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Abstract

While vaccines in general have eliminated many infectious diseases in most of the Western World and beyond, levels of vaccination coverage, personal vaccination documentation and motivation for vaccination are still variable and this variability leads to a range of problems. In this paper, these problems are identified and analyzed from a process-oriented point of view. The focus for this analysis is the international certificate of vaccination; a paper based document (short: vaccination card). By identifying gaps and challenges in the existing vaccination process in Germany, possible alternatives were identified. Literature research and studies of related work considering electronic vaccination card applications form the foundation for a new concept for a vaccination card application for mobile devices. A catalogue of requirements for an electronic vaccination card application is identified and presented. Based on this requirements catalogue, the concept for an application was developed and prototypically implemented. Finally, further development of the concept and prototype, as part of a continuous design research cycles are discussed. This work should be regarded as research in progress and presents just one aspect of a wider mobile health care research program.

Keywords: mobile application, vaccination card, mobile health care, Design Research.

1 Introduction

Vaccinations make a significant contribution towards fighting many infectious diseases by reducing the probability of infection and by minimizing the severity of certain diseases. The

main goal of vaccinations is the preventive protection against a dangerous disease. Furthermore, it is only by reaching high vaccination rates that collective protection against infectious diseases within the population can be achieved. Considering this, vaccinations are seen as the most important and effective preventive measures in modern medicine (Meyer et al. 2002; Poethko-Müller, Kuhnert & Schlaud 2007; Schmitt 2001).

In Germany, physicians choose vaccines for their patients often from a wide range of licensed and available products. Vaccines recommended by the Robert Koch Institute in Berlin and the public health authorities of the 16 German states are paid for by all health insurance companies in the country with a few exceptions. All Germans are covered regarding health insurance and all important immunizations are offered to them free of charge (Meyer et al. 2002; Poethko-Müller, Kuhnert & Schlaud 2007; Schmitt 2001).

The international certificate of vaccination[1] is a standardized paper document, which is issued for each newborn baby in Germany and is also available at any health department or via the Deutsches Grünes Kreuz in Marburg. The legal foundation of this process is regulated in *§22 Infektionsschutzgesetz*[2]. A properly maintained vaccination card shows which immunizations a person has received, gives further information about a specific immunization and when certain vaccinations become due for renewal. An entry always includes the date of the immunization, the name of the vaccine, its batch number, the name of the infectious disease and contact data of the vaccinating physician as well as his signature. In general, entries in the vaccination card should help to prevent false, unnecessary or the repeating of already existing immunization. The paper form of the vaccination card and the general process of vaccination in Germany cause problems concerning information about vaccination, motivation for vaccination and control over the vaccination record. In addition to the handwritten entries in the vaccination card, which can often only be read by the physician himself, the limitations in space available for entries represents an additional restriction. Furthermore, a significant percentage of the German population has no vaccination card at all (lost, relocated, not obtained, etc.). Because of this, information in the vaccination card is often outdated or incomplete and many people do not know their vaccination status (Bartholomäus 2009; Dippelhofer et al. 2002).

Due to the problems identified above, changes concerning the vaccination process or the paper-based vaccination card are worth discussion, especially in the light of technological progress. In this paper an electronic, mobile and application based approach for a vaccination card is proposed, conceptualized and implemented. Mobile devices such as smartphones and tablets are increasingly used in the medical and health care field. They offer a high level of personal commitment, permanent availability and nearly ubiquitous access to stored information. There are numerous applications that allow support in everyday life situations and especially medical treatment of the user. The advantages of mobile devices are not only their great mobility, but also the user-specific and context-dependent configuration they offer.

1 In this paper, the term „*vaccination card*“ is used and relates to the paper-based document.

2 http://www.gesetze-im-internet.de/ifsg/__22.html

This allows access to information whenever relevant (Kulkarni & Öztürk 2007; Taylor & Dajani 2008; Wyne et al. 2009).

