

Migration of Telemedicine Applications to National Telematics Infrastructure using Epilepsy Treatment as an Example

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Abstract: Digitization in epilepsy treatment, which usually is an intersectoral effort, offers great potential. Aggregated healthcare information from different actors involved in the treatment process provides an important basis for therapy decisions. More and more telemedicine solutions for the treatment of patients with epilepsy focus in particular on patient involvement via a digital seizure diary. This is intended to replace the currently mostly paper-based diaries. However, there is no widespread use in practice. The introduction of the national telematics infrastructure (TI) offers the opportunity to make telemedical applications accessible to a larger group of patients and medical institutions in Germany. The E-Health Act, which came into force on December 29, 2015, defines a roadmap for the gradual introduction of a telematics infrastructure in the German healthcare system. In addition to the specified TI components for secure and standardized data exchange, health IT service providers can migrate their existing digital solutions for healthcare in the TI. This article describes the migration of a developed telemedical infrastructure for epilepsy care into the national telematics infrastructure. First, an analysis of the telemedicine infrastructure is made with regard to supported integration options. Then, considering the chosen approach, an integration concept is designed using an example scenario.


1 INTRODUCTION

Epilepsy is considered a complex chronic disorder that is highly prevalent worldwide (Beghi, 2020) and requires treatment by multiple healthcare providers (Bast et al., 2017). In addition, patient self-management and family involvement can be critical to identify and optimize an appropriate diagnosis and treatment (Kobau and DiIorio, 2003). Telemedicine can support the coordination of epilepsy care among stakeholders by using communication and information technologies in order to share relevant data for diagnosis and treatment. A major leap in the development of telemedicine solutions for epilepsy patients was triggered by the Corona pandemic (Power et al., 2020; Cross et al., 2021; Datta et al., 2021; Banks et al., 2021). Previously, there were few studies describing the use of telemedicine health technologies in epilepsy care, mainly with the aim of providing consistent care in rural and geographically isolated areas (Ahmed et al., 2008; Rasmusson and Hartshorn,

2005; Haddad et al., 2015; Lua and Neni, 2013). Most of them cite benefits in terms of patient satisfaction and lower treatment costs. Although improving the quality and performance of care through integrated and comprehensive data collection as a basis for therapeutic interventions is obvious, health technologies for cross-sector communication with electronic health records are not consistently used in epilepsy care. Recent studies also emphasize that the implementation of a solution is not sufficient, but its integration into existing processes and systems is essential to achieve adoption by clinicians. Integrating epilepsy self-management applications into the treatment process can also create benefits. Typically, these applications include modules such as seizure diaries, medication adherence protocols, medication reminders, medication allergy diaries, and support in emergency situations (Alzamanan et al., 2021; Escoffery et al., 2018; Liu et al., 2016; Ranganathan et al., 2015). Page et al. (2018) criticizes that the information collected by self-management applications cannot be transferred easily to the clinical system and must be recorded in a redundant and time-consuming manner. In contrast to this, he positively

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highlights that a health record co-authored by the patient has the potential to reduce effort. Technologies for seamless data integration increase the acceptance of such solutions. Changing existing ways of collaboration supported by new technologies is challenging, and the management of separated electronic health records consumes additional effort if they are not integrated in the medical process and existing technology (Page et al., 2018). Project MOND, funded by the Ministry of Health, aims to integrate a developed telemedicine infrastructure for epilepsy treatment into the existing system infrastructure. This includes an epilepsy self-management application, a web portal for patient (and family) communication with physicians, and solutions for physician-to-physician communication based on international standards (Houta et al., 2020). Standardized integration into existing system landscapes has not yet been implemented and are subject of this paper.

