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USER-CENTERED DESIGN AND EVALUATION OF STANDARD-BASED HEALTH TECHNOLOGIES FOR EPILEPSY CARE

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Research paper

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Abstract

Sensor-based technologies for the detection of epileptic seizures and health technologies for the secure and standardized electronic data exchange between healthcare providers, patients, and their relatives help to create transparency in the therapy and thus to optimize the treatment. Particularly in the case of drug therapy, the detection and documentation of seizures and medical side effects is an important basis for decision-making. In this article, we analyze the requirements of such solutions from the user's point of view. To ensure the sustainability and integrability of our solutions, cross-functional requirements such as interoperability, data protection and data security are taken into account. Based on our requirements analysis, we have implemented an overall solution for sensor-based and standard-based health technologies. A subsequent evaluation study with the developed mobile application and web portal shows a strong interest of patients and relatives to integrate these solutions into their daily lives.

Keywords: epilepsy self-management application, sensor, electronic case record, HL7 FHIR, IHE, seizure documentation, user study.

1 Introduction

Epilepsies are among the most common neurological diseases worldwide and are considered a complex chronic health condition. It takes time for the patients and relatives to accept the realities of having a chronic health condition with lack of seizure control. Thus, patients can be affected also emotionally and socially and can have psychiatric comorbidity like depressive disorders (Fela-Thomas et al., 2016; Tadokoro et al., 2012; Cengiz and Tanık, 2019; Hermann et al., 2000). The chronic disease complications and the multimorbidity require the attention of multiple health care providers. Moreover, patient self management and family involvement can be crucial to proper diagnosis and treatment (Kobau and DiIorio, 2003). Telemedicine can help to coordinate the management of epilepsy disease between involved actors by using communication and information technologies for the exchange of relevant data for diagnosis and treatment. In recent years, several approaches regarding the development of telemedical health technologies in different medical fields have been launched (Ranjan et al., 2019; Kane-Gill and Rincon, 2019; Paré et al., 2007). Many studies have shown, that telemedicine is promising regarding the patient empowerment and influence on the behaviour (Basit et al., 2019; Peters et al., 2015; Paré et al., 2007; Suter et al., 2011; Bhatia and Sharma, 2008). The usage of telemedical health technologies in the field of epilepsy in daily clinical practice is still rare. There are few studies describing the use of telemedical health technologies in epilepsy care mainly with the aim of providing consistent care in rural and geographically isolated areas (Ahmed et al., 2007; Rasmusson and Hartshorn, 2005; Patterson et al., 2014; Haddad et al., 2015; Lua and Neni, 2013). Most of them state the benefits concerning patient satisfaction and reducing patients costs. Lua et al. (2013) show that already by the use of SMS-based epilepsy education programme positive impacts on health-related quality of life can be generated. Despite the fact that the improving of quality and performance of care is clear, given the fact of integrated and comprehensive data collection as a basis for therapy, there is no continuous use of health technologies for inter sectoral communication using electronic health records in epilepsy care. Page et al. (2018) points out, that changing existing working practices due to new technologies is challenging. Managing electronic health records causes time loss, as long as they can not be integrated into the medical process and the existing technology.

Concurrently, research in the field of mobile devices for seizure detection (Regalia et al., 2019; Ramgopal et al., 2014; Teohari et al., 2014) and epilepsy self management applications gains more importance. Typically these applications include modules such as seizure diaries, medication intake logs, medication intake reminders, drug allergy diaries and assistance in emergency situations (Escoffery et al., 2018; Liu et al., 2016; Ranganathan et al.; 2015). Page et al. (2018) criticized that information gathered by the self management applications can not simply be transferred to the clinical system and must be recorded redundantly and in a time-consuming manner. On the other hand he emphasizes positively that a patient co-authored health record has the potential to relief. Integration technologies for seamless data integration with semi automated clinical assessment increase acceptance of such solutions. Standards like Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) are used to bridge the gap between patient applications and electronic health records (Saripalle et al., 2019; El-Sappagh et al., 2019; Bloomfield et al., 2017). However, there is still no adaptation of these standards for the epilepsy application area.

In summary, health technologies in epilepsy care have a great potential. Due to the missing integrability of such solutions they have not been established in clinical practice. There are no telemedical health technologies, which incorporate (A) seizure detection devices, (B) epilepsy self management application, (C) health technologies for patients (and relatives) to physician communication, (D) health technologies for physician to physician communication, (E) technologies for integration in existing clinical infrastructure in an overall approach.

Thus, we strive for the following contributions: First is the development of secured and sensor-based health technologies for epilepsy care based on international standards comprising (A)-(E). Furthermore, we seek insights into the following research questions: (1) subjective additional benefit of the

health technologies compared to traditional paper diaries, (2) acceptance of the health technologies for everyday life and (3) preference / interest for different modules of the health technologies.

