Use of HL7 FHIR to structure data in epilepsy self-management applications

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***Abstract*—The expansion of health infrastructure to support the networking of actors in the healthcare system is rapidly growing and is forced by law in several nations. The solutions are based on international standards to ensure interoperability of existing and new health applications and future viability. In the EPItect project, a telemedicine infrastructure for epilepsy care was developed. This paper presents part of the conceptual work and focuses on the structural and semantic standardization of epilepsy data based on the international standard HL7 FHIR. The main contribution of this work is an implementation guide for the exchange of epilepsy related data between epilepsy self-management applications and health infrastructures.**

Keywords–Epilepsy, Seizures, EPItect, Wearables, Mobile Application, HL7 FHIR.

I. INTRODUCTION

Epilepsies are among the most common neurological diseases worldwide. Depending on the degree of severity, affected persons suffer from considerable restrictions of their autonomy. Characteristic symptoms are recurring epileptic seizures, which can be very stressful for affected people, relatives and carers due to the unpredictability of the time at which seizures occur, as well as the impairment of consciousness and the loss of control over body functions. Among other things, the mortality of people with epilepsy is increased by a factor of 2-3 due to severe epileptic seizures (e.g., failure of the respiratory center) and seizure consequences (e.g. accidents, suffocation) [1][2]. The early detection of seizures can possibly help to take of appropriate safety measures for the person concerned and to reduce sudden unexpected death in epilepsy (SUDEP). By using technical solutions for better supervision (e.g., video cameras, pulse oximeters) or rooming-in of relatives the SUDEP incidence in an epilepsy center shows a decreasing trend between 1981 and 2016 [3]. In addition to such early detection, an accurate recording of the seizures also helps in the individual planning of the therapy. In order to reduce seizure frequency or, at best, to achieve complete seizure control, a central component of medical treatment is the suppression of seizures by medication. Proper documentation of epileptic seizures by patients or relatives plays an important role in optimizing therapy. The documentation can be done on paper or web-based seizure calendars (e.g. EPI-Vista®) [4]. In recent years a number of mobile applications for epilepsy self management , which typically include modules such as seizure diaries, medication intake logs, medication intake reminders, drug allergy diaries and assistance in emergency situations have been developed[5][6]. Despite similar functionality and type of managed information these applications are insular solutions that are not interoperable. In view of the increasing digitalization and the politically driven development of health infrastructures for both care and research, standardization of procedures and protocols are urgently required. A standardized electronic data exchange between all involved actors (patient, informal and professional caregiver) in order to optimize the care process is missing. Concurrently to the increasing digitization of epilepsy care, lightweight standards for data exchange with mobile applications and sensors have been implemented in recent years [7]. Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) is a standard for health care data exchange. It was created by the HL7 International, a non-profit organization that promotes and defines standards for healthcare, based on previous data format standards (HL7 version 2.x and HL7 version 3.x). Unlike the previous data formats HL7 FHIR uses a modern technologies including HTTP-based RESTful protocol. The HL7 FHIR standard defines: (a) a set of different types of resource that represent healthcare related information both clinical and administrative (patient, observation, medication, appointment...) and (b) specification of transactions to exchange these data [8].

In this paper we propose an implementation guide for the standardized exchange of epilepsy data. The paper is organized as follows: Section 2 presents a brief literature review about existing research on harmonization of data in epilepsy care and the usage of HL7 FHIR in health it solutions. Section 3 describes the project EPItect including the components of the technical solution. Section 4 describe the methods. Section 5 provides information about the domain model and to the implementation of this in an epilepsy self management application using our specified HL7 FHIR profile as part of the implementation guide. Finally, Section 6 describes the conclusion and some thoughts with regard to future work.

II. RELATED WORK

The following sections outline existing harmonization efforts in the field of epilepsy. Subsequently, some research papers are listed that already implement HL7 FHIR.

A. Research on the harmonization of epilepsy data

A first approach deals with industry-wide standards for epilepsy data [9]. The aim of the consortium, which was formed in 2016 and which consists of stakeholders in industry, patient advocacy groups, and clinicians scientist, is to define a minimal data set for use in mobile applications for epilepsy patients based on JSON. The identified data objects were classified as ”frequent” (e.g. medication) and ”less frequent” (e.g. social history). Items have been classified as ”essential”, ”recommended” or ”optional.” The paper also deals with the classification of epileptic seizures and proposes to support individual terminologies and, in cross-system data sharing, using the International League Against Epilepsy (ILAE 2017 nomenclature). The exact technical standardization of the data remains open in the research work.