These advantages of mobile devices are a decisive factor in the overall research program and especially the conceptual design discussed hereafter. Increased information, better readability, strongly increased maintainability and additional features may be advantages of an electronic and mobile vaccination card solution. Based on this motivation, the following paper approaches the research, conception, design and development of a mobile vaccination card application.

2 Research question and research method

Several developments in the health care sector have resulted in the need for a more cost-effective and continuous patient-centered health care management. In the course of these developments the significance and the possibilities of portable medical systems were analyzed. Specialized applications for mobile devices form one aspect of the wide-ranging technological environment of patient-centered health management. One of the key goals in this research area is the "empowerment of the patient". This means a larger self-responsibility of the patients for their own health, which is seen as a basic building block for sustainable welfare of a society (Lau 2002; Lenert 2009; Salmon & Hall 2004). Health-oriented applications for mobile devices may be a way to put more sovereignty over medical data into the hands of the patient, thus allowing continuous monitoring. This in fact is seen as the essential enabler for self-responsibility behavior (Baumeister & Tierney 2011). Currently, there are numerous deficiencies in the usability and consistency of the systems mentioned. Furthermore, they are currently not designed to be used on smartphones and tablets or are only used for very specific needs in the widespread medical environment. The need for new concepts for various medical services as mobile applications is given accordingly.

As a research method for the identified problem and associated research question the design research cycle was chosen. This approach has been discussed since 2004 by Vaishnavi and Kuechler and its relevance for information systems research was shown by Österle et. al in 2011 (Österle et al. 2011; Vaishnavi & Kuechler 2011). The course of action of a design research process and the linked results of any concrete action (*Outputs*) are shown in summary in Figure 1. The starting point of this research approach is always the need for a solution to a practice relevant problem; in this paper the improvement of the vaccination process and the vaccination card in Germany (*Awareness of a Problem*). The next step is to work out and design a first solution based on a requirements analysis, taking into account the difficulty of the scenario and including relevant professionals (S*uggestion*). This methodic approach results in the development of a first prototypical implementation of a mobile vaccination card application (*Development*). The resulting artifact has to then be evaluated in a solid, real-world context (*Evaluation*). This could be a field experiment or interviews with professionals involved in the vaccination process as a starting point. The gathered information can then be analyzed, structured and prepared. It builds the foundation for a new re-designing development cycle (*circumscription*). This leads to a deeper understanding of the original problem. The evaluation findings of successive development cycles are used to improve the artifact and lead to a more and more explicit understanding of the total correlations concerning the original perceived problem (*operation & goal knowledge*). The whole process

results in a concrete examination of the problem and helps answering the research question related to the method (*Conclusion*).