In this paper we contribute integration approaches for telemedicine infrastructures into existing system landscapes. We use the national telematics infrastructure (TI), which has created the prerequisites for a nationwide exchange of medical data (Jorzic and Sarangi, 2020). In the Background section, this article first describes our telemedical solution to be integrated. Then, in the same chapter, Digital Health Applications and the TI, which are both regulated by law, are presented. Afterwards, the applied methods are explained in detail. In the Results section, decisions on the classification of our solution as well as different integration settings are presented using an epilepsy reference scenario as an example. This is followed by a discussion of the different integration approaches. The paper concludes with a summary and an outlook on the next steps.

2 BACKGROUND

2.1 Telemedical Infrastructure for Epilepsy Treatment with Electronic Case Record Integration

In a project funded by the German Federal Ministry of Education and Research, hospitals, technical partners, scientists as well as patients and relatives have jointly designed a telemedical infrastructure for epilepsy care with Electronic Case Record integration (TEPI). The components of TEPI (Figure 1) are described in more detail in the following sections.

2.1.1 Sensor-based Mobile Application

The sensor-based mobile application is a daily companion for the patient. The patient can record data (e.g., seizures, side effects, medication use, and mood) and share it with their therapists and family members via secure sharing mechanisms. In addition, the patient can receive data from their therapists. If a shared structured medication schedule is available, it can be used in the patient application as a basis for medication reminders. The mobile application is connected to a sensor that measures vital signs and events (e.g., seizure events). It uses the security and data exchange services of the telemedicine infrastructure to securely edit, store and share data. The developed mobile application is currently being restructured according to the guidelines of a Digital Health Application (BfArM, 2020).

2.1.2 Web Portal

Depending on the user role, the web portal either integrates just the services of the telemedicine infrastructure (e.g., if the user is a patient or informal caregiver), or the services of the ECR infrastructure (e.g., if the user is a physician) in addition. The portal provides authenticated physicians with a view of all epilepsy case records from their medical institution that are stored in the ECR infrastructure. The case records are created after the patient has provided a valid consent. Physicians can store various medical information relevant to intersectoral epilepsy care within the ECR and share it with other medical institutions involved in the treatment, provided they are also authorized by the patient to access the ECR. The portal allows storage of both unstructured information such as physician letters in PDF format and structured data such as the structured medication plan based on the FHIR format. Physicians can share medical information (e.g., medication plan) with the patient, and they can see if new data has been received from the patient (e.g., seizure documentation) and store that data in their own medical data management system. The web portal can also be used by patients and informal caregivers (e.g., parents) with the telemedicine infrastructure.

2.1.3 FHIR-based Telemedical Infrastructure

The patient as well as relatives are connected via the telemedicine infrastructure. The implementation is based on the lightweight HL7 FHIR standard, as the focus is on the connection of mobile devices as well as the transmission of structured data collected via the

