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# FHIRbox, a cloud integration system for clinical observations: a proposal

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**Abstract**

With the recent technological developments new possibilities arise for the use of wearables and medical monitoring devices by patients and their respective integration into the digital health ecosystem. FHIRbox is a distributed system under development by the authors for integrating data from various diagnosis devices, complying with FHIR - the latest HL7 standard for exchanging clinical information. The innovative aspects of FHIRbox constitute a reference to drive a paradigm shift in terms of access to health information; as it is a solution that places the patient as the true owner of his clinical data. In this work the authors present the project requirements and the system architecture.



*Keywords:* FHIRbox; HL 7; FHIR; health records; Health interoperability.

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## 1. Introduction

The Internet of Things (IoT) is definitely one of the most powerful accelerators of digital transformation in healthcare. As the range of "pluggable" devices and their extent to patients, professionals, medical equipment, medical-surgical equipment and medications increases, new applications based on IoT arise in this area.

With recent technological developments in the areas of telecommunications, microelectronics, sensors and data analysis, new possibilities arise for the use of wearables and medical monitoring devices by patients and their respective integration into the digital health ecosystem; the next generation of patients will require technological innovations in sharing information with health professionals [1–3]. It is, therefore, very important to integrate this data with the various health information systems in use in order for health professionals to obtain this information as an aid to diagnosis and monitoring during and after treatment or as prevention.

The use of wearables and enabled diagnostic devices for wifi / bluetooth connectivity has been increasing. Such devices provide data collection that may be clinically relevant but currently largely wasted.

As patients move through the health ecosystem their electronic records should be easily accessible, understandable, and highly available. It is therefore of vital importance to integrate this data with the various health information systems in use, so that health professionals have this information as an aid to diagnosis and monitoring during and after treatment or as prevention.

Typically, when it comes to storing and communicating data in cloud systems, there are concerns about information security. This type of concern is even greater in the health area due to the confidentiality and sensitivity of the data, which has given rise to several statutory and regulatory requirements to be taken into account in dealing with this type of information [4–6]. These issues are of concern to patients themselves who are increasingly seeking control over their clinical information.

This project consists of the design and prototyping of a distributed system, called "FHIRbox", for integrating data from various diagnostic devices such as blood pressure meters, thermometers or others that in some way perform the vital signs reading / monitoring and / or biometric data such as wearables (eg smartwatches, fitness trackers) for later storage and communication to various health information systems (eg EHRs, EMRs) that are subscribers of the same system or wish to collect data from them.

FHIRbox is a prototype of an interoperability platform that enables integration among existing systems, whether physical or digital (including Information Systems). Its main innovative aspects are: (1) the data of each patient will be available for all health systems via an integrating platform to which they register; (2) only the data that the patient allows will be available; (3) the patient can condition the type and moment of access to his data; (4) physicians can only access these data if the patient allows it.

As far as interoperability is concerned, FHIRbox will comply with FHIR (Fast Healthcare Interoperability Resources) - the latest HL7 standard for exchanging clinical information [1,7]. Particular attention will be given to information privacy, security of authentication methods, authorization methods that allow the patient to regulate access to their data, security of communications and the implementation of an audit logging system.

In this work the authors present the project requirements and the system architecture.

The paper is structured as follows. Section two presents some background information related to HL7 standard and FHIR, resources. Section three presents the methodology, section four the projects requirements followed by the proposed architecture. The paper finishes with the further work and conclusions, at section six.

## 2. Background

According to a Salesforce report[8], resulting from interviews to American patients aged 18-34, 63% of the American population of Generation Y would be interested in pro-actively sharing the health data collected by their wearables or medical devices wifi / bluetooth with their doctors so that they could monitor their state of health. Mobile devices and applications are at the top of the list of technologies that patients would like to see included in their healthcare experience. In addition to mobile tools, 57% of respondents would be interested in using state-of-the-art technology such as tablets capable of monitoring internal vital signs.

