

With a Little Help from My Conversational Agent: Towards a Voice Assistant for Improved Patient Compliance and Medication Therapy Safety

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Abstract: The chronically ill and the elderly often need to take several drugs, which increases the complexity of medication management. This frequently results in a decrease in patient compliance and raises the risks of their drug therapy. To support patients in medication management, we developed a multimodal assistant that includes a conversational agent supplied with data from a database managed by healthcare professionals via a web service. The developed artifact analyzes medication plans, identifies adverse drug reactions and side effects, and reminds patients to take their medication correctly and on time. Applying the design science research paradigm, we systematically identified 16 issues, derived eight meta-requirements, and elaborated three design principles. Based on this, the artifact was implemented and evaluated by three experienced pharmacists, who highlighted the usefulness of the solution and provided feedback for further improvements. Finally, we present an evaluation concept for potential users and discuss the implications of the medication assistant. Overall, the medical assistant comprises valuable functionalities to support patients, and it increases medication therapy safety and patients' compliance.

1 INTRODUCTION

Given global demographic change, the share of the elderly is increasing worldwide. Senior citizens are much more likely to suffer from chronic or multiple diseases and rely on several medications simultaneously (Peters et al. 2010). With high quantities of drugs, the complexity of medication management rises, thereby increasing the risk of medication errors and patient non-compliance (Schäfer 2011; Vrijens et al. 2008). Taking the wrong medication, an incorrect dosage, or a combination of several drugs can lead to dangerous adverse drug reactions (ADRs) (Reimers and Klein 2015). An ADR is a “response to a medicinal product which is noxious and unintended” (EMA 2017, p. 8), causing severe side effects and even leading to 25,000 annual deaths in Germany (Dormann et al. 2017). In addition

to ADR-induced medical implications, economic consequences are mirrored in the costs of ADR-related hospital admissions, which are estimated for only Germany at around 434 million euros per year (Rottenkolber et al. 2011), excluding the associated indirect costs (Stark, John, and Leidl 2011).

Yet, most ADRs are considered avoidable (Schurig et al. 2018), particularly with patients' adhering to their prescribed medication plans (Tafreshi et al. 1999). In many cases, patients do not take their drugs because they forget to take them (Kim et al. 2018), they fear side or adverse effects (Flávio Ferreira et al. 2014; W. T. Hsieh et al. 2018; Teixeira et al. 2017), or they are ignorant to the benefits of the medication (Flávio Ferreira et al. 2014; Sebillo et al. 2017; Teixeira et al. 2017). Therefore, to achieve effective patient compliance, the provision of information on drugs and their medication is of central importance (Grube, Dehling, and Sunyaev

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2017). In this context, eHealth technologies can support patients to comply with their therapy (Mertens et al. 2015; Sedlmayr 2018). In particular, conversational agents (CAs) offer promising potential for improving medication self-management and reducing intake errors (EmmaHome 2020; Flavio Ferreira et al. 2013; Jesús-Azabal et al. 2020; Teixeira et al. 2017). A CA in the healthcare domain is an “artificial intelligence program that can conduct an intelligent conversation via auditory or textual methods regarding healthcare issues” (Wang and Siau 2018, p. 1). The use of CAs for medication management can allow for avoiding medication errors by providing the necessary information in a more natural human-computer interaction, thus improving the usability and accessibility, especially for the elderly who have less technological know-how (Teixeira et al. 2017). However, available solutions often offer only reminder functions without providing comprehensive information about the medication (EmmaHome 2020; Jesús-Azabal et al. 2020). Moreover, the functionalities often primarily utilize information that is based on data managed by the patient (MyTherapy 2020; Sebillo et al. 2017; Silva et al. 2013). Thus, most CAs reflect the error-prone input of the patient, without any monitoring by healthcare professionals who can assure data quality and the safety of drug therapy. Drawing on these shortcomings in assuring the safety of drug therapy for patients, we pose the following research question:

RQ: *How Can CAs Be Designed and Implemented to Increase Medication Therapy Safety for Patients?*

To answer this research question, we design and implement a multimodal assistant comprising a CA to increase medication therapy safety by allowing a patient to use voice commands to inquire about the side effects or reactions of their medication. The system is complemented by a web portal for healthcare professionals which receives input from a central pharmacy data service and allows for the management of patients’ medication plans. Driven by the design science paradigm (DSR) (Gregor and Hevner 2013), we structure the remainder of this paper as follows: We introduce our DSR multistep research approach and the applied methods for the development and evaluation of the application in Section 2. Then, outlining the theoretical background, we summarize the related work and derive issues for medication assistants in Section 3. Based on the identified issues, we derive meta-requirements and elaborate design principles in Section 4. The subsequent Sections 5 is devoted to describing the designed and developed artifact and the evaluation concept. Finally, the paper concludes by discussing

the implications for research and practice, presenting the limitations, and providing an outlook for future research.