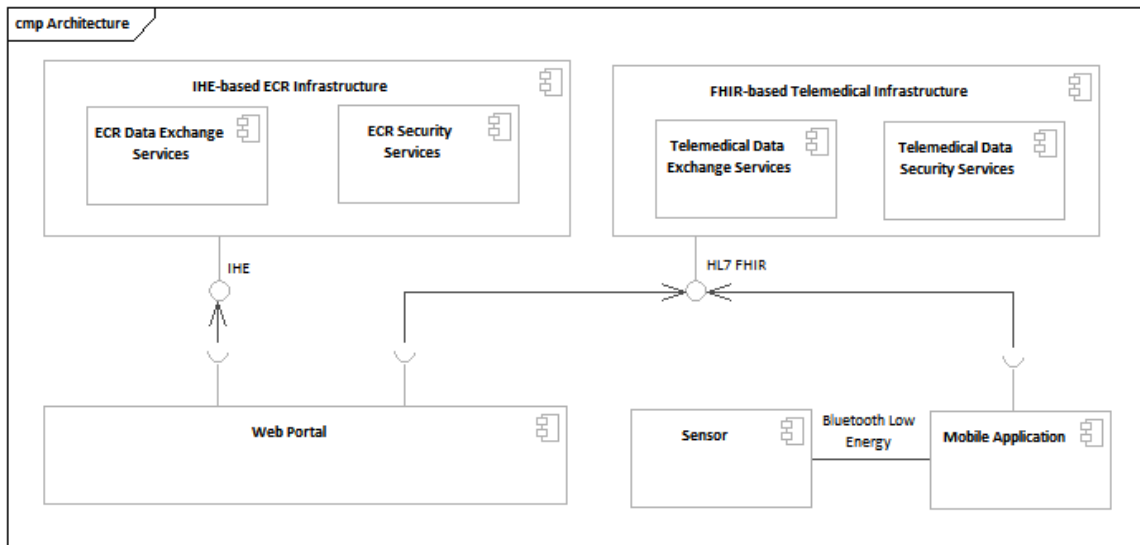


Figure 1: Telemedical Infrastructure for Epilepsy Treatment.

app or transmitted by the sensor. The telemedicine infrastructure includes both data exchange and security services. Security mechanisms ensure that authenticated patients can give selected healthcare providers access to therapy-relevant data. Access is possible both via the mobile application and the web portal. Authenticated and authorized healthcare providers can use the web portal to retrieve patient data or share data with the patient.

2.1.4 IHE-based ECR Infrastructure

For the exchange between medical stakeholders involved in the treatment we use the Electronic Case Record (ECR). The ECR was developed in Germany to support communication between physicians involved in a treatment case (Kuhlisch et al., 2012). It targets the treatment of diseases involving multiple physicians and focuses in particular on "long-term patients" with severe or chronic diseases, whose treatment progress needs to be tracked and regularly coordinated by multiple stakeholders. The architecture of the ECR is based on Integrating the Healthcare Enterprises (IHE) profiles and takes into account national privacy and data security requirements. Case records are tied to a diagnosis or purpose and thus are not non-specific data collections. The ECR is "physician-led," meaning it is authored and controlled by physicians, and thus, unlike patient-managed records, provides a reliable basis for treatment decisions. The ECR infrastructure includes data exchange and security services. In order to involve non-medical actors in the data exchange, the ECR Infrastructure can be connected with the telemedical services (Deiters and Houta, 2015).

2.2 Digital Health Applications

Digital health applications (DiGA) are medical devices of risk class I and IIa according to the Medical Device Regulation (MDR). Physicians and physiotherapists can prescribe DiGAs for health insurance benefits as a part of a therapy since the Digital Health Care Act (DVG) came into force on December 19, 2019. Patients and physicians are the target users of the developed DiGA. Thus, physicians will receive additional remuneration if additional services become necessary with the use of the DiGA. For a DiGA to be prescribed, it must be listed in the so-called DiGA directory. Manufacturers must provide scientific evidence of a positive supply effect of the application. After inclusion in the DiGA directory, the medical reimbursement system is adjusted with the medical services required in connection with the DiGA. In addition to demonstrating a positive care effect, manufacturers of DiGAs must meet requirements including security and functional suitability, conformity with the General Data Protection Regulation, user-friendliness, and compatibility commitments regarding support for standards and the telematics infrastructure. (BfArM, 2020)

2.3 National Telematics Infrastructure in Germany

According to § 291a (7) (2) SGB V, the company Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH (gematik) creates an interoperable and compatible TI and coordinates its operation. The TI is a closed network that can only be used by reg-

istered users with special ID cards and connectors or access gateways (Figure 2). It connects stakeholders in the field of health (e.g. doctors, hospitals, pharmacies, patients) and ensures the cross-system and secure exchange of information (Jorzig and Sarangi, 2020). The complete specification is available on the gematik portal. The rough architecture is described below.

2.3.1 Consumer Zone

The Consumer Zone is located in healthcare organizations and consists of information systems and their interaction logic. TI applications can be integrated via client modules (e.g., medication add on) into existing systems.