### 2.1. Interoperability standards

These data suggest that the next generation of patients will require technological innovations in sharing information with their healthcare professionals. The opinion of this age group is really important because their preferences and habits represent the expectations of the future in the health area.

Health records are increasingly digitized and, as previously mentioned, in terms of their interoperability, the use of standards is imperative. FHIR is the latest health communication standard, suited to mobile and IoT technologies, being developed by the non-profit organization HL7. Briefly, the FHIR is a RESTful API for exchanging health information. As such it uses the HTTP protocol and is resource oriented. It defines a universe of clinical, administrative, financial and infrastructure resources. The API supports authoring, reading, updating, retrieval, and search operations, as well as a framework for ad-hoc operations [7].

At the beginning of this project, this new standard was in version DSTU21, published on October 24, 2015, and, as of the date of delivery of this document, it is already in version STU32, published on February 21, 2016, being it is expected that the release of the Normative3 edition will take place in October 2018. In addition to the FHIR, HL7 also has two main standards (HL7 v2, HL7 v3), which are directed towards the interoperability of health information systems. These are currently the most relevant standards in the area given their level of implementation and maturity[7].

Significant benefits in FHIR are recognized when compared to HL7 v2 and HL7 v3[9]. In addition to the FHIR addressing some shortcomings of v2 and v3, this standard has two major objectives[1]:

- To maintain the position of the HL7 organization as SDO while cloud technology platforms and solutions mature;
- To enable health organizations to implement FHIR-based solutions using technologies that favor cloud-based and mobile-friendly platforms with a faster implementation cycle.

The FHIR aims to simplify implementation without sacrificing the integrity of information. It builds on existing logical and theoretical models to provide a consistent, easy-to-implement, and rigorous mechanism for data exchange between health applications [1].

### 2.2. FHIR Resources

The base element of the FHIR is the resource. Hence the name "Fast Healthcare Interoperability Resources". All types of interoperable content are defined as features in FHIR, each with its structure.

The FHIR defines numerous features that can be queried in the specification, but some examples of features are[10]:

- Patient - Demographics and other administrative information about an individual or animal receiving care or other health-related services;
- Practitioner - A person who is involved directly or indirectly in the provision of health care;
- Observation - Measurements and simple assertions made about a patient, device or other;
- Allergy Intolerance - Risk of harmful or undesirable physiological response that is unique to an individual and associated with exposure to a substance.

Some elements of a resource can be references to other resources. There are two types of references:

- Internal "contained" references - references to other resources packaged within the resource itself; and
- External references - references to resources found outside the resource itself.

In order to be clear about the concept of what a FHIR resource is, an example of defining the Patient feature in UML can be found in Figure 1.

The resources of the FHIR have been designed mainly taking into account implementations based on RESTful services[11]. However, the specification allows resources to be exchanged using any method other than RESTful Web Services, for example, can be exchanged using SOAP4 or message engines such as MLLP5 or MQTT6. The latter may be of particular importance in the IoT context because of the low code / memory footprint requirements and bandwidth associated with the devices in question.