B. Use of HL7 FHIR in mobile applications

Various research deals with the implementation of HL7 FHIR-based communication between patient-centric and provider-centric IT applications [10][11][12]. In [13], an FHIR-compatible infrastructure (SMART on FHIR) was set up and tested in several patient applications. To support patient-health-provider communication, the framework has been successfully integrated into an Electronic Health Record (EHR). In the field of radiation oncology, the problem of lack of interoperability is also addressed by using and adapting the HL7 FHIR standard for data transfer [14]. Medivate uses HL7 FHIR to enable a structured exchange of medication data between clinical applications and patient application to keep the medication list and vaccine list accurate [15]. Further research shows the use of HL7 FHIR for the continuous monitoring of vital signs in the field of "Cardiologic Reha Monitoring"[16]. In [17] HL7 FHIR is used to incorporate genomic cancer data into existing EHR platforms with the aim to provide pracitioners with context-dependent information (population cancer mutation, knowledge bases) for gene-driven decision-making in cancer treatment.

In summary, HL7 FHIR is used to bridge the gap between (a) patient applications and electronic health records and (b) electronic health records and research infrastructures / knowledge bases. However, there is still no adaptation of the HL7 FHIR standard for the epilepsy application area. Particularly in the care of epilepsy patients, data collected by the patient, such as seizure documentation, play a major role. A standardized interface can help to provide this efficiently.

III. EPItect

The focus of the project EPItect is to develop a non-invasive sensor system, which reliably detects those bio signals that enable automated detection of epileptic seizures. In addition, the second important objective is to enable the electronic exchange of epilepsy-relevant data via a standardized and secured telemedical infrastructure. The infrastructure supports the data exchange (a) between healthcare providers, (b) between the patient and informal caregivers (e.g. parents), (c) between the patient and healthcare providers. The components of the technological solution are the sensor (EPISENS), the mobile application (myEPI), the portal (EPICASE Portal), the networking infrastructure (EPICASE Infrastructure), the research infrastructure and the EPItect ML Framework.

The components of the technological solution are shown in Figure 1: the In-Ear sensor (EPISENS), the mobile application (myEPI), the portal (EPICASE Portal) and the networking infrastructure (EPICASE Infrastructure). EPISENS (1) includes sensors to optimize seizure detection and seizure counting. It sends vital data, raw data and alarm events via Bluetooth Low Energy to the myEPI App. myEPI App (2) is a mobile companion for the patient. The app includes an alarm module. Upon receipt of alarm events, selected persons (e.g., parents or partners of an affected person) should be informed. The patient can use a simple action on the smartphone to confirm the seizure event or classify it as a false alarm. This information is used in the next step to optimize the specificity of the

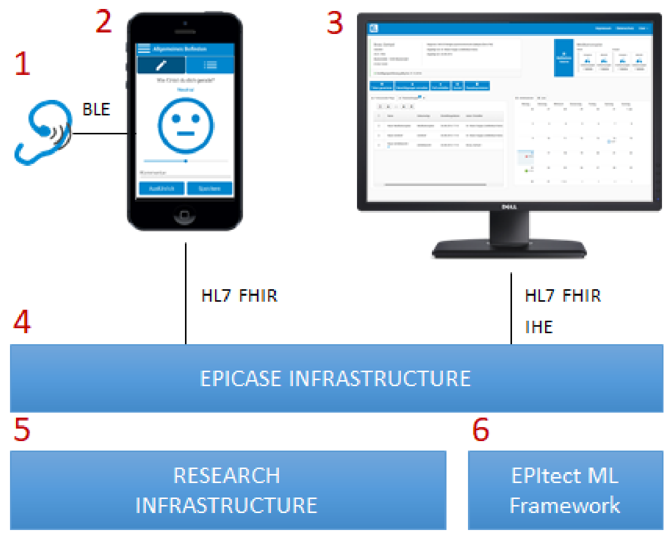

Figure 1. EPItect architecture.