2.3.2 TI Core - Decentralized and Central Zone

The core of the TI infrastructure is comprised of the decentralized zone and the central zone. The components of the decentralized zone include all TI components that are set up and installed in a healthcare organization to enable the secured use of the TI. These are, for example, smart cards, card terminals and the connectors. Smartcards are issued to individuals or healthcare organizations and aim to ensure secure data exchange through authentication and encryption. Specific e-Health Card terminals for use with the TI can be connected to the TI connector. Each time a connection between an e-Health card terminal and a connector is established, the terminals must authenticate themselves to the connector. Access to a patient's medical data located in the Provider Zone of the TI is only possible via a two-factor authentication process. Both the physician and the patient must authenticate themselves with their smartcard using the card terminals. The connector then represents a gateway to the TI network with security features such as a firewall and VPN connections. It enables information systems of the healthcare organizations to securely access smart cards and the e-Health card terminal. The TI connector also ensures that systems in the medical organisations are protected against attacks originating from the TI network. The central zone hosts central services of the TI that are essential for communication and data exchange. These include, among others, the OSCP responder and the configuration services as well as a healthcare directory service.

2.3.3 Provider Zone

The Provider Zone is directly connected to the Central Zone and includes all TI applications. Applications of the TI are standardized solutions that ad-

dress central and modular use cases in healthcare. The goal of this approach is to create uniform implementations of these use cases in the health IT landscape and thus to facilitate and support development of added value and interoperability. The TI defines the following applications: Electronic Prescription, Electronic Patient Record (ePA), KIM - Communication in Medicine, Electronic Medication Plan, Emergency Data Management, Qualified Electronic Signature, Management of Patient Data and TI Messenger. All TI applications must comply with the specifications of the TI platform to ensure secure and standardized operation. Applications are accessed via client modules that are part of the Consumer Zone.

The core application of the TI is the ePA, which supports data exchange between the patient and the healthcare provider, but also data exchange between several healthcare providers. The patient can use the ePA via an access gateway of the ePA front end, which is provided by the patient's health insurance company. Healthcare providers can access the ePA via the TI connector, but must be authorized to access data by the patient using an identification card. The connector establishes the secure and standardized exchange of systems in medical organisations with the ePA system in the TI. A new draft law from the German Federal Ministry of Health stipulates that patients should be able to send data from DiGAs to the ePA and vice versa from April 2023 (Ärzteblatt, 2021). Prerequisites for this are created with the ongoing specification of HL7 FHIR-based medical information objects (MIO) (Weber and Heitmann, 2021).

2.3.4 Existing Application Zone

gematik intends to ensure the use of the telematics infrastructure for other applications of the healthcare system as well as health research in accordance with § 291a (7) sentence 3 SGB V. For this purpose, gematik sets the conditions for the use of TI by other applications to be met by providers, as well as the details of the confirmation process as well as the necessary test criteria. These "other applications" ("Weitere Anwendungen für den Datenaustausch in der TI", WANDA) are distinguished into the WANDA Basic and WANDA Smart applications. WANDA Smart addresses other health care applications which are embedded in the Provider Zone of the TI. These applications have access to TI services. WANDA Basic are other health care applications without access to services of the TI in connected healthcare networks. The difference between these application types is the degree of integration into the TI. The deeper the integration, the more complex the approval process. After a successful approval, an application is listed in the