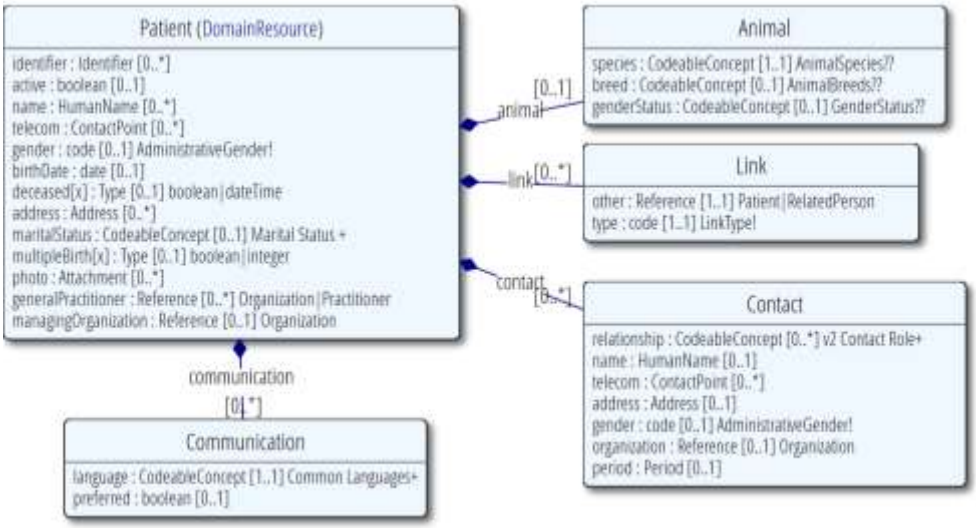


Fig. 1. Definition of the “Patient” resource in UNL [12]

### *2.3. Security and privacy*

With respect to the storage and communication of data in systems made available in the cloud, there are concerns regarding the security and privacy of the information.

The FHIR does not define any security protocol nor does it require the implementation of a specific mechanism for this purpose, but it does provide some recommendations: Communications security; Authentication - of clients and users (the use of OAuth8 is recommended); Authorization / access control; Audit; Digital signatures; Attachments; Security Labels; Narrative.

In addition to the FHIR considerations, it is also important to take into account the recommendations of IHE9, especially the Internet User Authorization Profile (IUA), which is a profile specifically developed for authentication and authorization purposes in RESTful services.

The General Data Protection Regulation (GDPR) of April 2016 [13] defines a set of changes which have a significant impact on all systems dealing with personal data of the end users as well as on the use of interoperability standards and as such , is something to be taken into account in the present work by the nature of it.

In addition to these points, as regards the confidentiality of data, through the use of the FHIR Security Labels, it is possible to provide the context of use of a particular resource (Purpose Of Use), the level of confidentiality of the resource (Confidentiality) even, define a flow of control through tags placed in the resources at the time of their sharing that define whether the same resource should be deleted or not be reused after its use for the purpose for which it was shared.

## 3. Methodology

The methodology of development of this project will go through a set of activities / practices oriented to the design and prototyping of the final "product". As the final product consists of a functional prototype, due to the associated time constraints, a RAD (Rapid Application Development) methodology will be used.

The RAD model is based on prototyping and iterative development without specific planning. The coding process of the software also involves the planning necessary for the development of the product.

This methodology focuses on the definition of requirements through workshops or discussion groups, in the first tests of the prototypes by the "client" using an iterative concept, in the reuse of existing prototypes (components) and in the continuous integration and quick delivery [14].

As the product will be demonstrated and tested as it is being developed, and because it is only a prototype, the testing phase itself will be conditioned by the time constraints associated with the duration of the project.

This paper includes the project requirements and the system architecture, to be detailed in the next sections.

## 4. Requirements Analysis

This section presents the functional and non-functional requirements for this project

### *4.1. Functional requirements*

For the description of the functionalities to be included in FHIRbox, the authors opted to use user stories for their ability to briefly describe "who" needs "what" and, optionally, "for what." It was therefore decided to follow the format "As <actor> I want <functionality / objective> for <benefit>".

The following were identified:

US1. As a patient I want to register with FHIRbox;

US2. As an administrator of FHIRbox, I want to be able to register new customers as manufacturers of medical devices and healthcare institutions in order to integrate the network of systems supported by the platform;

US3. As a patient I want to send clinical comments from my smartphone to my FHIRbox account;

US4. As a medical device manufacturer, I want to be able to request permission from a patient to send data to their FHIRbox account;

US5. As a medical device that has a valid access token granted by a patient, I want to send remarks readings to that patient's account in the FHIRbox;

US6. As a patient I want to access all my history of clinical observations, as well as their source;

US7. As an EHR system I want to be able to ask a patient for a certain purpose about their data in order to perform the required operations;

US8. As a patient I want to be notified whenever my authorization is required;

US9. As a patient I want to be able to authorize or deny access to my account by third parties whenever requested by them;

US10. As the requesting authority for a certain scope I want the access token to be sent to me after authorization by the patient so that I can perform operations on patient data in the FHIRbox for the required scope.

