that issued the device identification value provided

Some observations are composed of multiple results, like a blood pressure measurement, containing systolic and diastolic blood pressure, as well as heart rate. In these cases, those component results are expressed as separate code value pairs that share the same attributes, using the "component" element of the Observation resource, which contains the following attributes, which should be fulfilled the same way as the ones already mentioned:

- component.code.coding.system/code/display
- component.valueQuantity.value
- component.valueQuantity.unit
- component.valueQuantity.system/code

CDMP

The description of the participation of one patient in the CMDP project is the following:

1. **Enrollment**: patient receives indication by his doctor to have his COPD monitored at home; doctor explains the monitoring program to the patient and asks him to sign the enrollment forms.
2. **Setup**: a technician arranges a visit to the patient home, to configure the sensors to the patient, to its internet connection and the adequate alarms.
3. **Monitor**: patient uses the sensors according to the clinical prescription, and the corresponding collected data is sent to the monitoring server, through the internet connection.
4. **Alarm**: if the values of the vital signs collected are below the threshold defined, or if the monitoring system does not receive any value from the devices for a specific time, an alarm is triggered, and the responsible technical and clinical teams are warned.
5. **End of enrollment**: when, for some reason, the patient must be no longer monitored, the devices are picked from his home, a full report of the patient's evolution is generated, and the devices are reset and cleaned to be used by a new patient.

The data centralization and treatment component of this architecture is composed of a FHIR server, responsible for validating and storing all the resources posted by the sensors. So, the sensors use RESTful architecture to communicate with the FHIR server, in particular, using the POST method, which body is the FHIR Observation resource of the measure. Each company sends the resource with the data captured from the sensor, using an internal identification value of the patient and/or the device. Then, the data centralization and treatment component has to deal with the patients' identification problem, translating each received identification into the value that is used by the recipient system, unifying all the different identifications for the same patient used by the sensors. For this to be possible, in the mentioned setup of the project, the step that configures the sensors to the patient consists in associating each device identification to a global patient identification. So, the resource Observation posted in the FHIR server is processed to change to the global patient identifier, and then it is sent to the dashboard interface's database, that aggregates all the patient COPD data to be analyzed by the doctor.

EH4C

For the EH4C project, the process of patient participation is different. Around ten residents of a Portuguese nursing home will be participating in the project's pilot, after their consent. The vital signs will be measured everyday using the Plux devices mentioned with the help of the staff. In Figure 1, there is a UML sequence diagram that represents the process of acquisition of data from the sensors to the EHR and Dashboards, through an integration BUS.

The architecture used within this project is different from the previous one, as here messages are used instead of a RESTful architecture. For this reason, all the JSON Observation resources sent by the sensors were encapsulated in Bundles, of type message, together with a MessageHeader resource. This was done this way as there is no FHIR server in this solution, and instead there is an integration BUS, responsible for receiving and performing eventual transformations needed. The Plux sensors' data had to be sent to two different players – the EHR and the dashboard. Since the EHR has been developed using OpenEHR archetypes, they did not pretend to receive data in FHIR format, but instead through a JSON which variables are concordant with OpenEHR. On the other hand, VoH.Colab was willing to receive data in FHIR format, even though they did not have experience with it. As so, the integration BUS processes and transforms the Bundles to send the information to the EHR in their required format, and it also acts as a pass-through to send the Bundle received from the sensors to the dashboard, as it is.

Discussion

One of the main findings from this study is the general lack of knowledge of the FHIR standard of most of the entities involved in the projects. Either they have never heard of the standard, nor used it to exchange information with other entities. Therefore, the process of implementing the standard to exchange their date was a bit slow. This process was carried out by the technicians of each of the companies, together with a functional profile with knowledge of the FHIR standard. We acknowledged that this would have been difficult to accomplish without the know-how of the FHIR standard. In addition, trying to use the standard without proper knowledge of it has its associated risks, namely the eventual exchange of data using incorrect resources or improper elements, which may lead to misinterpretation of the clinical information. To overcome this difficulty, companies should be qualified for FHIR, through training and certification. This will favor companies to level up and expand abroad, since they can talk in an international language of interoperability. At the same time, by being aware of the standard and participative in its development, they can help to identify new requirements of the standard for its use in medical devices.