2 RESEARCH APPROACH

The design, development, and evaluation of the artifact in response to our research question follows the design science research (DSR) methodology by Peffers et al. (2007). DSR aims to address important real-world problems that remain unsolved or require further investigation via a technological artifact (Hevner et al. 2004). In this paper, we address the issues of the current available solutions for medication management to increase patient compliance and medication therapy safety by developing a multimodal assistant comprising a CA and a web service that handles patient queries by accessing a managed medical database. The process, in pursuit of realizing the solution, involves the identification of an observed problem, followed by the design, implementation, and evaluation of the artifact (cf. Figure 1) (Peffers et al. 2007).

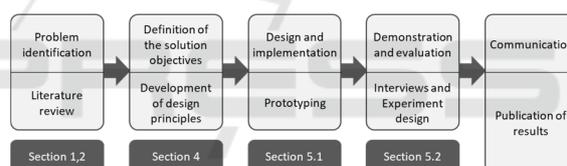


Figure 1: DSR Approach of this Study (Peffers et al. 2007).

As a starting point for problem identification, we conducted a systematic literature analysis (vom Brocke et al. 2009). We queried titles, abstracts, and keywords in the interdisciplinary databases SpringerLink, ScienceDirect, AISel, IEEE Xplore, Emerald insight, JSTOR, and EBSCOhost using the search string (“requirements” OR “design principles” OR “Anforderungen”) AND (“medication assistant” OR “health assistant” OR “medical agent” OR “Gesundheitsassistent” OR “Medikationsassistent”). Ever since Apple introduced the voice assistant Siri in 2011, the research and general interest in CAs have increased significantly (Luger and Sellen 2016); hence, we included papers from 2011 onward and filtered for the languages English and German. The resulting 621 publications were analyzed based on the following inclusion and exclusion criteria: We considered any theoretical and practical work involving medication assistants or their development and excluded studies that have a broader research focus in the eHealth field without focusing on drug

management. After applying the inclusion and exclusion criteria, the remaining eight studies served for a forward and backward search that yielded another nine studies, resulting in a literature corpus of 17 studies. An analysis of the literature yielded the identification of 16 issues (Is), from which we derived nine meta-requirements (MRs) for the solution, which we finally combined into three design principles (DPs). Based on the systematically derived DPs, we developed a multimodal system consisting of three sub-systems, as presented in Section 5. Finally, we evaluated the artifact by interviewing three experienced pharmacists regarding their assessment of its usefulness and their evaluation of areas for improvement of the artifact (Myers and Newman 2007). We analyzed the interviews according to Mayring (2010), and incorporated the experts' suggestions for improvements in order to prepare the CA for the next evaluation cycle with patients, which will be presented as an experimental design.

3 THEORETICAL BACKGROUND

3.1 Complexity of Patient Compliance and Medication Therapy Management

In Germany alone, more than 100,000 approved medications exist, which may contain a variety of ingredients (ABDA 2019). Nearly half of these medications are available only by prescription (Rx). In contrast, over-the-counter medications (OTC) are available to every customer without restriction. Approximately 23% of German citizens take more than three medications simultaneously (ABDA 2019). This can lead to a high risk of ADRs, especially if patients are treated by several healthcare professionals without a central medication plan (Reimers and Klein 2015), thus necessitating that the patients notify the treating physician of their medications themselves. Patients might forget to mention medications, assume they are not relevant, or deliberately withhold information out of shame.

In addition to the high risks of polymedication, many patients must change their way of life due to their drugs. The challenge of integrating their medication intake into a daily routine poses a barrier for many people causing them to forget or even refuse the medication. This results in a reduction in patient compliance, which “[...] describes the extent to which a person's behavior (in terms of taking medications,

following diets or executing lifestyle changes) coincides with medical or health advice” (Haynes 1979). The concept of compliance has evolved from a directive model (obedience to therapy) to a passive model (loyalty to therapy) and from an active model (cooperation in therapy) to an interactive model, in which the patient participates in the treatment and cooperates with the doctor as a means of empowerment (Schäfer 2011). Patients can be divided into three categories when assessing compliance: If patients follow at least 80% of their therapy guidelines, they are described as “compliant” (Schäfer 2011). A compliance level between 20% and 80% categorizes a patient as “partially compliant.” It can be assumed that this patient group can best be persuaded to adhere to therapy measures. Compliance levels below the threshold of 20% are called “non-compliant.” Non-compliance may be intentional (e.g., due to religious reasons, exaggerated fears, general distrust of medicine, reservations about side effects, or convenience), or it can occur unintentionally by accidentally choosing the wrong dosage or changing the duration or frequency (Petermann and Mühlig 1998).