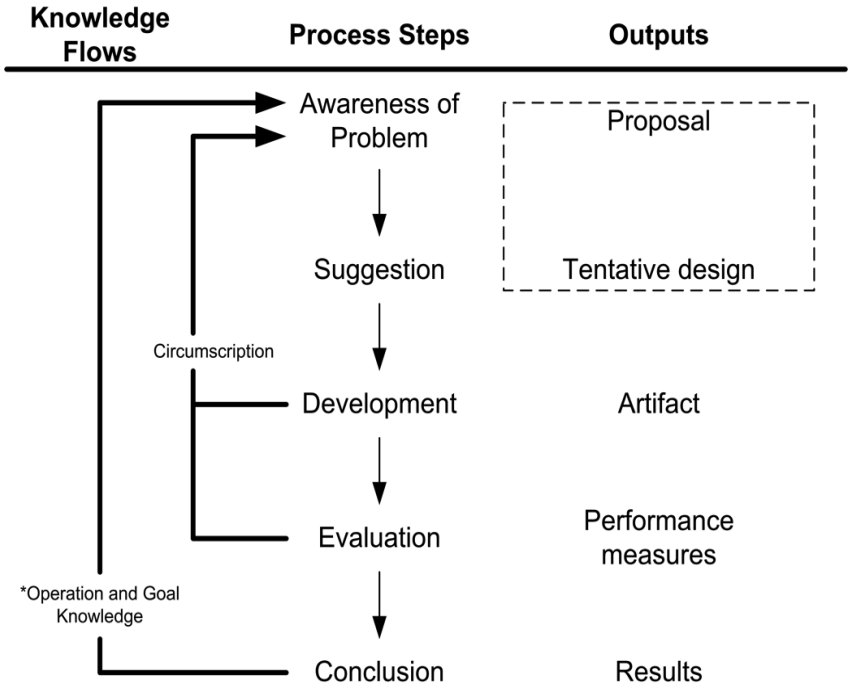

Figure 1: Structure and Course of Action of the Design Research Cycle (Vaishnavi & Kuechler 2011)

As this paper is marked as a *"research in progress"* the first three phases of the design research cycle are presented with the specific process steps and results annotated in the text. To clarify the perceived problem with the paper-based vaccination card, a detailed analysis of the vaccination process in Germany is presented. This leads to the idea of an electronic approach for a vaccination card. To illustrate the problem of existing electronic vaccination card solutions and to demonstrate the need for a new concept, a comprehensive literature analysis and a market overview of current systems is given. Afterwards, a new approach for a mobile vaccination card application is designed and implemented. The prototype and further possible evaluation and development steps are discussed in the last part of this paper.

3 Analysis of the vaccination process in Germany

In Germany, many serious diseases such as poliomyelitis, diphtheria or invasive Hib were virtually exterminated by vaccinations. Nevertheless, most of the still occurring cases of invasive Hib in Germany are related to un-vaccination or under-vaccination. For example, there is only a vaccination coverage rate of 70% against measles, which leads to regular outbreaks of the disease in Germany (Schmitt 2001). Data has shown that about 10% of German children have gaps in their primary immunization record and more than 50% are vaccinated too late (Schmitt 2001). Although there is enough money for vaccination available in Germany, there are different barriers to the appropriate use of vaccines to reach a sufficient

coverage of immunization in the country (Schmitt 2001). More than 50% of parents feel uninformed or insufficiently informed about vaccination, which leads to misperceptions on the benefit of vaccination and its side effects (Schmitt 2001). There are a few people who refuse all vaccinations in general, but most of the Germans name "missed appointments" as the main cause for an incomplete vaccination status (Schmitt 2001).

In Figure 2, the vaccination process in Germany is illustrated in a 4-step-cycle with problems connected to every step. These problems were identified by a detailed literature research as well as interviews with medical practitioners.