algorithms developed. In the app, the patient also has the opportunity to collect additional data (contextual information on seizure events, mood, medication administration, side effects). He can selectively release data for doctors or relatives. The data is transmitted securely via the EPICASE infrastructure (4) and can be viewed by relevant actors via the EPICASE portal (3). The EPICASE portal is a case based communication portal for patients as well for professional and informal caregivers. It enables exchange of treatment-relevant data (e.g,. medication order, medication administration, seizure documentation, diagnosis). The EPICASE infrastructure connects the IT applications. It is based on international standards and fully complies with data protection and data security requirements. The project EPItect also provides a research infrastructure (5) for pseudonymization, data capturing and integrating and storage of case based generated data. The integrated data is the basis for the machine learning framework (6).

The consortium of the project EPItect coordinated by the epileptologists of the University Hospital Bonn consists of five institutions and two associated partners in Germany: Department of Epileptology at the University Hospital Bonn, Fraunhofer Institute for Software and Systems Technology ISST, Department of Neuropediatrics of the University Kiel (UKSH), the North German Epilepsy Center in Schwentinental-Raisdorf, Cosinuss GmbH Munich, the University for Healthcare Professions in Bochum, and the Epilepsy Bundes-Elternverband e.V. [National Epilepsy Parents Network] in Wuppertal.

IV. Methods

We have realized our approach using Model-driven Engineering (MDE) an established methodlogy to increase productivity of complex systems. The focus of this method is on creating and using domain models, which represent concepts related to the problem domain [18]. The abstraction from the technology due to using artifacts closer to human understanding simplifies the design process and enhances the communications in the interdisciplinary team working on the system [19]. The domain models form the basis for the technical artifacts. The model transformation is done with the HL7 FHIR Profiling.

This section first introduces our methods for Domain Modeling. Afterwards an overview of the HL7 FHIR Profiling will be given.

A. Methods for Domain Modeling

We used several methods for seeking common concepts and semantics involved in the epilepsy domain, with the goal of providing a conceptual foundation that can be used in all digitalization projects in epilepsy use cases.

1) Reference Process: With the first appearance of an epileptic seizure, a lengthy treatment process usually begins in various medical institutions with the aim of making an exact diagnosis and planning an individual therapy for the patient. At the beginning of treatment, it must first be clarified whether there actually is an epilepsy disease. A precise description of the seizure, including self- and foreign-anamnesis, can help to make the initial assessment. Further clinical examinations, such as video EEG records, imaging and laboratory tests, provide clear information on the presence of epilepsy. Reducing seizure frequency or, at best, gaining complete control of seizures by medication is a central part of therapy. Various anti-epileptic drugs are available, which are used depending on the individual situation (for example age, weight). The therapy's focus is not only on the freedom of seizure, but also on the tolerability and interaction with other medications. The combination of the results of the examination and the documentation of epileptic seizures by patients or relatives play a major role in diagnostics and therapy in order to have as complete a basis as possible for therapy decisions.

We have investigated clinical guidelines [20] for epilepsy. Building on this and on actual processes in the hospitals, we have defined a reference process that also includes aspects of patient involvement with mobile applications and the integration of sensors for seizure detection. The reference model was used to derive relevant data for the domain model.

2) Analysis of existing questionnaires for seizure documentation and seizure diaries: To optimize the therapy of an epilepsy it is necessary to document seizures in a suitable and well-structured manner. On the one hand, observations performed by the affected person itself, friends and family have to be recorded. On the other hand, vital signs and other technical data written by the in-ear sensor and the smartphone of the affected person need to be saved. Physicians can use these data to draw conclusions about the source of the epilepsy and for example adjust medication. In order to construct a comprising seizure documentation form, questionnaires of many different hospitals and several scientific publications were compared and considered [21][22].

B. HL7 FHIR Profiling

The HL7 FHIR specification is generic and targets all countries and all use cases. For specific use-cases it is important to tailor the specification. The result of the adjustment for a use case is documented in an use case specific HL7 message profile, which presribes a set of precise contraints upon one or more standard HL7 messages [23]. A profile is an interface specification that can be shared within a team or project or other international team working on the same use case. It serves as a basis for the implementation of interfaces and it also allows to define test-scenarios to validate the integrated technical solution. A profile contains information about data format, data semantics and message acknowledgment responsibilities. There are many free and commercial tools on the market that are relevant to the specification of HL7 FHIR profiles. We used the Forge tool proposed by the HL7 Community to create and refine and validate profiles. As a result, an implementation guide, which describes how FHIR is adapted to support a certain use case is to be developed.