The paper is structured as follows: Firstly, we present two application areas of Health Technologies which serve as a basis for the requirements analysis (Section 2). Secondly, we outline the requirements analysis and the results (Section 3). Afterwards, we present the design and implementation of the health technologies (Section 4). Then, we present the evaluation by terms of method and results (Section 5). Finally, the paper gives a conclusion and an outlook (Section 6).

2 Application Areas

The identification of areas that would benefit from the usage of technologies is the precondition for effective requirements engineering. In this chapter, we introduce two areas with high priority from user's point of view, which have provided major input for the conception of our health technologies.

2.1 Managing the Treatment Process of Epilepsy Patients

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 the epilepsy diagnosis is actually correct. A precise description of the seizure, history-taking with patients and carers including history-taking with patients and carers or relatives, can help to make the initial assessment. Further clinical examinations, such as video-electroencephalography (EEG) records, imaging and laboratory tests, provide clear information on the presence and possible causes 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 (with respect to e.g. epilepsy type, seizure severity, age, gender, body weight). The therapy's focus is not only on seizure freedom, 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. In order to facilitate the coordination between the healthcare providers and to contribute to patient empowerment our health technologies focus on:

- Managing secured data exchange between medical institutions (epilepsy centers, doctor's office, …), patients and relatives
- Integration of value-added services for different user groups (e.g. medication reminder, statistical analyzes, seizure diary)

2.2 Managing Seizure Documentation and Emergency Situations

Proper documentation of epileptic seizures by patients or relatives plays an important role in coordinating therapy. The documentation can be done on paper or web-based seizure calendars (e.g., EPI-Vista R) (Rabeding et al., 2002). However, previous studies show that approximately 50% of seizures are not documented and approximately two-thirds of patients provide incorrect data (Hoppe et al., 2007; Blum et al., 1996). The main reasons for the faulty seizure documentation are, for example, the disturbed perception of one's own seizures, amnesia for seizures or later forgetting to document a seizure that has taken place e.g. at night. The seizure documentation by relatives or caregivers is also prone to failure as relatives do not notice symptom-poor epileptic seizures (Akman et al., 2009). Sensor-based detection of epileptic seizures plays an extremely important role in achieving complete and accurate documentation of epileptic seizures. The detection can also serve as the basis for an alarm system. 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) (Forsgren et al., 2005). Another problem is the occurrence of epileptic seizures in unobserved situations, such as during personal hygiene or when sleeping. This is particularly signifi-

cant as the occurrence of unobserved generalized tonic-clonic seizures can lead to cardiac and respiratory arrest and is a major cause of increased premature mortality in epilepsy (sudden unexpected death in epilepsy, SUDEP) (Thomson et al., 2016). Health technologies, which are meant to support seizure detection and documentation as well as emergency alert, have to address the following aspects:

- Accurate detection and automated documentation of seizures with sensors for everyday use
- Managing detailed seizure information from patients and other observers
- Managing emergency configuration which intervenes in emergency situations

2.3 User Groups for the Health Technologies

We have identified different user groups in the context of the described application areas. (a) Patients. (b) Professional caregivers: Persons who have received state-approved medical or nursing education. (c) Informal caregivers: Persons who take care of a patient with epilepsy without having received state-approved medical or nursing education (e.g. relatives). Our work aims at providing health technologies for the identified user groups. Table 1 assigns the health technologies to the user groups.

Health Technology	Patients with epilepsy	Professional caregivers	Informal caregivers
Sensor	Yes	No	No
Mobile Application	Yes	No (reason: use of familiar working environment is preferred)	Yes
Web Portal	Yes	Yes	Yes

Table 1. Assignment of technologies to user groups.

3 Requirements of Health Technologies

3.1 Method

The goal of Requirements Engineering is to discover, document and manage requirements of an IT-based system, which, as far as possible, are complete, consistent, relevant and reflect the users needs (Sommerville and Sawyer, 1997). To identify the requirements for a sensor based IT infrastructure for epilepsy care, different approaches for obtaining requirements have been combined.

Co-creation workshop: A co-creation workshop with relevant actors, such as people with epilepsy, parents of children with epilepsy and professional carers, was conducted at the beginning of the project. In interactive collaboration, using the world café method, requirements for the sensor, the mobile application for the patient and the nursing portal were derived and prioritized.

User surveys: A questionnaire for patients, informal carers and professional carers was developed. A total of 551 persons took part in the survey (225 patients, 61 professional caregivers, 265 informal caregivers). Table 2 gives an overview of the focus of the survey.

Question	patient	informal carer	professional carer
General			
• demographic data • Previous experiences with seizure detection • Need / relevant situations for sensor-based seizure detection • if teacher: frequency of seizures in school classes	x x x	x x x x	x x x
Sensor			
• Acceptance of the used in-ear sensor • Concerns associated with the sensor being used	x x	x x	

• sensor requirements	x	x	x
Mobile Application			
• mobile application requirements • context of an alarm system (which persons should be informed, how should persons be informed, accepted number of false alarms)	x x	x x	x x
Web portal			
• portal requirements • concerns associated with a computer based solution • if teacher: Integrability in everyday school life • if doctor: use cases for the web portal in clinical practice	x x	x x x	x x x
Supplement			
• current ways of exchanging health information with relevant persons • Expected changes and benefits of a sensor-based seizure detection • willingness to pay for an it-based therapy / monitoring	x x x	x x x	x x

Table 2. Structure of the questionnaires.