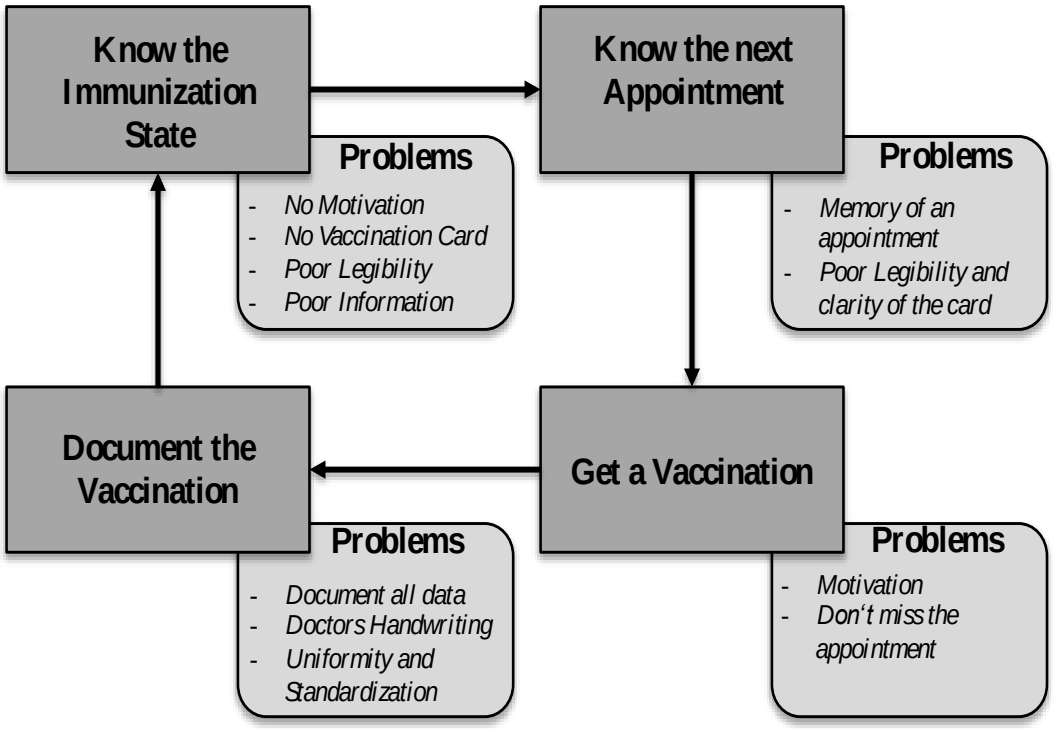

Figure 2: Vaccination process and identified problems during the process in Germany

Putting the different visualized problems together, four explicit problem categories could be identified:

- Poor information about vaccinations, the benefit of vaccinations and the process of immunization.
- Motivation issues of the patients due to lack of understandable information and medical education.
- Appointment making with the doctor and remembering a vaccination appointment.
- Organizational issues due to the paper form of the vaccination card like poor legibility, poor clarity and little space for information.

Following the Research Design Method, those categories symbolize the realization of a real problem in an everyday life situation (*Awareness of a problem*). Better information, improved readability, better maintainability and additional features such as remembering vaccination appointments may be reasons for an electronic vaccination card solution. The above-mentioned advantages of mobile devices like ubiquitous access to information and changes in the modern information technology society clarify this need for an approach for a mobile vaccination card application.

The advantages of mobile devices are a driving factor in the present context of vaccinations. Regarding tetanus, for example, it makes sense to know the vaccination status directly after an injury causing the risk of an infection. The benefit of this would be the access to any information about a user's immunization status at any time. Consequently, the user is much better informed about his health and vaccination status. Because of these aspects, the research for a mobile vaccination card application solution is suggested and will be examined in the following chapters of this paper (*Suggestion*).

4 Literature research and related work

A comprehensive literature review has shown that an electronic vaccination card solution is hardly regarded in academic literature so far. The basis of the search were relevant terms such as "vaccination record", "vaccination", "vac-cine", "immunization", "immune", "application", "app", "mobile device" and "Smartphone" in all combinations. This research only provided literature on the use of mobile devices for mobile health care in general and applications for the design of vaccines. Concepts of a general implementation of an electronic vaccination card only exist in the form of a "white paper" and preliminary studies whereas special literature regarding the implementation of a mobile application could not be found (Bartholomäus 2009; Lindenmann 2012).

In a second research, existing mobile applications from the Apple iTunes Store and Google Play were considered. A selection of freely available applications was examined in detail. This analysis of existing applications was based on a predefined set of criteria that includes mandatory and optional components of an electronic and mobile vaccination card application. Those criteria derive from the statutory requirements for the certificate of vaccination and the expected value functions, which can provide mobile devices. Table 1 shows this catalogue of criteria.

Essential Requirements	Optional Requirements
Statutory Requirement I Personal Data of the Patient (complete name, sex, birth date)	***Travel Vaccinations*** (for trips to tropical areas or critical countries regarding infectious diseases)
Statutory Requirement II Record of immunizations (date, vaccine, charge, disease, doctors data and signature)	***Further/Additional Medical Data*** (blood group and rhesus factor, further risk factors such as allergies)
Statutory Requirement III Details how to act after unusual or critical reactions to vaccines	***Allow temporary Access to Vaccination Data*** (for example for supervisors at children's camps, teachers in school, coaches at sport, etc.)

