Telehealth Ecosystems in Practice
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Design and Adoption of a FHIR IG to Support a Telemonitoring Environment in Gatekeeper Project

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Abstract. Telemedicine can provide benefits in patient affected by chronic diseases or elderly citizens as part of standard routine care supported by digital health. The GATEKEEPER (GK) Project was financed to create a vendor independent platform to be adopted in medical practice and to demonstrate its effect, benefit value, and scalability in 8 connected medical use cases with some independent pilots. This paper, after a description of the GK platform architecture, is focused on the creation of a FHIR (Fast Healthcare Interoperability Resource) IG (Implementation Guide) and its adoption in specific use cases. The final aim is to combine conventional data, collected in the hospital, with unconventional data, coming from wearable devices, to exploit artificial intelligence (AI) models designed to evaluate the effectiveness of a new parsimonious risk prediction model for Type 2 diabetes (T2D).

Keywords. HL7 FHIR, Type 2 Diabetes, telemedicine, AI models, living environments, interoperability standards, health and wellness, chronic diseases.

1. Introduction

The pandemic showed us the benefits that telemedicine can provide when in person medical visits are inconvenient or prone to health risks. At the same time, it has highlighted problems that must be faced before it can become part of standard care. For example, in chronic diseases as diabetes it is important to allow patients to seamlessly share their data in consistent interoperable data format [1]. The European Institute of Innovation and Technology (EIT) performed an analysis on medical device innovation and indicated both technical and legal interoperability as unsatisfied needs for the success of eHealth initiatives within the European Union [2]. The adoption of medical informatics standards to support interoperability in telemonitoring environments, where

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heterogeneous devices are used, is a well-defined topic presented in the literature. However viable solutions are not adopted in clinical practice and relevant innovations rarely reach the population at large who are confronted with the inconvenience of fragmented sources of data [3,4]. The GK Project has been funded to create a platform, which connects all the actors involved in the care circle of elderly citizens. Among them there are healthcare providers, businesses, entrepreneurs and the communities in which the citizens live in. The execution of independent pilots in 8 regions of 7 European countries demonstrates the effect, benefit value, and scalability of this platform in 8 connected medical use cases. The need for developing digital innovations for the elderly population is confirmed by many studies. Yang et al. [5] demonstrated that the internet usage has a positive effect on well-being of the elderly population. Zhang et al. reported also a positive effect on the reduction of depression level in elderly individuals [6]. However, Bianchi reported that the adoption of internet services among elderly could be a challenge due to resistance to technology adoption and health impairments. This aspect can be mitigated thanks to the help of family members [7]. Sun et al. concludes that more actions are needed to promote the use of digital health technologies in elderly population [8]. Furthermore, Park confirms that elderly people living alone meet more difficulties learning how to use the technology for digital management of chronic diseases like diabetes [9]. In particular, people affected by this specific disease (T2D) are involved in the pilot described in this paper which also presents the use in practice of a HL7 FHIR IG to support interoperability.

2. Methods

The aim of the GK Project is to design and develop a platform, which allows, starting from real data collected during the pilots, to obtain value through inductive and deductive artificial intelligence models. In the design of the platform different technologies were adopted; here are mentioned the only ones we used. To model the healthcare domain and support the syntactic and semantic interoperability of the underlying data integration process, FHIR, SNOMED Ontologies, LOINC Vocabulary were considered. Artificial intelligence (AI) models were developed be other partners of the project to allow early prevention and intervention. In the architecture (Figure 1), there are different data sources e.g. Electronic Health Record (EHR), telemedicine applications, and devices (e.g., smartphones, smartwatches etc.), which through specific core platform components, fill the core GK Data Federation Server with data structured in FHIR resources. These data are available for AI algorithms or applications, designed and implemented either inside the project or outside the project. All applications are managed and available through the GK Developer Portal and Marketplace directly connected with the WoT (Web of Things) Management System to map the resources stored within the GK Data Federation Server.