V. Results

A. Domain Model

The domain model shown in Figure 2 includes data collected in a clinical context (e.g. diagnosis, clinical findings) as well as from the patient or relative (e.g. seizure documentation, mood).

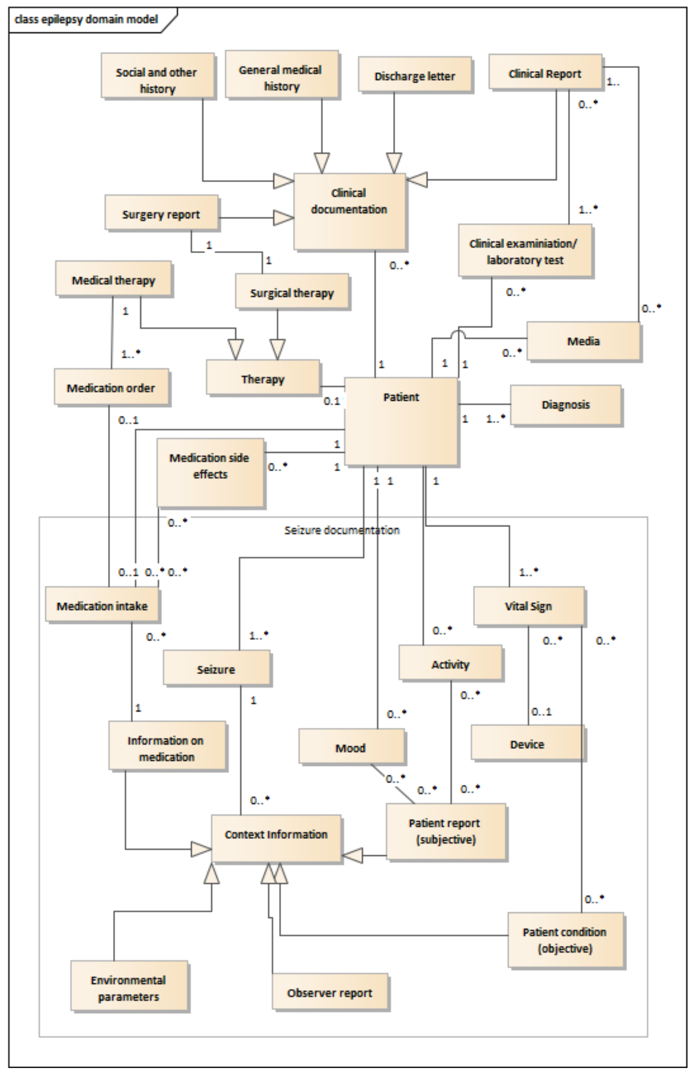

Figure 2. Epilepsy domain model.

The sensor data is represented via the domain class "Vital Sign", which is linked to the registering device. In the project, the seizure documentation describes a grouping of elements that represent subjective representations (e.g. observer perspective, patient descriptions) as well as elements that comprise objective data (e.g. vital parameters present at seizure time, location of the seizure).

All elements of the domain model can be described semantically by terminology. For the semantic description of clinical documents Logical Observation Identifiers Names and Codes (LOINC) is used, as well as for the semantic description of vital parameters. Diagnoses are desribed by the ICD 10 code. The classification of seizures is based on the ILAE 2017 nomenclature. A data element can be described semantically by specifying several codes from different value sets, so that additional organization-/ project-specific codes can be added. Further information is added to the attributes of the domain classes, such as author details, unique IDs, values and time information.

B. Implementation Guide

The domain model formed the basis for creating an HL FHIR profile. In the FHIR profiling process, we specified the technical mapping of the domain model by restraining or augmenting HL7 FHIR resources. A HL7 FHIR resource represents a granular clinical concepts (e.g., Observation, Patient) [24]. In addition, value sets have been specified for the resources.