3.2 Issues for Medication Assistant Application

Based on the literature review described in Section 2, we derived issues of and requirements for medication assistant applications. Of the 17 identified studies, we found eight papers that focus specifically on applications developed for seniors, while nine papers present solutions engineered for patients in general. The user interfaces of the identified applications include either CAs, web interfaces, specific hardware components, or a mixture of multiple components. We identified 16 issues to be addressed using our medical assistant. First, patients are often confronted with an information overload (**I1**) (e.g., in form of endless information from leaflets), which renders it difficult to find relevant information regarding the proper medication intake (Dehling and Sunyaev 2013; Tiwari et al. 2011). On the other hand, medication errors can occur due to missing information (**I2**) (e.g., concerning the medication storage) (Flávio Ferreira et al. 2014; Mira et al. 2014; Sebillo et al. 2017; Teixeira et al. 2017). Regardless of the information quantity, a language that is too complex or contains technical terminology (**I3**) can cause misinterpretations (Chang et al. 2019; Dehling and Sunyaev 2013; Farhadyar and Safdari 2018; Flavio Ferreira et al. 2013; Flávio Ferreira et al. 2014; Jesús-Azabal et al. 2020; Kim et al. 2018; Teixeira et

al. 2017). This can then lead to situations in which the identification of medications is based on appearance or storage rather than the technical product name. A too-small illustration of information **(I4)** causes comparable problems (Chang et al. 2019; Dehling and Sunyaev 2013; Farhadyar and Safdari 2018; Flavio Ferreira et al. 2013; Flávio Ferreira et al. 2014; Silva et al. 2013; Teixeira et al. 2017; Tiwari et al. 2011). Numerous studies indicate that medical assistants are generally too complex to use **(I5)** (Flávio Ferreira et al. 2014; P. J. Hsieh 2016; Tiwari et al. 2011). In particular, a complex initial set-up or a required adjustment of the medication plan can reduce acceptance among users (Sebillo et al. 2017). Additional issues arise in the registration of medications **(I6)** (Dayer et al. 2013; Flavio Ferreira et al. 2013; Flávio Ferreira et al. 2014; W. T. Hsieh et al. 2018; Sebillo et al. 2017; Silva et al. 2013; Teixeira et al. 2017). The manual integration of information can produce mistakes and might be perceived by the patient as requiring too much effort (Dayer et al. 2013; Silva et al. 2013). A prerequisite for acceptance and thus an efficient application is for patients to trust the CA without worrying about misinformation **(I7)** (Flavio Ferreira et al. 2013; Flávio Ferreira et al. 2014; Sneha and Varshney 2012; Teixeira et al. 2017; Tiwari et al. 2011). In this context, data security concerns **(I8)** may hinder such acceptance (Dehling and Sunyaev 2013; Kim et al. 2018; Santo et al. 2016; Sneha and Varshney 2012). In addition, many patients suffer from unintended drug interactions due to polymedications **(I9)**, which can lead to serious health problems and avoidable hospital admissions (Dayer et al. 2013; Dehling and Sunyaev 2013; W. T. Hsieh et al. 2018; Kim et al. 2018; Mira et al. 2014; Silva et al. 2013). Further health problems can occur due to side effects **(I10)** (Dehling and Sunyaev 2013; Farhadyar and Safdari 2018; Flávio Ferreira et al. 2014; W. T. Hsieh et al. 2018; Teixeira et al. 2017; Tiwari et al. 2011). Moreover, uncertainty of patients often results in a false dosage of medications **(I11)** (Chang et al. 2019; Dayer et al. 2013; Farhadyar and Safdari 2018; Mira et al. 2014; Sebillo et al. 2017; Silva et al. 2013; Sneha and Varshney 2012; Tang et al. 2011; Teixeira et al. 2017). This could be addressed by increasing the transparency and traceability of doctors' visits **(I12)** (Chang et al. 2019; Dayer et al. 2013). Fourteen papers mention problems related to polymedications **(I13)**, and 16 of the 17 relevant papers identified that patients forget or deny medication intake **(I14)**. Chronic patients often require long-term medication **(I15)** (Chang et al. 2019; W. T. Hsieh et al. 2018; Jesús-Azabal et al. 2020; Mira et al. 2014; Santo et al.

2016; Sneha and Varshney 2012; Teixeira et al. 2017; Tiwari et al. 2011) which requires strong discipline and well-organized medication management **(I16)** (Chang et al. 2019; Dayer et al. 2013; Farhadyar and Safdari 2018; Kim et al. 2018; Santo et al. 2016; Sebillo et al. 2017; Tiwari et al. 2011).

Existing applications focusing on the safety of drug therapy include *hanahealth*, *Mytherapy*, *Emma Home*, and *mediteo* (EmmaHome 2020; hana health 2019; Mediteo 2020; MyTherapy 2020). Applications such as SapoMed and Sedato, for the elderly and rural areas, have been highlighted in the scientific literature (Flavio Ferreira et al. 2013; Jesús-Azabal et al. 2020; Sebillo et al. 2017; Silva et al. 2013). However, to the best of our knowledge, the existing solutions focus on specific target groups or offer rather limited functionalities for patient safety and compliance, such as medication reminders. This study aims to create an age-independent assistant for the management of multiple medications, which considers side effects, ADRs, and medication reminders and enables a combination of medication data with continuously measured vital signs. Our artifact represents an enhancement of the FeelFit platform (Meier et al. 2019). FeelFit aggregates measured vital parameters of several devices (e.g., weight, pulse, and blood pressure) and visualizes the medical record for the patient, authorized physicians, and pharmacists.