User stories based on clinical practice and medical guidelines: We have investigated clinical guidelines for epilepsy (Thijs et al., 2019). 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 use cases for the sensor-based health technologies. We described the usage scenario for each use case to define the boundaries. This includes the pre- and postconditions, the core tasks with subtasks and the actions and reactions of the system. Based on the detailed description of the scenarios, we have derived requirements for the components of the health technologies and prioritized them together with the users. Based on the usage scenarios, prototypes for mobile application and web portal are designed including all user interfaces for the usage scenarios. The prototypes are used to check their meaningful feasibility and to verify the requirements.

Analysis of relevant frameworks: We have analyzed the legal basis for data protection and data security in health technologies especially with focus on the use of mobile devices. In addition, we have investigated frameworks for the implementation of user-friendly software (e.g. DIN EN ISO 9241 Part 110 Principles of Dialog Design). We paid particular attention to interoperability to ensure seamless integration into existing system infrastructures. Therefore, we have conducted a search for existing international standards both in general for health care and explicitly for the epilepsy domain.

Our combined approach for requirements engineering not only makes it possible to identify system specific functional requirements but also general and quality demands. The collected requirements were prioritized with the users.

3.2 Results

According to Pohl (Pohl, 2010), single requirements can be documented as requirement artefacts. We specified a number of criteria for the structured and consistent collection of artefacts, such as unique name, criticality, objective, priority, related use cases, etc. Since the listing of the fine-grained specification of requirements would exceed the scope of this paper, all elicited requirements were aggregated to high-level descriptions in the following sections.

Requirements for the web portal: The portal must provide the ability to store epilepsy data and exchange it between medical institutions in a secured manner. In addition, the involvement of informal caregivers and patients is important. There must be support for data exchange between all actors. Reliable activation mechanisms must be implemented to establish the link between the case record and the

mobile application. In addition, value-added services, such as, for example, statistical analysis and the collection of structured data (e.g. medication, seizure documentation) must be supported.

Requirements for the mobile application: The mobile application must support the registration in such a way that a link to the electronic case record in the medical institutions is possible. Data collected via the mobile application must be explicitly released by the patient for selected persons (groups) or organizations. The patient must be able to import data released for him (e.g. medication plan) into the mobile application. The mobile application must implement medication management (medication reminder, and medication intake), emergency management, seizure documentation, registration of (medication) side effects and alerting. To support emergency management and seizure documentation, the mobile application must receive and display data from the sensor and trigger an alarm in critical situations. In order to detect false alarms and to use them for the future optimization of the seizure detection algorithm, it should be possible in the mobile application to classify seizure events that have been erroneously recorded by the sensor as false alarms. Moreover, the patient should be able to manually document seizures not detected by the sensor. It is desirable, that the mobile application can display statistics for example to seizures. For a targeted use of the mobile application, this must be individually configurable for the patient. In addition to the above-mentioned mandatory requirements, modules for the documentation of well-being or quality of life can be implemented. To ensure that the functions of the sensor are used as consistently as possible, the patient should be informed about the battery status or bad data quality (e.g., if the sensor is not in good position).

Requirements for the sensors: The sensor must support the acquisition and transmission of movements and vital signs (e.g. temperature, heart rate). These also serve as a basis for the detection of epileptic seizures. A continuous use in everyday life requires quality improvements such as water resistance, prolonged battery life and a low false alarm rate additionally. Moreover, the sensor must inform of certain events (e.g. low battery level, missing connection to the smartphone). In addition to these important requirements, there were suggestions for designing the sensor as a lifestyle accessory (selectable color design, combinability with speaker functions or fitness tracker functions).

Usability requirements: The user-friendliness requirements of the system were derived from DIN EN ISO 9241 Part 110 (Principles of Dialog Design). This standard distinguishes the requirements in 7 categories: Task adequacy, self-descriptiveness, expectation of conformity, learning convenience, controllability, fault tolerance and customizability. For every category, a list of requirements exists. The requirements for the category self-descriptiveness address all aspects which must be fulfilled by a dialogue to the extent that it is always obvious to the user which dialogue is active, which step of the dialogue is active, what actions can be taken and how they can be carried out. A description of all requirements for each category would go beyond the scope of this paper.