Every pilot is independent: each one is on its own cloud infrastructure and premises for the benefit of the GDPR compliance and can choose what devices to use. It can also opt for filling the GK Data Federation Server either directly with FHIR resources or interacting with the GK Data Federation Integration Engine. Among the 8 Reference Use Cases (RUC), we considered: Lifestyle-related early detection and interventions (RUC1), Chronic obstructive pulmonary disease (COPD) exacerbations management (RUC2), Diabetes, predictive modelling of glycaemic status (RUC3), Predicting readmissions and decompensations in Heart Failure (RUC5), Multi-chronic elderly patient management (RUC7) and eHealth solutions for the management of High Blood Pressure (RUC8). To constrain the flexible structure of FHIR profiles to the project purposes and to share the same logical model, after analysing all data to be managed by the AI services, a GK FHIR IG, based on FHIR Release 4, was developed.

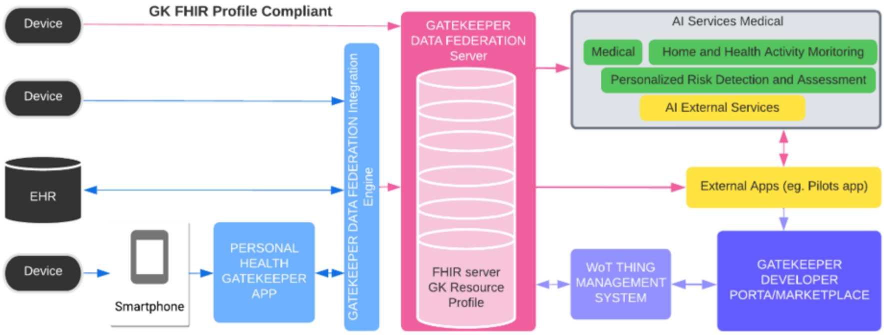

Figure 1. GK platform architecture: The arrow color corresponds to the data exchange format: blue arrows for proprietary format, pink arrows for FHIR resources and violet arrows for WoT.

3. Results

The GK FHIR IG defines more than 40 resource profiles : 1 Appointment, 26 Observations, 1 CarePlan, 1CareTeam, 1 Condition, 2 Consent, 1 DocumentReference, 1 Encounter, 1 FamilyMemberHistory, 1 Location, 1 MedicalRequest, 1 NutritionOrder. 1 Patient, 1 Practictioner, 1 QuestionnaireResponse, 1 ResearchSubject, 2 ServiceRequest, 1 Task. In this profiles no extensions were defined and LOINC and SNOMED codes were adopted where possible. It was necessary to define specific code systems to manage some concepts, which were not present in any international standard terminology, used by GK apps or to represent specific parameters recorded by new sensors developed by other GK partners. These resource profiles were adopted as logical models for the data collected in each specific pilot. GK is thus enabling the possibility of designing, deploying and testing other AI models and services that can generate valuable outcomes for patients and healthcare professionals. Among them are, depending on the specific EU pilot, adherence scores, prediction of exacerbation of diseases (like COPD), the short-term prediction of hypoglycaemic events, and the prediction of cancer patients' quality of life.

In Italy, the Puglia region was involved as pilot side and 2 independent pilots were set up. One pilot is contributing to the RUC3 and it is focused on the prediction of T2D control through conventional data, collected in the hospital and used in the current clinical practice, and by the use of additional data, generated by wearable devices used by the participating patients. The idea is to exploit the AI techniques, developed by other project partners, to evaluate the effectiveness of a novel parsimonious risk prediction model based on the use of both categories of variables. 100 patients have been involved in the pilot for a 18 month study. The participants are screened by a doctor, involved after signing the informed consent, and registered in the study through a custom GK application, hosted within the hospital intranet; the application is also responsible for the management of the association between the local user identifier and the GK identifier. Conventional data are collected during the patient visit at the hospital: blood tests (e.g.