4 DESIGN PRINCIPLES

We categorized the identified issues into groups, namely usability, information processing, and medical issues to derive MRs and consolidate DPs according to Gregor et al. (2020). By following these guidelines, we ensure to consider aim, context, and mechanism within the design of our artifact (Gregor, Kruse, and Seidel 2020). The linked Is, MRs and DPs are depicted in Figure 2.

To counteract the issues of information overload **(I1)** and missing information **(I2)**, the medical assistant should present the information in a context-sensitive manner **(MR1)** by emphasizing only relevant information (e.g., appearance of the pill and intake information). If necessary, it should provide the user with additional information upon request. Furthermore, terminology that is too specialized or technical **(I3)** and a representation that is too small **(I4)** should be avoided. Therefore, we derive **MR2**, for which the information should be presented in an understandable and clear way. To enable the intuitive operation of the application **(MR3)**, complex interfaces that are difficult to use **(I5)** should be

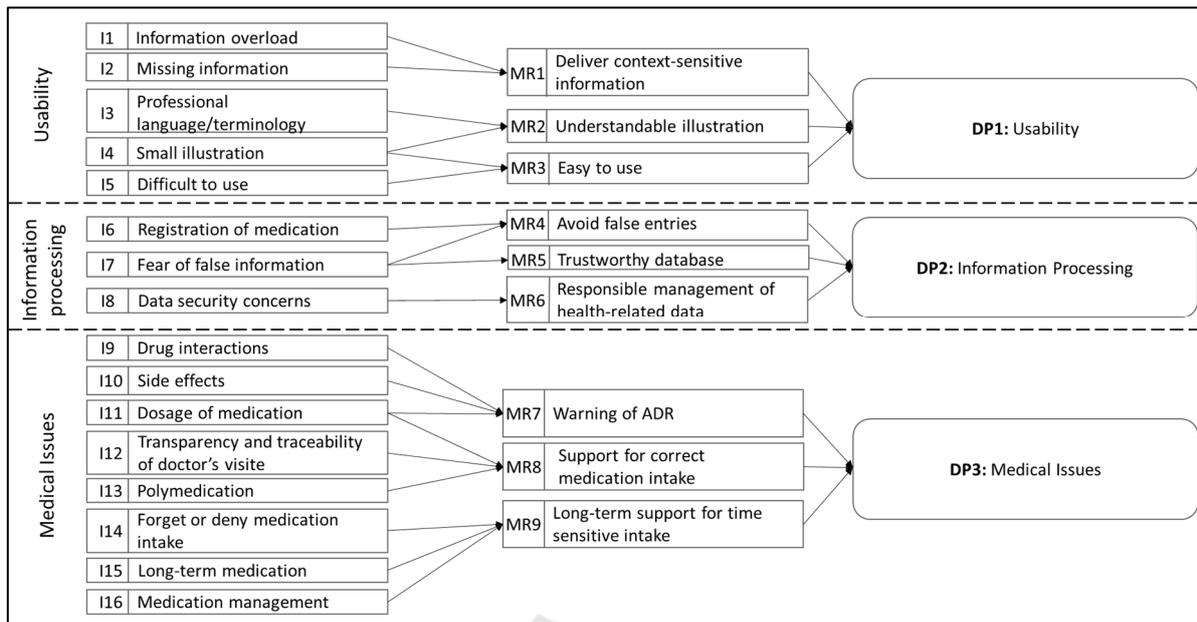


Figure 2: Issues, Meta Requirements, and Design Principles.

avoided alongside I3 and I4. As a result, the medication assistant should be easy to use by users who have little technical experience and during exceptional situations. MRs 1-3 were assigned to the category usability and can be consolidated into the first design principle:

DP1: To provide users with comprehensive information, provide an application with relevant information in a context-sensitive and understandable way, because this sparse and manageable display of the information protects the user from being overwhelmed and enables an easy and efficient application of the relevant information

Problems with the registration of medication (I6) and false information provided by the medication assistant (I7) should be avoided. For this purpose, the input of incorrect data should be prevented through the design of the application (MR4). Data entry should be designed to be as simple as possible and managed by medical professionals. Furthermore, to avoid incorrect entries (I7), it must be ensured that the basic information on the drugs is correct. Therefore, a trustworthy drug database must be used (MR5). Furthermore, the data security concerns of users must be considered (I8), which requires responsible handling of private health data (MR6). This implies parsimonious data storage so that only the necessary user data is saved in the databases. Furthermore, this data should be managed securely. The guideline for

information processing can be summarized as follows:

DP2: To enable trustworthy information processing, provide an application that ensures integrity, secure and reliable data management, because health data are considered to be particularly "sensitive" and are subject to special protection and, in addition, false or incorrect data can lead to health consequences.