Interoperability Requirements: A seamless integration of the telemedical solutions in the medical process determines whether the user acceptance of such solutions is given. As medical facilities already use information technology (e.g. hospital information systems), it is important to ensure the interoperability of the new health technologies with the existing system infrastructure in the medical facilities. Interoperability is defined as the ability to exchange data between different system components (Wegner, 1996). At least two levels of interoperability must be considered (Veltman, 2001). Functional and syntactic interoperability allows systems to communicate through standardized functionality and message structures, such as via defined transactions of the (Integrating the Healthcare Enterprises) IHE profiles (Haarbrandt et al., 2013) and HL7 FHIR (Bender and Sartipi, 2013). Due to migration of new healthcare technologies in the the telematics infrastructure in the German healthcare sector (Zwicker et al., 2011), standards like IHE gain in importance during conception and implementation of new health technologies. Besides, many hospital information systems are already supporting IHE. Semantic interoperability provides a common understanding of the data being exchanged using consistent terminology, such as for example, ICD for diagnosis (Jette et al., 2015) or the ILAE classification (Engel, 2006) to determine seizure type. To achieve interoperability, the health technologies have to integrate structural and terminological standards of the healthcare domain to exchange epilepsy data and must cope with their versioning cycles. Since existing standards do not address all aspects of the epilepsy domain, new data exchange formats (e.g. for seizure documentation) based on existing

standards must be defined. A first approach deals with standardization of an minimal epilepsy data set using JSON (Goldenholz, 2018).

Requirements for confidentiality, privacy and data security: The informed consent of the patient is essential for data exchange. The EU general data protection regulation 2016/679 (GDPR) forms the legal basis for data processing. Articles 4 (11), 6 (1)(a), 7, 8, and 9(2)(a) and Recitals 32, 33, 38, 42, and 43 of the GPPR deal with the conditions for consent. In addition to the GDPR which applies to all European Union countries, there are also german regulations (German Federal Data Protection Act). The consent must be clearly written in simple language. It must contain specific contents such as demographic data of patient, identity of the controller, general information about the data exchange and data processing, type and purpose of electronic data exchange as well as scope of data exchange. In addition, a list of access permissions must be part of the consent. Further building blocks of the consent are patients' declaration of voluntary and informed consent including a time period and that he or she received information about withdrawal of consent, privacy protection rights and data exchange processing. It must be ensured that only registered users have access to the infrastructure. In addition, the system must provide role-based user access for authorized users, due to the fact that the functionality and the access rights differ. Each user can only access her or his own data. For data exchange, technical rights are granted based on patients' consents. Besides encrypted data transfer, the encrypted data storage in the mobile application as well as in the telemedical infrastructure must be ensured. All changes must be stored in an audit trail. Integrity, validity and legal certainty of exchanged data must be ensured. This can be achieved with digital signature technology (Wang et al., 2001). The Bavarian data protection authority has provided guidance on data protection requirements for mobile application providers based on German privacy regulations (Kreis, 2014). This guidance tackles for example the usage of the location data. The storage of the location data on the device may only take place if it is necessary for the functionality. Location data may only be transmitted to emergency managers in case of an alarm. In order to achieve a higher level of protection, it should be checked whether two-factor authentication is possible (e.g. QR code, certificates). If a minor does not have the necessary insight and mental maturity, the collection and use of minors must be done by the parent or legal guardian. In this case the consent of the parents to the data processing must be given.

4 Implementation of Health Technologies

Based on the requirements analysis, we designed and implemented the health technologies. Figure 1 shows the overall architecture.

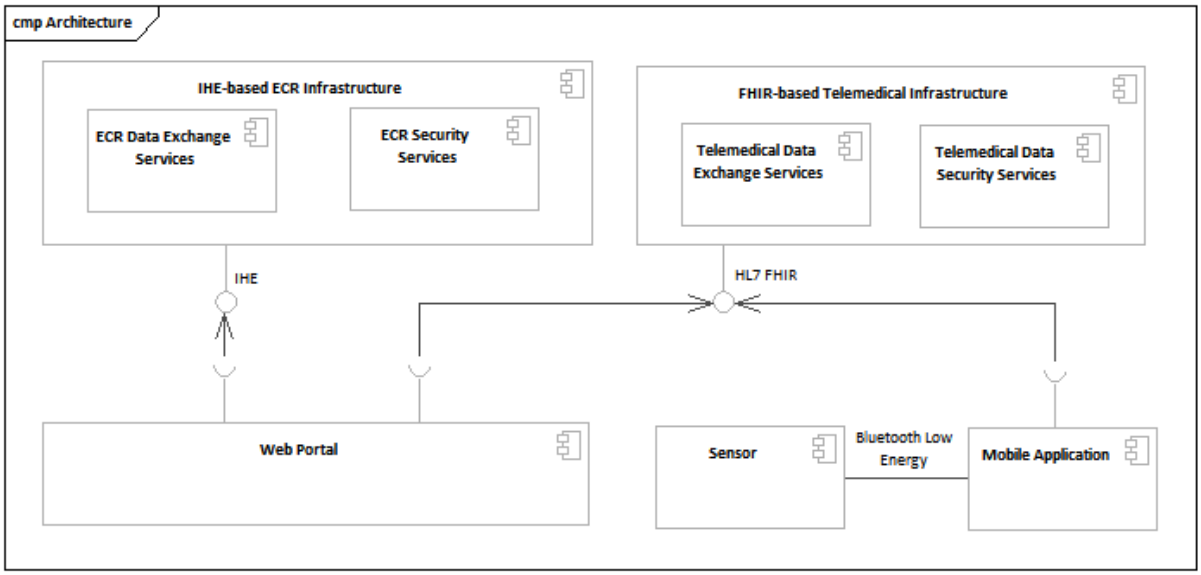

Figure 1. Overall architecture of the health technologies.