glycosylated haemoglobin, total cholesterol, etc.) are stored in the hospital EHR while Case Report Forms (CRFs) are filled, with the application, during the clinical interview. The application, collaborating with other existing components, extracts the EHR and CRF data with the patient identifier and sends them to the GK Data Federation Server interacting with the GK Data Federation Integration Engine, responsible for the conversion in the FHIR resources compliant to the GK FHIR IG profiles. To manage additional data collected by the smartwatch (number of steps, distance, walking time, type of activity, burned calories, sleep duration and characteristics, heart rate, and heart rate variability), the Samsung GK App interacts with the Samsung Health App and on a regular (typically daily basis) communicates with the GK Data Federation Integration Engine to send data automatically collected by the Samsung smartwatch to GK Data Federation Server. Also the second pilot have adopted the Samsung GK app to feed the GK Data Federation Server with smartwatch and smartphone data. It has 2 sampling types: RUC1 for health promotion e-coaching in healthy subjects aged 55+ (currently 600 involved patients) and RUC2, 3, 5, 7, 8 for monitoring chronic patients enrolled in the regional Chronic Care Model (CCM) (500 estimated patients). For RUC1, it was decided to collect the daily number of steps and, optionally the nutritional diary. For the monitoring of chronic patients, depending on each disease, specific devices were selected from GK Marketplace and therefore the data sent to GK Data Federation Server can be observations of heart rate, blood pressure, glycaemia, body weight, and Oxygen saturation (SpO2). For the monitoring of the data recorded in the GK Data Federation Server, the monitoring dashboards are cases of external apps represented by the yellow rectangle in Figure 1.

4. Discussion and Conclusions

In telemonitoring/telemedicine environments, where device producers have their own proprietary data formats fit for their specific technical requirements, allowing patients to share their data is fundamental to create solutions able to support interoperability for AI models that need harmonized data. The adoption of medical informatics standards as FHIR in not enough to guarantee interoperability in real working applications. In fact, the flexible structure of FHIR resources must be constrained to the specific use context by profiling them through the definition of an IG. GK Project allowed to perform this activity at European level, however the long-term goal is to create a global HL7 FHIR IG for physical activity monitoring. We presented the IG to the HL7 Mobile Health Working Group as first step to create the possible global HL7 FHIR IG. A next step could be the contribution to the initiative sponsored in 2022 by the Physical Activity Alliance (PAA) to create an HL7 FHIR IG whose physical activity monitoring profiles are well aligned to those of the GK FHIR IG. Referring to the specific code system defined in the IG, we have been requesting a LOINC extension of missing coded concepts. The GK FHIR IG guide has been developed in an agile manner with feedback from the pilots to harmonize different wearable technologies (e.g. Samsung Smart Watch and BIOBEAT Smart Watch) as well as Internet of Things (IoT) devices (e.g. Smart Scales, Blood Pressure Monitors etc.). In addition, we consider the IG as work in progress and expect its quality to improve hand in hand with the maturity of FHIR resources involved even if there was no contribution to the development of FHIR Release 5. However, such an implementation has already enabled, in the context of GK, the development of downstream AI services to work on a coherent and enriched data level through the use of standardized terminologies. Moreover, we expect that it will also facilitate the use of the AI services with third party consumer for further exploitation. At the present, we are collaborating with other GK partners to define operations able to use FHIR resources both as input and output format for the AI models.

Another important topic is the adoption of wearable devices data in the clinical practice. In the pilots presented in this paper, the wearable device data are used together with conventional data to develop and test the AI algorithms to predict the glycated haemoglobin value. However, at the moment, physicians do not use the wearable device data to take clinical decision on the patients. At the end of the study, the physicians will analyse collected data to evaluate and validate the capability of the implemented AI models to predict the level of glycated haemoglobin. To effectively use the wearable device data in clinical practice validation additional studies need to be undertaken. In many Countries, as Italy, the Healthcare Ministry allows interventional studies which only adopt data coming from certified medical devices. At the present, only few wearable devices as smartwatches are certified; there are problems related to the quality of collected data and to the real association with the patient, which for example cannot correctly wear it, or take it off or lose it. We hope that the presented research work will improve the risk prediction in patient affected by chronic diseases as T2D, and will be the base for an HL7 FHIR IG that could be adopted in the context of the European Health Data Space (EHDS), as part of globally adopted health information domains under the European EHR exchange format (EEHRxF) for telemedicine/telemonitoring.

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