The application is intended to prevent problems pertaining to interactions (I9), side effects (I10) and dosage (I11). To achieve this, the medication assistant should warn patients about possible ADRs (MR7). On one hand, new drugs must be checked for interactions with already-recorded medications. In this way, possible ADRs can be identified during the prescription process. On the other hand, ADRs should be identified as a possible cause of the existing symptoms by analyzing recorded drugs based on their side effects. In addition, issues of tracking visits to the doctor (I12) and difficulties in taking several medications (I13) should be avoided by helping patients to take their medication correctly (MR8) by raising the transparency of information. Moreover, the application should make it easier to distinguish drugs, and it should provide information regarding the correct type and quantity of medication. In addition, forgetting or refusing to take the medication (I14), non-compliance with long-term medication (I16), and problems in medication management (I17) should be avoided. Therefore, users should be

supported in the long term through taking all medications at the right time (**MR9**). In this way, the user should receive important information at regular intervals and throughout the entire medication period. Furthermore, the application should remind the user to take the medication on time and obtain follow-up prescriptions. From these MRs follows the DP3, which focuses on the medical issues:

DP3: To protect users from medical problems, provide an application that supports chronic disease management by identifying ADRs and reminding patients to take the right medications at the right time, because these features help to improve medication management and patient compliance.

5 MEDICAL ASSISTANT

5.1 Software Architecture

An overview of the software architecture of the multimodal assistant is provided in Figure 3. The arrows depicted in the overview indicate the direction in which data is transferred. The three main modules of the application are the web application (Med-Portal), the RESTful web service (Med-REST), and the CA (Med-CA).

Med-REST: This subsystem serves as the interface to the Med-Portal and Med-CA and functions as a data communication link between the components. An essential component of the web service is the medication data provided by *ABDATA Pharma-Daten-Service*, a division of *Avoxa - Mediengruppe Deutscher Apotheker GmbH*. The data comprises all available Rx and OTC medications in Germany with various drug information including the ingredients, storage and application methods, side effects and possible interactions with other drugs. In addition, the

database includes economic and legal information entailing the medications' price, distribution channels, or information on dispensing conditions (Pharma-Daten-Service 2019). As we emphasize drug safety and patient compliance in this study, we neglect the economic and legal drug information. To enable an enhanced query of the data, we imported the relevant data into a relational database (ABDA-DB) using the open-source H2 Database Engine (Database 2019). Since we are determined to prevent changes in the ABDA database to avoid misinformation, we implement only HTTP-GET methods for the individual resources of the web service. In addition, we created an authentication method for security purposes that acts as the interface for using the web service. With each call, the system first checks whether a valid token of the Med-Portal or the Med-CA has been transferred, so that only registered users can access the web service. If authentication is successful, the request is forwarded to the corresponding class in the application. All data is transmitted encrypted via the Hypertext Transfer Protocol Secure (HTTPS).

Med-Portal: To allow medical professionals to use the Med-Rest interface and manage the medications of their patients, we created an HTML-page. First, we added a search field that allows for searching the web service (Med-REST) for medication information. To do so, a GET-function of the service is called by the client. We implemented the possibility of using wildcards (“%”) to enhance the search usability. The method returns the trade name, potency, and manufacturer of the queried drugs, displayed in a table.

If a new drug must be added for a particular patient, another GET-function is applied to check whether possible interferences between the new drug and the patient's existing medication plan can be identified. If possible interactions occurred, a

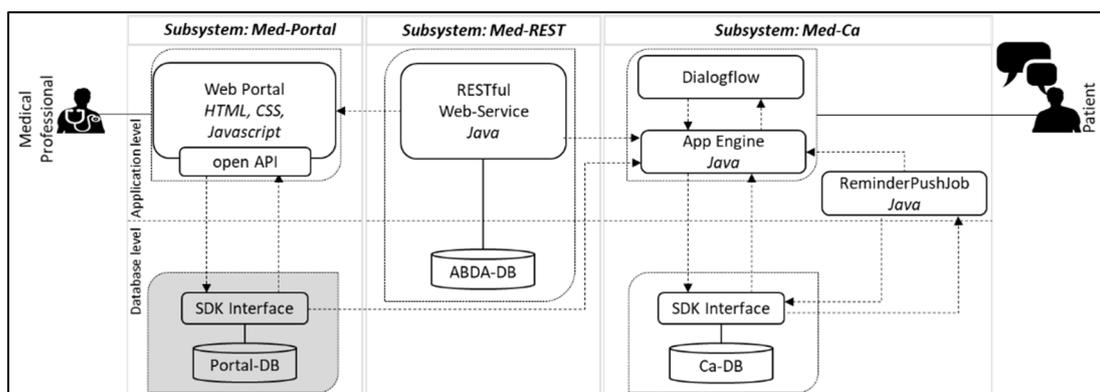


Figure 3: Software Architecture of the Medication Assistant.