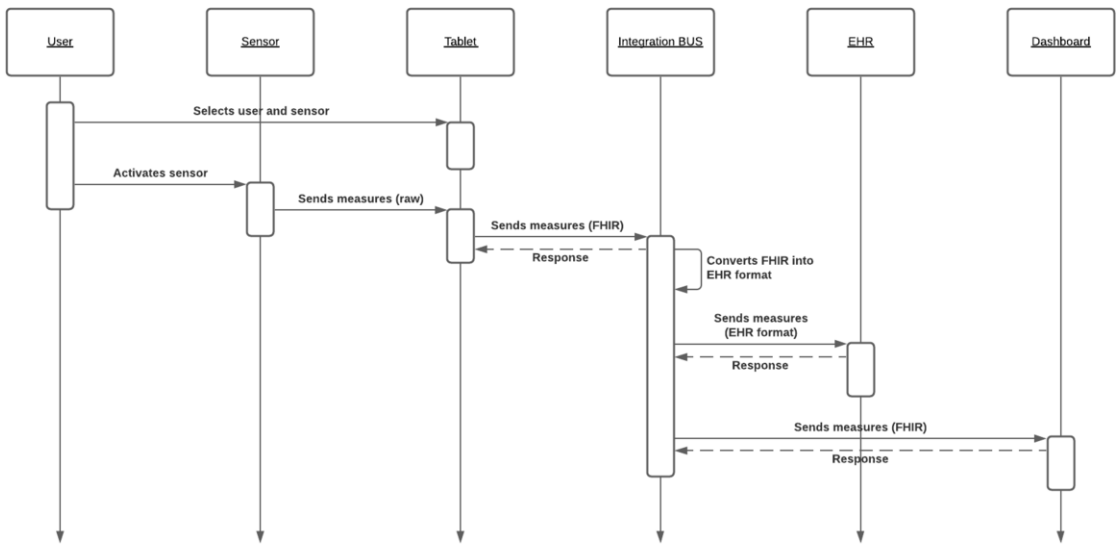

Figure 1– UML sequence diagram of the EH4C communication process between sensors and the data recipients EHR and dashboard

Moreover, a good implementation of the FHIR standard requires the use of terminologies such as LOINC or SNOMED, so that the medical terms can be communicated and interpreted effectively, especially considering integration with foreign countries. Nonetheless, the usage of clinical terminologies within the FHIR standard implementation adds a layer of complexity to it. In fact, this is another of the weaknesses of the project's partners. They did not have their variables coded using any terminology, so we had to do this process together as well. Since this is not a technological issue, but rather a clinical one, it should be done or supervised by the clinical team of the company. In the end, we were able to assign a LOINC or SNOMED code to each of the observations in question. This was by far easier for the vital signs' measurements like blood pressure and temperature, for example, in part because the FHIR specification has already defined specific profiles for these observations, indicating the correct codes to use for each one.

Despite some difficulties experienced during the process, in the end compliance with the FHIR standard was achieved by all players. Nevertheless, it is important to sensibilize them to the interoperability issues and its importance. A crucial action that must be taken to encourage the continued use of the standard by companies is the promotion of awareness raising actions on this subject. Portuguese companies could be encouraged by some regulation to be FHIR compliant.

In terms of FHIR suitability for these kinds of projects involving different players communicating data from devices, in general we can say that it is confirmed. As a matter of fact, it was designed for that very purpose. However, some flaws can be pointed out. Particularly, for describing physical activity the FHIR resource Observation was used, but we had some doubts about that. Taking into account the wide use of wearables and devices to track this kind of data, FHIR specification should be more assertive in how to deal with it. We investigated the use of another resource that would better fit the data to transmit and found that a PhysicalActivity resource has already been proposed [7], but not yet contained on the specification.

We recognize that this particular study is based only on a few companies and may not represent all the Portuguese scenarios. It is important to highlight however that entities involved are diverse.

Conclusions

From this study, we conclude that Portuguese companies interested in the development of medical sensors and devices are still far behind when it comes to using this standard. To turn Portugal into a competitive player in this field, the companies need to wage on complying with international standards like FHIR, since it is being adopted by some of the giant technology companies with an influence on healthcare, wellbeing, and fitness, like Apple and Google.

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