The components are explained in more detail in the following sections.

4.1 IHE-based Electronic Case Record Infrastructure

The Electronic Case Record (ECR) was developed in Germany in order to support the communication among physicians involved in a treatment case (Raik et al., 2012). It aims at treating diseases involving multiple physicians and focuses in particular on "long-term patients" with severe or chronic diseases, whose treatment progress needs to be tracked by several stakeholders and regularly coordinated. The technical solution of the ECR is based on international standards and takes into account national data protection and data security requirements. Case records are basically bound to a diagnosis or a specific purpose and thus no unspecific data collections in stock. The ECR is physician-led, i.e. authored and controlled by physicians, and thus represents a reliable decision-making basis for therapy. The infrastructure of the ECR includes data exchange and security services. Only health care providers registered in the Health Provider Directory (HPD) can use the services of the infrastructure after authentication via the Identity Provider (IDP).

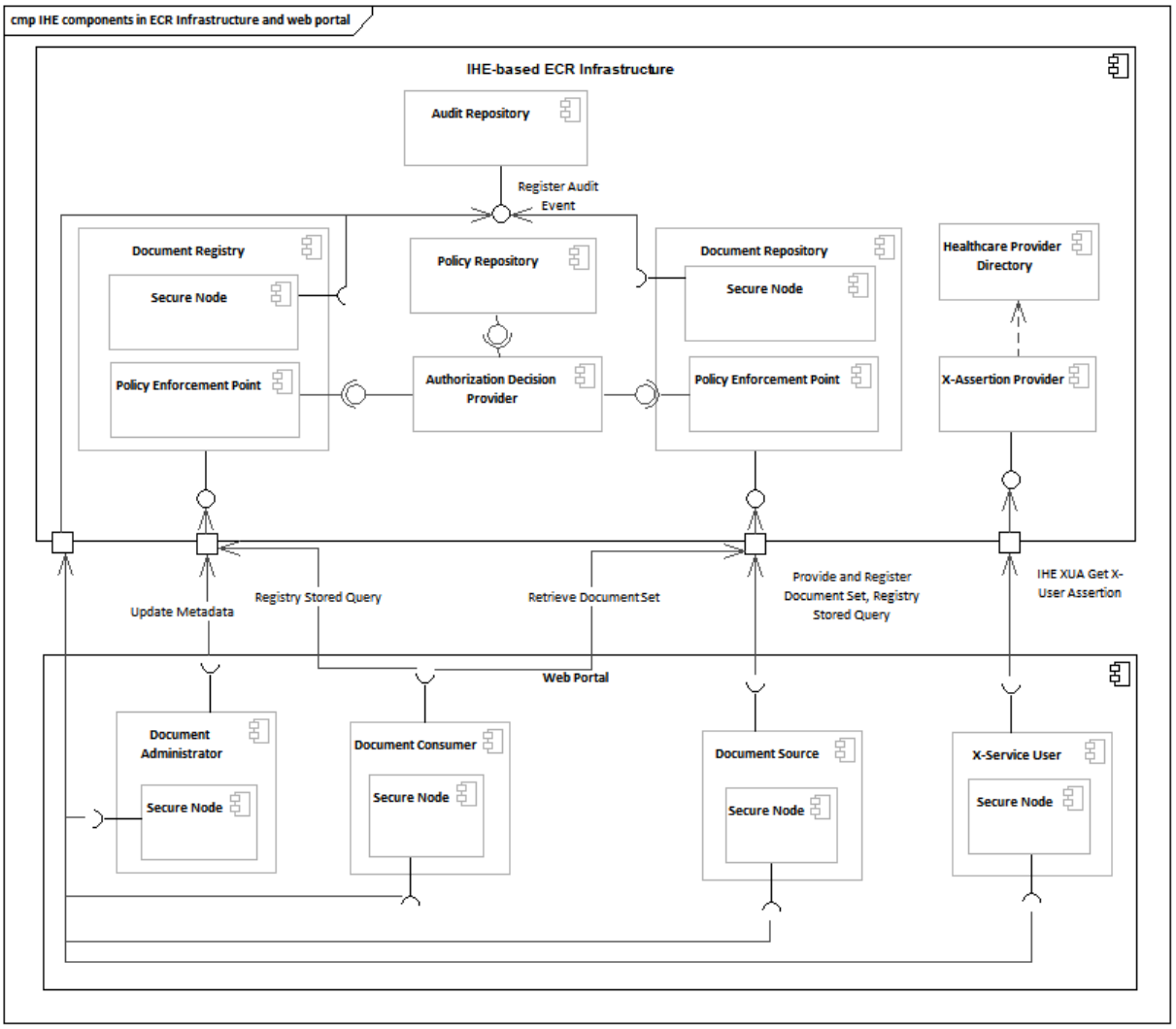

Figure 2. Data exchange and security components of the ECR infrastructure.