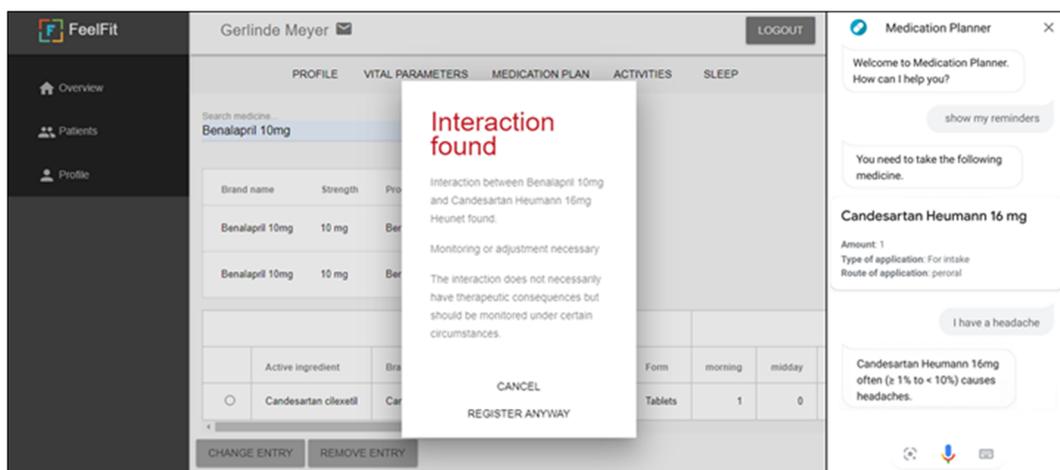


Figure 4: User Interface: Med-Portal (left) and Med-CA (right).

warning message displays the trade names of the interacting drugs, any recommended actions, and a description of the effect (cf. Figure 4, left image). Based on this, the medical professional can decide whether to cancel the process or enter the drug despite the possible interactions. To add the new drug, the ingredients, trade name, dosage and shape of the drug are retrieved from the web service via a dedicated function. Furthermore, the physician can manually enter the intake time (morning, noon, evening, night), unit quantity, notes, reason for ingestion, reminder time (morning, noon, evening, night), and remaining stock for the patient.

Med-CA: This subsystem represents the module used by the patient (cf. Figure 4, right image). The Med-CA utilizes Google's Dialogflow platform for speech processing (Google 2020). The voice commands issued by the patient are performed by the corresponding functions on the server side on Google's App Engine platform. These functions are fed by general medication information via the Med-REST service and can be supplemented by patient-specific data from a medical database (Portal-DB) connected to the open API. As mentioned, we used the FeelFit database (Meier et al. 2019) as the Portal-DB for testing purposes, which stores various patient-specific data such as blood pressure or patient activity. In addition, a software development kit (SDK) is used to access another database from the App Engine (CA-DB). This database stores data that is relevant only for the functions of the Med-CA and serves as the foundation for the *ReminderPushJob* application. The *ReminderPushJob* checks whether there are reminders defined in the database for a given time, which triggers the sending of a push notification containing the medication information to the user.

The information comprises the medicine (product name), doses, color of the drug, method, and intake advice derived from the ABDA database. The remaining stock stored in the Portal-DB is automatically adjusted based on the applied medication. If the remaining stock drops below a threshold of 10 units, a warning message is stored in the CA-DB and is issued to the patient.

5.2 Evaluation

The evaluation is aimed to validate whether the system meets the proposed design and to analyze the systems performance (Kuechler and Petter 2012). In the first evaluation cycle, we interviewed three experienced pharmacists. The second evaluation cycle is supposed to generate insights on user's acceptance. To do so, we present an experimental design for a future long-term study.

First Iteration: Expert Interviews.

To evaluate the medication assistant regarding its usefulness, the quality of the information, and the potential for improvement, we interviewed three qualified, self-employed pharmacists based in Germany (E1: 25, E2: 20 and E3: 29 years of experience). After presenting the medical assistant and the functionalities of the system to the pharmacists, we conducted a semi-structured interview (Myers and Newman 2007).

According to the experts, the target group of the **Med-CA** are patients with chronic diseases suffering from asthma, diabetes, or cardiovascular diseases (E1, E2, E3). The CA could support patients in organizing their medication management, particularly by checking the remaining stocks and

reminding them to reorder medications (E1). In addition, reminders for medication intake and respective advice (intake: oral, injection, liquid, and so on) could increase patients' compliance. According to E2, an improvement in functionality would be the confirmation of the patient's drug intake following a reminder. Furthermore, E2 remarks that if a patient is not at home when receiving a notification, the patient should be reminded on a loop until the final intake is confirmed. The pharmacist E2 stressed that notifications of all types should avoid complex and professional terminology, which our artifact based on I3 considered. Therefore, information on the medication intake, storage, and side effects from the ABDA-DB should be translated into generally understandable language. The process of identifying certain drugs could be supported by providing pictures of the respective pill on the patient's smartphone (E2). In addition to notifications concerning medication intake, patients could also be reminded to measure their vital signs, such as blood pressure (E2). These measurements should be stored directly in the patient's profile to enable the pharmacist or other healthcare professionals to check whether the patient's medication is correctly adjusted.