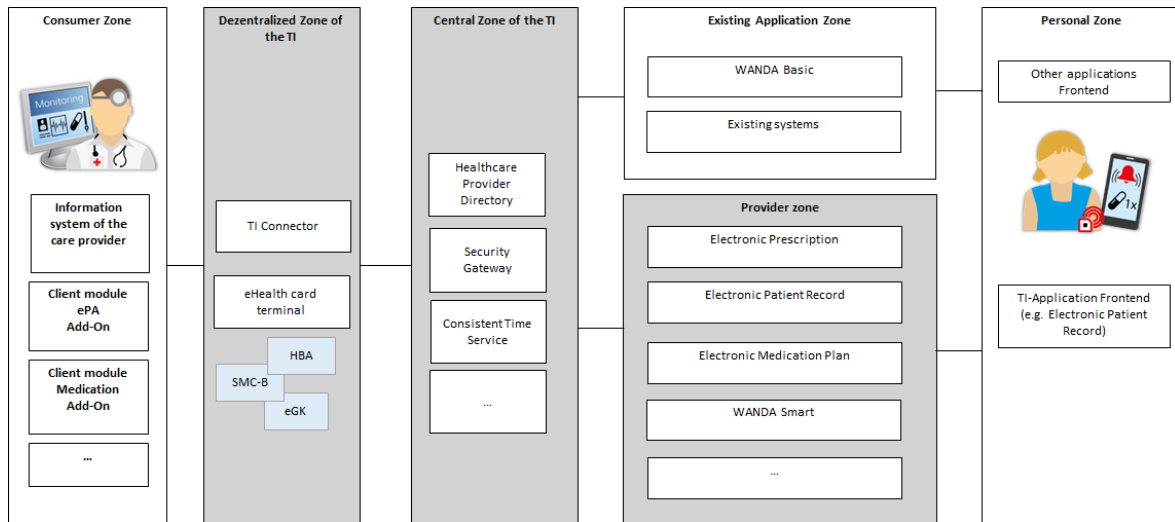


Figure 2: German National Telematics Infrastructure.

interoperability directory vesta (Grode and Lückhof, 2021).

2.3.5 Personal Zone

The patient’s applications are located in the personal zone and are also under the patient’s control there. Access to the TI (e.g. via the ePA front end) is secured via access gateways.

3 METHOD

With the analysis of the legally regulated DiGAs and TI, we were able to identify basically two integration paths for TEPI.

- Integration as a WANDA
- Integration via the ePA

To conceptualize the integration as a WANDA, we first applied gematik’s criteria to TEPI to determine which type of application best represented our application. Subsequently, based on the medical guideline for epilepsy (Bast et al., 2017), we formulated an example scenario describing different sections in the treatment process in different participating institutions and considering patient involvement via an epilepsy self-management application. Along the scenario, we have outlined a hybrid integration design considering integration as a WANDA and integration via the ePA.

4 RESULTS

4.1 Classification

Since we develop and operate several telemedical applications with ECR integration that we intend to migrate to the TI, we are pursuing the integration of an Existing Application Zone in the TI. For the use case we are developing, using TI services does not add significant value to interoperability. For example, the TI directory service does not map all the groups of people that should have access to the epilepsy data in our use case, and therefore cannot be used. Thus, our integration strategy follows the WANDA Basic approach.

4.2 Integration Settings

With the approval as WANDA Basic, the TEPI remains in its own network, but is accessible via the TI for other TI users. Moreover, linking the ePA with our Mobile Application, which is intended to be approved as a DiGA, enables the exchange of structured data, such as seizure documentation via the ePA. Thus, several integration settings are conceivable, which are outlined in Figure 3 and discussed below.

4.2.1 WANDA Basic - Loose Integration

This integration solution uses the TEPI, which is integrated in the TI as WANDA, for data exchange in the context of epilepsy treatment. All TI users have the option of using the TEPI applications, provided this is defined organizationally. In this solution, only the web portal and the mobile app are used for the