### *4.2. Non-functional requirements*

In addition to the functional requirements, the following non-functional requirements have been identified to respond to the project objectives and to guarantee the quality and compliance with the state of the art:

- methods of authentication and authorization / access control;
- privacy of information;
- communications security;
- audit logging system;
- compliance with the FHIR specification.

## 5. The system architecture

To define the system architecture, the functional and non-functional requirements as well as the specifications mentioned were taken into account.

In this way, the following components were identified:

- FHIR server - the FHIR resource server which is the core of the system because it will serve as a resource repository and will be responsible for servicing them through a RESTful API conforming to the FHIR;
- Authorization server - responsible for authenticating and issuing tokens according to the OAuth2 protocol;
- Gateway - The gateway is the only entry point into the system and this is where the fhirbox API is exposed. It must be accessible from the outside only by HTTPS (TLS) in order to cover the non-functional requirement Communications security. In addition, this layer will validate the presence of a valid access token before serving as a reverse proxy for the FHIR server, as well as enforcing other security policies. This layer can also be used for orchestration in order to make new services available using those provided by the FHIR server and Authorization server or even third-party APIs.

Together, these three components form the FHIRbox as a distributed and loosely coupled system and communication between them is guaranteed through REST APIs. Figure 2 illustrates this architecture:

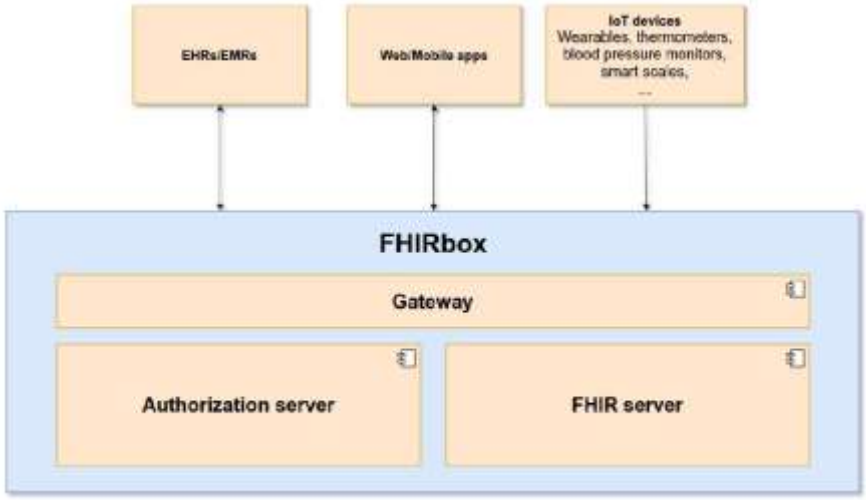


Fig. 2. FHIRbox architecture

## 6. Further work and Conclusions

The aim of FHIRbox project is to harness data from medical devices in a clinical setting. To do this, it is necessary to record such clinical data for subsequent sharing of clinically relevant patient information to healthcare professionals in a safe and fully controlled by the patient.

Health interoperability is a complex problem, for which existing solutions resort to standards accepted by industry. As such, it became necessary to monitor the development of HL7 FHIR. However, security, information privacy, authentication / authorization mechanisms, and audit trail mechanisms are intertwining themes for other areas for which there are various standards accepted by the industry. Thus, it became necessary to study several of these patterns and to conjugate them in order to fit a solution that would serve the objectives of this project.

It is expected that the product of the present study may serve as a reference for a paradigm shift in relation to access to health information for a solution that places the patient as the true owner of the information.

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