All pharmacists agreed that they could integrate the **Med-Portal** into their daily work routine. However, they indicated that additional effort should be minimized (e.g., by interfaces to already-used software) (E2, E3). In particular, compatibility with nation-wide standardized medication plans should be ensured (E3). Furthermore, pharmacists require additional individual advice options on the dosage or storage of medicines (e.g., in the form of notes to a particular entry) (E1, E3). In case of questions, patients should also have the ability to contact their pharmacist directly via chat (E3). In addition to automatic ADR analyses, pharmacists should be able to perform regular manual assessments of the medication plan to identify potential redundant prescriptions or obsolete drugs (E3).

Regarding **Med-REST**, the experts mentioned that the web service should feed on data that goes beyond the ABDA-database, as not all potential interactions might be listed, and patients could take additional substances that are relevant to their medication plan but are not included in the pharmaceutical database (e.g., nutritional supplements) (E1). Complementary health-related data such as vital signs, blood-, liver- and kidney-values, weight, allergies or food intolerances should be integrated into the patient's profile as they might be relevant for the effective use of certain medications (E1).

Overall, the basic functions of the assistant were assessed by the experts as beneficial in terms of supporting users in drug management and improving patient compliance. The features for further improvement can be categorized in data and functional improvements and are summarized in Table 1.

Table 1: Feedback of Interviewed Pharmacists.

No.	Data Improvements	Frequency
1	Easy Language	1
2	Detailed advice to medication intake	2
3	Information about storage	1
4	Pictures of drugs	1
5	Additional data: vital signs, nutrition supplements, allergies, intolerances, weight	1
No.	Functional Improvements	Frequency
6	Interfaces to existing software	1
7	Notifications for vital signs measurement	1
8	Integration of vital signs	3
9	Integration of laboratory values	2
10	Consideration of chronic diseases	1
11	Confirmation of intake	1
12	Notification-loop	1
13	Chat	1

Second Iteration: Experimental Design.

After evaluating the CA with experienced pharmacists, the system needs to be tested and evaluated by potential users. To prepare the second evaluation cycle, we conceptualize a suitable experimental design which will be operationalized in a future study. The study design is supposed to be an experiment. It will be held in a smart home showroom, which creates a comfortable atmosphere in which participants feel at ease. Thereby we can avoid biases due to a laboratory setting.

First, we will survey participants in regards to their demographics, pre-experience and general attitude towards technology. Second, they will be introduced to a scenario involving a specific person, who suffers from multiple diseases, takes several medications, lives alone and is not able to visit the pharmacy on his or her own. Nevertheless, the person obtains his or her medication supply through home deliveries. In addition to the delivery service, the pharmacy that supplies the person offers a CA for the medication management. After being introduced to the scenario, the study participants will be asked to conduct the following three tasks:

- I. *Ask the CA, which medications must be taken today and ask a follow-up question about the appearance of the pill.*
- II. *Ask the CA, when you need to reorder medication according to your therapy plan. If necessary, order new medication from your local pharmacy.*
- III. *Report side effects to the CA, resulting from taking medication, e.g. headache, and find out causes for the symptoms.*

After completing the tasks, participants have to answer a user experience questionnaire. We will apply the user experience questionnaire based on Schrepp et al. (2014). Besides initial questions towards the acceptance and the trust towards the technology, participants have to share their impression of the system by rating 26 items on a scale of two contradictory features, e.g., good/bad, slow/fast or enjoyable/annoying. The user experience questionnaire provides insights in terms of novelty of the artifact, stimulation, dependability, efficiency, perspicuity and attractiveness. In addition, it allows to establish a benchmark with comparable artifacts.

6 DISCUSSION

The management of the risks associated with polymedication is of great medical and economic importance (Taylor et al. 2013). Therefore, patients in Germany, who take more than three different prescribed medications have been eligible for a standardized medication plan since 2016. In addition, some pharmacies manage customer profiles to track customers' individual medication records (Reimers and Klein 2015). However, most patients do not request such a medication plan, as they are unaware of their right to a managed plan and the possible ADRs of their medication. Furthermore, medication plans often do not consider OTC drugs, and ADRs might just as well occur with fewer than three prescribed drugs. To support medication management, digital assistants such as CAs can be found in many popular app stores and are designed to support patients in their medication therapy (EmmaHome 2020; MyTherapy 2020). However, these applications often support only a reminder function for medication intake (EmmaHome 2020; Jesús-Azabal et al. 2020) and rely on the error-prone input of the patient to create a medication plan (MyTherapy 2020; Sebillio et al. 2017; Silva et al. 2013). As a result, the safety of medication therapy is not emphasized in these particular solution

approaches. The CA presented in this study enters into dialog with patients using simple language to provide them with important information concerning the medication to be ingested, and it considers side effects and ADRs with other drugs. The system enables patients to self-manage their medications and provide access to selected healthcare professionals, who can access their medication plan via a web service. Through the integration of healthcare professionals such as pharmacists or doctors, it is possible to strengthen the intersectoral cooperation, to send secured notifications about medication intake to the patient and to reorder medications directly, thereby simplifying the integration of therapy plans into everyday life and increasing patient compliance on several levels. Moreover, the ADR check function and the associated notification of interferences and information concerning the composition of drugs, side effects, and symptoms increases the health competence and health awareness of patients.