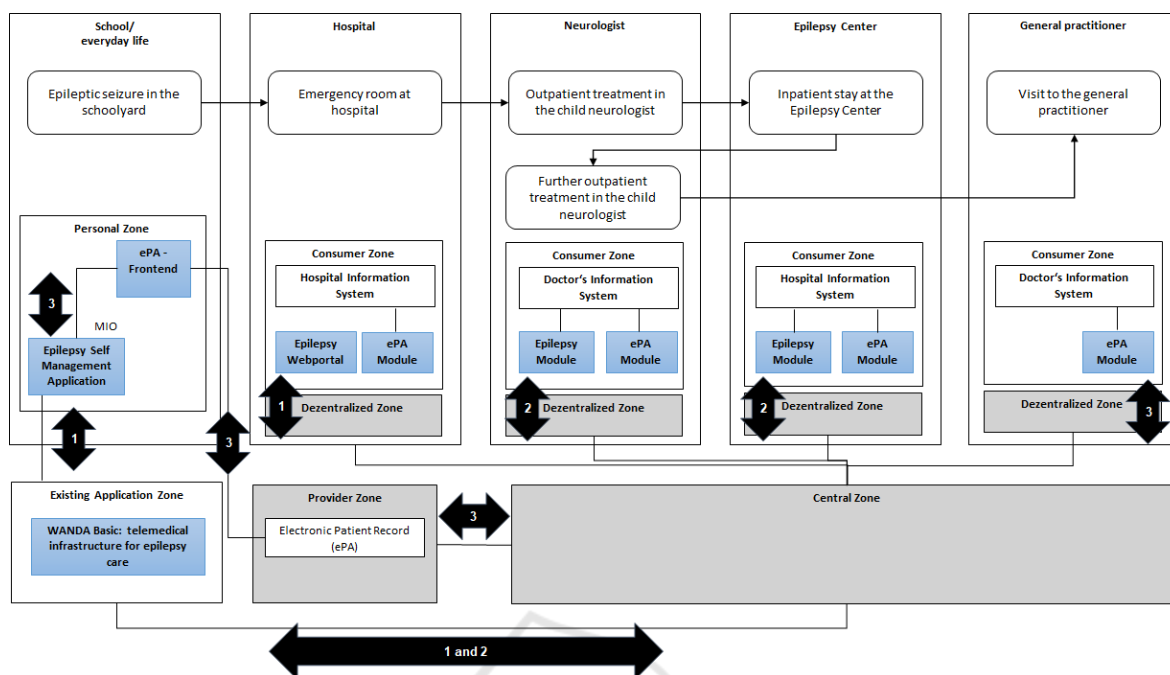


Figure 3: Integration Settings in Epilepsy Treatment. 1: WANDA - loose integration; 2: WANDA - deep integration; 3: DiGA-ePA integration.

exchange via TEPI. This enables cross-institutional secure exchange between care providers involved in treatment and between care providers and patients via the TI for all TI users. However, requirements for seamless communication without media disruptions are not met. Data must be recorded redundantly and time-consumingly by the service providers in order to get from the TEPI to the existing systems or vice versa, since there is no integration in the existing system landscape in this setting.

4.2.2 WANDA Basic - Deep Integration

In this setting, a greater depth of integration is sought. Since TEPI is based on IHE and ECR, systems supporting these standards can easily be extended with client functionalities for importing or exporting data. For example, seizure documentation from TEPI can be displayed via a hospital information system and transferred to the local patient record after validation by healthcare providers. Similarly, data originating from hospital information systems can be shared with additional healthcare providers or the patient. In addition to the interfaces for sending data, security functions (e.g., authentication to TEPI) must be considered in the primary systems separately, since the authentication services of the TI are not used for TEPI.

4.2.3 WANDA Basic - DiGA-ePA Integration

In this setting, the mobile application (DiGA) is integrated via the ePA. The patient sends data (MIOs) from his DiGA to his ePA and authorizes relevant healthcare providers for access via the ePA front end (Figure 4). Authorized physicians can view and use the patient’s data via the ePA module in the medical facility. The implementation of integrating DiGAs and ePAs is still in its early stages, but promises to be far-reaching as data from the DiGA reaches physicians who do not (want to) use other systems besides the ePA to exchange data with other physicians or patients.