After successful authentication users get a signed identity assertion according to SAML (Security Assertion Markup Language) from the IDP according to the specification in IHE Cross-Enterprise User

Assertion Profile (IHE XUA). The SAML contains a unique id of the user as well as role and organizational information. It is included within all data exchange requests and is essential for verifying authorization to access an ECR and its data via the Policy Services. The policies for data access decisions are transmitted to the infrastructure according to the patients will via a structured consent document based on the IHE Advanced Patient Privacy Consents (IHE APPC). The SAML assertion is also used for logging the transactions in the Audit Repository as described in IHE Audit Trail and Node Authentication (IHE ATNA). For network authentication, we also used IHE ATNA. Figure 2 shows the interaction of the web portal with the ECR infrastructure with regard to data exchange and security services. For the sake of clarity, the figure does not include all the relevant components (e. g. the management of patients is not shown, but is also part of the infrastructure). The ECR Infrastructure can be connected with the telemedical services to involve non-medical actors in the data exchange (Deiters and Houta, 2015). Further the integration into existing hospital information systems is easily possible if the manufacturers already implement the relevant IHE interfaces.

4.2 FHIR-based Telemedical Infrastructure

The Telemedical Infrastructure represents the transfer point between a patient as well as relatives and healthcare providers. The implementation is based on HL7 FHIR, as the focus is on the connection of mobile devices as well as the transmission of structured data, which are collected via the app or transmitted by the sensor. HL7 FHIR is a standard for health care data exchange (Bender et al, 2013). It was created by the healthcare standardization Organisation Health Level Seven International based on previous data format standards (HL7 version 2.x and HL7 version 3.x). Unlike the previous data formats, HL7 FHIR uses modern technologies including the HTTP-based RESTful protocol. The data can be represented in JSON, XML or RDF. We have developed a data model for epilepsy data based on HL7 FHIR (Houta, 2019). The Telemedical Infrastructure covers both data exchange and security services. It supports activation mechanisms and secures data by implementing authentication, identity check, authorization and auditing. The data exchange between app and server is encrypted. Further, the data is organized in compartments in order to support purpose-based access. The patient might define different compartments for user groups (e.g. “my private box”, “family”, “my doctors”). With use of data release mechanisms of the Telemedical Infrastructure, the patient can transfer data to the different compartments.

4.3 Sensor-based Mobile Application

The development of the mobile app is based on the cross-platform framework Xamarin (Petzold, 2015) and is done with the development language C#. The goal was to develop a platform-independent solution that can be used on operating systems such as Android and iOS. The mobile application uses the services of the Telemedical Infrastructure. First, a registration of the mobile application must be done via the app. For this purpose, the patient receives a token from his caring doctor. At the same time, this also serves to link the ECR with the patient's record in the Telemedical Infrastructure. After authentication with the security services of the telemedicine infrastructure, the patient receives a signed JSON Web token based ID token in the mobile application, which is sent along with all further requests. Similar to the ECR infrastructure, this also serves as an authorization check as well as for auditing the ID information stored in the token. The data collected via the mobile application and the sensor are stored in the patient record of the Telemedical Infrastructure. If there is no internet connection, the data is cached locally and synchronized when the internet connection is established. The data from the sensor (in-ear sensor) is transmitted via Bluetooth and displayed in the Mobile Application. The patient data is encrypted by the Realm database with AES-256 + SHA2. Figure 3 gives an overview of the mobile application.

Figure 3. Sensor-based mobile application.

4.4 Web Portal

The web portal is based on Java EE and the Vaadin Framework. Depending on the user role, the web portal either uses only the services of the Telemedical Infrastructure (e.g. is user role is patient or informal carer) or additionally the services of the ECR Infrastructure (e.g. if user role is physician). The portal provides a view of all case records of their medical facility to authenticated physicians, which are stored in the ECR Infrastructure. The case records are created after the patient's consent. For the activation of a patient compartment in the Telemedical Infrastructure, a consent of the patient is also needed. Then, an activation token is created and handed out to the patient. Physicians can store various medical information relevant for intersectoral epilepsy treatment in the ECR. These information can be viewed by all health care providers with access to the ECR. The portal allows both the storage of unstructured information such as medical reports in PDF format as well as structured data such as the structured medication plan based on the FHIR format. Physicians can release medical information (e.g. medication plan) for the patient into the telemedical patient compartment and they can see if new data has been received from patients (e.g. seizure documentation) and store these data into their own medical data management. The web portal can also be used by patients and informal carers (e.g. parents). The functionality is adapted to the role. Figure 4 gives an overview of the web portal.