To collect structured patient data, the HL7 FHIR resource "Patient" is used. Observations on the patient can be made via the "Observation" resource. To classify the observation more precisely, the resource's "code" attribute specifies the semantic meaning of the "Observation" (e.g. LOINC code 8867-4 for heart rate). To map a medication, the two resources "MedicationOrder" and "MedicationAdministration" are needed. The "MedicationOrder" is a prescription medication protocol and "MedicationAdministration" is a receipt protocol. The dosage is specified in detail via the attribute "doseInstruction" of the resource. You can enter exact intake times or intervals. The coding of the medication can be specified via drug codes or medication. In our implementation, we have used the Acute Toxic Class (ATC) list. Clinical documents are linked via "DocumentReference". Videos or images are represented by the resource "Media". The seizure event is also an observation on the patient. To gather context information about the seizure event, we used the resource "Composition" to define a special new data type. The "Composition" represents a set of healthcare-related information that is grouped logically. To group the elements of the seizure documentation, specific sections were defined based on the domain model (e.g. patient report, observer report). The seizure event section is required. All other sections are voluntary and provide the extended documentation on epileptic seizure. The seizure event section references a resource "Observation" that includes the seizure with its metadata. The attribute "value" is used to classify the seizure type. In addition, a reference to the device that recorded the seizure event can be added. The patient report or the observer report is collected via questionnaires. For this we use the resource "Questionnaire". In the sections "Patient report" and "Observer report" the "QuestionnaireResponses" are embedded.

C. Implementation

We have developed an EPI-FHIR service based on the defined profile. This was embedded in the EPItect infrastructure, and can be used by both the portal and the mobile application. Figure 3 shows a user interface for collecting seizure documentation. The patient can send data from the mobile application in standardized format via the EPI-FHIR service. Care givers can retrieve the data via the portal. The transactions are embedded in a security context so that they are securely transmitted and only authorized persons can access this data. The mobile application includes the following HL7 FHIR based modules: vital signs module, medication module, seizure documentation module, health module, settings module, statistics module, approval center, emergency management module.

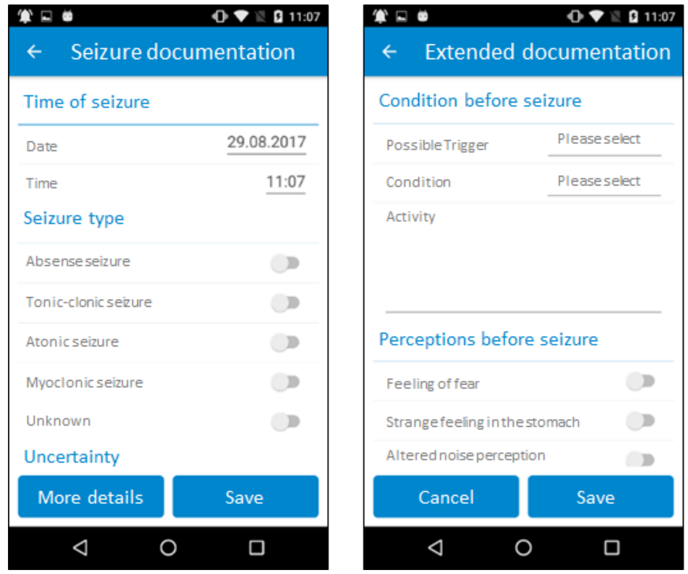

Figure 3. Seizure documentation in mobile application.

VI. Conclusion and Future Work

The exchange of data between actors is essential in the treatment of epilepsy. Information on side effects and the number of seizures help, for example, to adjust the medication therapy individually for the patient. With the spread of mobile epilepsy self-management applications and seizure detection sensors, standardized data exchange formats for integrating patient-related information into therapy are becoming increasingly relevant. The presented research on the implementation of standardized documentation in epilepsy care is a first step towards interoperability between IT solutions in the epilepsy domain. The Implementation Guide was tested using the example of the applications myEPI App and the EPICASE Portal. In an ongoing clinical trial, the two applications will be evaluated for patient functionality and user acceptance. It is planned to bring the achieved results into national and international standardization committees. An exchange with other epilepsy consortia is planned to further refine the domain model. One focus will be the depth of information as well as the terminology to be used for the semantic description of data objects.

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