4.2.4 Discussion

This paper discussed the importance of integrating existing telemedicine solutions into the existing system landscape in medical facilities. The basis for integration is the legally required TI. The integration approaches described are not mutually exclusive, but represent approaches that can be operated in parallel. While the loose integration of WANDA can be deployed quickly with little effort and adaptation of existing systems, the other integration settings involve greater implementation effort. This The additional effort is beneficial, since a deeper integration of patient co-authored data supports the medical and organizational process by avoiding redundant documenta-

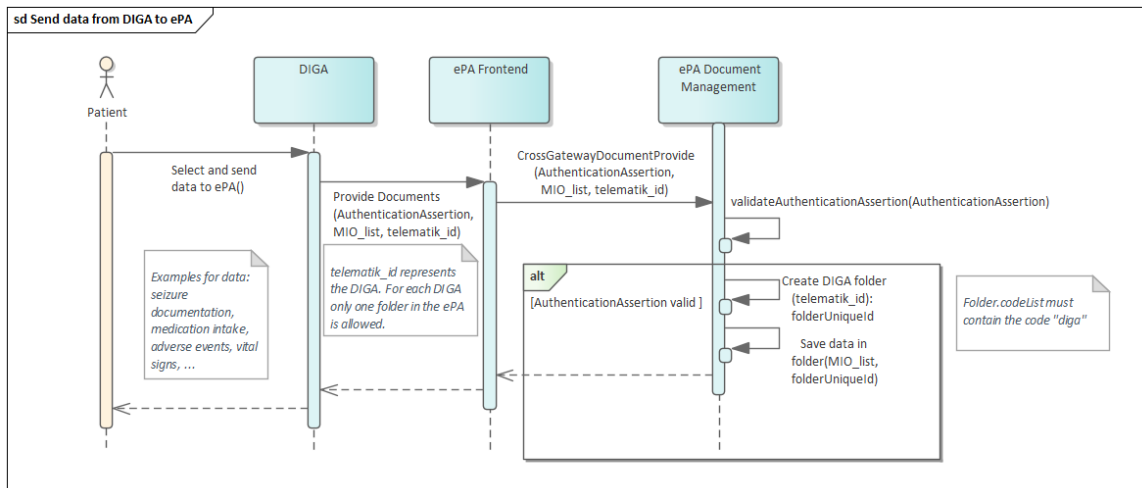


Figure 4: Sequence Diagram Send Data from DIGA to ePA.

tion. For a short time-to-market, it is advisable to start with loose integration and, if the system manufacturers are willing to implement appropriate interfaces, to replace the loose integration with deep integration.

We decided to take a hybrid approach, as both ePA and ECR-based solutions like TEPI have different goals. While ePA pursues a digital aggregation of all patient data from different medical facilities and is patient-driven, ECR addresses case-related communication between service providers and is controlled by them. Thus, TEPI can be used as a WANDA in the narrow treatment concept of epilepsy and can be specifically used and coordinated by physicians involved in the treatment of epilepsy. Nevertheless, there are information objects that are also relevant in other treatment contexts (e.g., medications). Here, the integration to the ePA offers a possibility to exchange them across treatment cases.

A restriction with regard to the integration of all actors in our use case via the TI still exists due to the restriction of the possibility of also connecting informal caregivers to the TI. Therefore, an informal caregiver can only be integrated into the data exchange via the patient as an intermediary.

5 CONCLUSION

Our goal in this paper was to present a concept for integrating a telemedicine infrastructure with the TI. A detailed analysis of the types of systems (DiGA) or infrastructures (TI) in healthcare driven by law was our starting point. Using an example scenario, we developed and discussed integration settings for TEPI. There is no solution that can be applied to all medical facilities. Here, depending on the willingness of sys-

tem vendors to adapt their systems as well as on the treatment context, it has to be decided which integration setting is suitable in a medical organization.

We are currently working on a regulatory roadmap for the introduction of the developed system solutions into the healthcare market. A prerequisite for the operationalization of our solution is the successful completion of the confirmation procedure, taking into account the gematik approval criteria, as well as the approval of the mobile application as a DiGA. A complete implementation of our integration approach is not yet possible, as concepts for the integration of DiGA and ePA still have to be awaited. Here, we want to get involved in the development of MIOs to harmonize epilepsy data nationwide. Another important step is to approach the manufacturers of the systems of the participating hospitals in order to prepare a deep integration into their systems. Ideally, this should also be based on already established user-centered concepts of process support in epilepsy treatment by technical systems in order to promote acceptance by users.

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