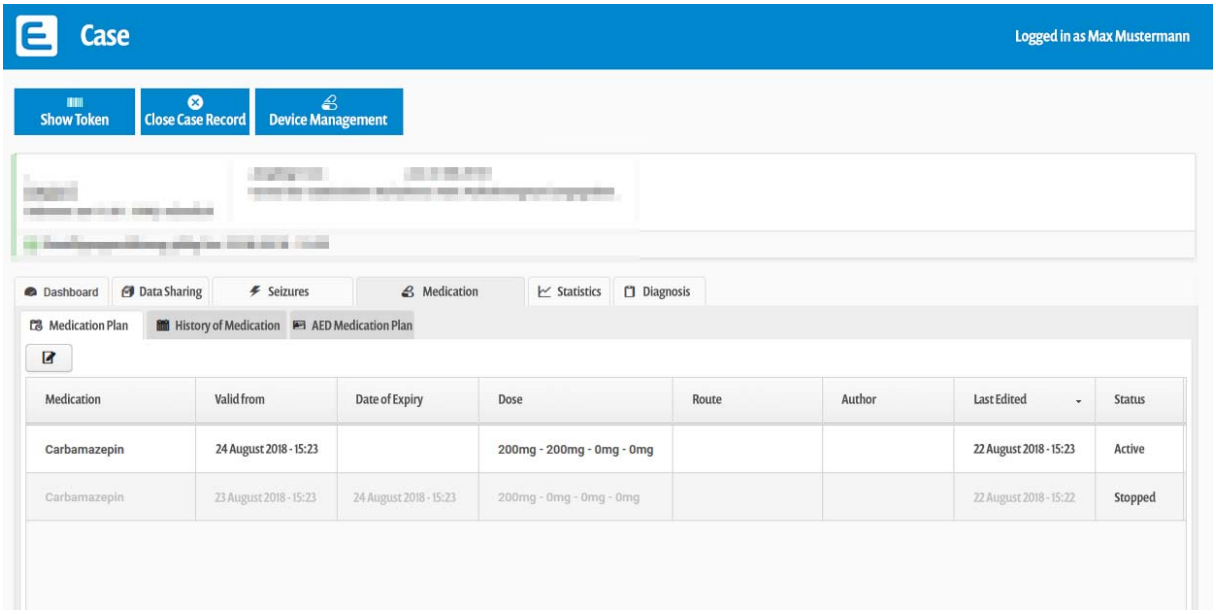

Figure 4. Web Portal.

5 User Study

5.1 Method

Forty patients in two different German epilepsy centers Department of Epileptology at the University Hospital Bonn and North German Epilepsy Center in Schwentinental-Raisdorf were offered the chance to use the mobile application and the web portal during their inpatient stay. They were provided mobile phones and laptops with wifi connection. The IT infrastructure was hosted online by a medical IT service provider.

The different functions of portal and app were demonstrated by trained personnel and additional information material was provided.

The patients had some time to familiarize themselves with the devices and used them independently for 24 hours up to several days. For identifying the usability, the acceptance and the user requirements they subsequently filled out questionnaires concerning demographic data (sex, age, education), prior use of a seizure diary, personal importance of seizure diary, subjective additional benefit of the app / portal compared to traditional paper diaries and if they would include the app or portal into their daily routine. Additionally, patients rated their interest in the different functions of app and portal on a likert scale from 1 (not at all interested) to 6 (very interested), and indicated preference for one or the other. The patients were also invited to give additional critical comments and recommendations for usability. In the case of pediatric patients, their parents or caregivers filled out the questionnaires.

5.2 Results

Twenty adult patients (aged 19 - 70, M=35.55, SD=12.06; 7 (35%) male) and 20 pediatric patients aged 2 - 17 (M=9.70, SD=4.23, 13 (65%) male) were offered the use of both devices. Due to technical difficulties concerning wifi or server connection, only 13 adults and 18 children were able to fully experience the mobile app and 9 adults and 12 children the online portal. Most of the participants (25 (62.5%)) indicated that they regularly use a seizure diary. Of those patients that were able to try out the mobile app, 29 (93.55%) indicated that they see additional benefit compared to analogue seizure diaries. 27 (87.1%) would incorporate it into their daily routine.

Table 3 summarizes the self-rated interest in different features of the mobile application and the web portal. Altogether, interest was quite high. Patients were most interested in a way to allow doctors remote access to their seizure diary and in the emergency management center. They showed least interest in the mood diary and vital parameter notifications. Open questions revealed some usability issues such as an easy way to edit or delete false input. Some patients preferred the “monthly” view of the seizure diary over weekly or daily, though it is impractical for a smaller screen (e.g. cell phones). Some parents were looking to track more health data apart from seizures, such as the height and weight of their children.