All interviewed pharmacists emphasized the relevance of vital parameters for medication therapy safety. We connected the FeelFit database to our system to integrate vital signs from various devices (Meier et al. 2019). On one hand, this enables pharmacists to check whether the medication doses are correctly adjusted. On the other hand, a continuous visualization of vital signs can demonstrate the consequences of non-compliance to the patient (Meier et al. 2019). This is especially relevant for non-compliant patients who do not take their chronic diseases seriously, intentionally refuse adherence to their therapy plan, or secretly deny medications because of inconvenience (Petermann and Mühlig 1998).

Implications for Research and Practice: All the pharmacists involved in the evaluation agreed that our multimodal prototype has a high value for medication management safety and patient compliance. From the perspective of a practitioner who works in the healthcare sector, the application could provide more transparency into the ongoing therapy of patients and thereby intervene in the treatment more quickly and proactively, thereby increasing the overall quality of healthcare supply. This is particularly important, since ADRs could often be avoided by increasing the transparency for healthcare professionals and thus reducing healthcare expenses caused by avoidable hospital admissions due to medication errors (Salvi et al. 2012; Taylor et al. 2013). Furthermore, the active management of patients' data (e.g., by pharmacists) can increase the importance of local healthcare experts and enhance the relationship with patients (Mossialos et al. 2015). Given the challenges of

increasing e-commerce and the loss of rural infrastructure due to urbanization and the shortage of physicians, the number of German pharmacies has decreased over the past 10 years (ABDA 2019). Our artifact could provide a new interface in the patient-pharmacist relationship (Volland 2015). In this context, the combination with blistering business models might be a valuable future service for local pharmacies. From the patient's perspective, the medication assistant can not only support the safety of drug therapy but also increase the integration into everyday life and thus promote patient compliance. As a result, this facilitates healing and supports health prevention. However, to establish integrity to our system, it requires a trustworthy and reliable data management and compliance standards for all involved users.

Our findings contribute to theory, as we shed light on guidelines to design and develop multimodal medical assistants for medication management. With the derived DPs in this study, we provide context-oriented guidelines for medical assistants that complement more generic DPs of CAs. With our modular approach, we enable the connection to other applications, such as FeelFit and thus the enhancement of functionality in the realm of personal medical health assistants. On this basis, further research can be initiated, and additional functionalities and improvements can be developed based on our evaluation.

Limitations: As with any study, our research is subject to limitations. First, we conducted only one iteration of the DSR cycle. The feedback of the expert interviews must be implemented into the prototype during the next iteration cycle. Especially the readability of a standardized medication plan by scanning the QR code, should be added in the next development cycle. Second, we have not yet evaluated the CA from the perspective of potential patients. Since evaluations with patients require a comprehensive study design, we presented an evaluation concept which will be operationalized in a future study. Third, we have not yet analyzed the integration of the system into existing healthcare initiatives or patient portals. Future studies with patients should investigate the connection to current systems like advanced patient portals or virtual health coaches. Finally, our CA is partially focused on the German healthcare system. The prototype and its evaluation might be biased by legal, structural, and cultural influences. Nevertheless, the demand for medical assistants rises internationally, and the results of our study can be transferred to any other healthcare system.

7 CONCLUSION

Our study aimed to develop a multimodal assistant that supports and secures patients in their medication management, thereby increasing safety and facilitating adherence to therapy plans. Within a DSR project, we identified 16 Is to describe problem areas that must be considered when developing an application to enhance medication therapy safety, and we derived nine MRs and consolidated them into the three DPs focusing on usability, information processing and medical issues. Those were built in a prototype consisting of three components.

First is the **Med-Portal** component, which can be accessed by medical professionals to manage patients' medication plans and provide individual advice. The second is the **Med-REST** web service, which is the interface of the German ABDA database that contains all available Rx and OTC medications. Last is the **Med-CA** component, which enables patients to follow their medication plan and obtain additional information regarding the correct intake, storage, and side effects. Notifications about medication intake and reordering can support patients in integrating therapy management into their everyday lives. An evaluation with experienced pharmacists has demonstrated the high relevance and usefulness of our developed medication assistant. Finally, an evaluation with patients is conceptualized for the application within a future study. So far, the designed artifact offers the potential to increase patients' compliance and medication therapy safety and to improve the relationship between patients and pharmacists.

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