Function (mobile application)	interest [*M*(*SD*)] parents of paediatric patients (*n*<=20)	interest [*M*(*SD*)] adult patients (*n*<=20)	all patients (*N*<=40)
vital parameters	3.06 (1.70)	4.46 (1.61)	3.65 (1.78)
daily documentation AED	4.11 (1.97)	4.69 (1.44)	4.34 (1.77)
documentation medication change	4.94 (1.06)	4.69 (1.38)	4.84 (1.19)
documentation AED side effects	5.05 (1.18)	3.92 (1.73)	4.61 (1.50)

electronic seizure diary (simple)	5.11 (1.24)	4.77 (1.48)	4.97 (1.33)
electronic seizure diary (detailed)	4.79 (1.55)	4.54 (1.56)	4.69 (1.53)
seizure time course	5.16 (1.01)	4.62 (1.45)	4.94 (1.22)
mood diary	3.11 (1.70)	2.77 (1.24)	2.97 (1.51)
Function (web portal)			
data access center	4.53 (1.65)	4.69 (1.38)	4.59 (1.52)
emergency management center	4.72 (1.53)	5.38 (1.19)	5.00 (1.41)
AED medication plan	4.93 (1.22)	4.13 (1.13)	4.65 (1.23)
personal online seizure diary	4.69 (1.66)	3.89 (1.69)	4.40 (1.68)
Data exchange center for family	3.81 (1.91)	4.22 (1.99)	3.96 (1.90)
electronic communication with doctors	5.25 (1.34)	4.11 (1.90)	4.84 (1.62)
allow doctors access to seizure diary	5.41 (1.18)	4.56 (2.00)	5.12 (1.53)
allow doctors access to AED documentation	5.31 (1.19)	4.33 (1.87)	4.96 (1.51)
statistics module: correlation AED seizures	4.94 (1.39)	4.89 (1.36)	4.92 (1.35)

Table 3. Self-rated interest in the different features of the mobile application and the web portal (rating from 1=no interest at all, 6=very strong interest).

6 Discussion and Conclusion

Summary: In this paper, we presented two application areas in the context of epilepsy treatment that would benefit from the usage of health technologies (Section 2). Based on a detailed requirements analysis (Section 3), we presented the development of health technologies, which intends to support the secured exchange of medical data between all relevant actors and the automated seizure detection for documentation and emergency alarm (Section 4). Finally, we evaluated the health technologies with patients and relatives using surveys (Section 5).

Contributions and Limitations: Feasibility of an overall solution based on international standards could be demonstrated. The application communication between sensor, mobile application and electronic case record works seamlessly and standardized. Thereby, this enables secured communication between the medical institution and the patient and relatives. Due to missing IHE interfaces in the hospital information systems of the involved epilepsy centers, the project did not implement any integration into the clinical information systems. However, integration of our solution into the existing system landscape is possible provided the system manufacturer implements IHE interfaces. With the E-Health Act, which came into force on December 29th, 2015, there is a roadmap for a gradual introduction of a telematics infrastructure in the German healthcare sector. An extension of the existing

medical information systems to IHE interfaces is to be expected, since the telematics infrastructure is based on IHE (Hissel, 2019). Our HL7 FHIR-based Telemedical Infrastructure contributes to open and sustainable development. An integration was successfully demonstrated with the developed mobile application. Further mobile applications of other providers are conceivable if they implement the HL7 FHIR interfaces.

Due to the time scale of the study, only a limited number of patients were able to try out and evaluate the mobile application and even fewer the web portal. Additionally, the connectivity in the hospitals was sometimes erratic. Thus, the portal could not always be used, which led to a smaller than anticipated sample size. A sample bias due to self-selection cannot be excluded: The patients who tried both devices are more likely to be at least passingly interested in and able to use mobile technologies. Thus, the interpretability of the findings is limited.

However, the evaluation study demonstrates a strong interest in mobile technologies in medicine. Most participants would be willing to integrate the mobile application and / or the web portal into their daily routine. There are some interesting differences between adult patients and the parents of paediatric patients. While adult patients seem to see the mobile application as part of a health conscious modern lifestyle (e.g. they are interested in a display of sensor data such as step count and heart rate), parents might place more value in the aspect of easy online communication with their child's doctor or offering their children more autonomy without sacrificing security.

Conclusion and Outlook: The next step would be implementing both devices in an outpatient setting while receiving regular feedback on usability and functionality. This would make it possible to test functions that were disabled during the inpatient study: Alerting informal carers when the device detects a seizure and implementing a comprehensive plan for emergencies is impractical in a clinical setting but may be quite desirable for patients and their families in the future.

In case of extending the user study towards seizure detection and alerting our mobile technologies will become subject of the quality and documentation requirements of the Medical Devices Act (Gordon and Stern, 2019) and thus further development and clinical studies must be performed in accordance with the Medical Device Act. However, a close watch will have to be kept on the further development of seizure detection devices.

In addition, future research will address the integration of health technologies for epilepsy care into the existing system landscape and national telematics infrastructure in Germany.

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