Administration of multiple vaccination cards (for e.g. other family members like children or grandparents, for nursing staff, etc.)	***Additional information about the patient*** (address, phone number, contact information of the family doctor)
Handover of vaccination cards (possibility to transfer administrated vaccination cards to e.g. children or new responsible person)	***Calendar function*** (date of the next vaccinations, vaccination appointment reminder)
	Backup and possible export of data (save the vaccination cards on an external server)

Table 1: Essential and optional requirements of a mobile vaccination card application

When reviewing existing applications, the above-mentioned search terms of the literature review were used to search for already existing vaccination card applications in the iTunes Store and Google Play. From the resulting list, the applications shown in Table 2 were chosen as a representative selection and a detailed functional analysis with regard to the criteria defined above was performed.

The evaluation shows significant deficits of current mobile vaccination card applications. The table clearly shows that all applications analysed lack information that is required by law. Even myViavac, the official electronic vaccination card of Switzerland, has no validation of vaccinations provided by a doctor. A handover of the vaccination card e.g. to children when they attain the age of majority is generally not possible in any of the applications. Furthermore, there is no connection to the calendar (plus synchronization with backend systems) of the mobile device. Only a few applications offer reminders of vaccinations outside the actual application (for example in the calendar of the mobile device). Entering travel vaccinations to the mobile vaccination card application is either done manually (the infectious disease must be known) or there is a fixed, predetermined list for input. Other useful additions within the electronic and mobile environment are not implemented in most of the listed applications. This includes for example a way to back up data, which is essential when the device is lost or changed.

Category / Application	**APPzumArzt**	**Impfkalender**	**Impfpass**	**Online Impfpass**	**myViavac**
Developer	Valiton GmbH	Medicus42 GmbH	Cencurio AG	SKHB mbH	Abondo SA
Implementation of legal Requirements	Not fully implemented	Not fully implemented	Not fully implemented	Not fully implemented	Not fully implemented
Multiple Vaccination Cards	Yes (without handover)	Yes (without handover)	Yes (without handover)	Yes (without handover)	Yes (without handover)
Travel Vaccinations	No	Manually	Yes (given list)	Yes (given list)	Yes (given list)
Further medical Data	No	No	Yes	No	No
Temporary Access for 3rd Parties	No	No	No	No	Medical Staff
Further Patient Data	No	No	No	Some	Some
Calendar Function	Own without Reminder	No	Own without Reminder	Own without Reminder	No, but Reminder

Data Backup	No	Yes	No	Yes	Yes

Table 2: Evaluation of a selection of existing mobile vaccination card applications

Putting all these facts together there is a lack of an easy-to-use, understandable and fully featured mobile application of the vaccination card (*Awareness of a problem*).

5 Conception of a mobile vaccination card application

The analysis carried out in chapter 4 shows the need for a mobile vaccination card application, bypassing the existing problems and realizing the above-mentioned criteria. This chapter describes the design of such an application. The design of a new mobile vaccination card application was based on the previous results and an analysis of usage scenarios. This analysis was performed by categorizing four major segments for the usage of a mobile vaccination card application. These categories are the requirements for a vaccination card in general, the requirements for a mobile application, the use cases for an electronic vaccination card (especially as mobile application) and finally the usability and operation of a mobile vaccination card application.

The data volume of a vaccination card consists of general basic information, which is divided into personal and medical information, as well as the registered vaccinations. For a legally binding use the vaccination card must have a unique assignment of the vaccination to a vaccinated person. This can only be ensured by recording birth name and birth place in addition to the aforementioned personal information such as full name, date of birth and gender. The medical information includes risk factors such as unusual vaccine reactions, allergies and optional blood type and rhesus factor. Information about the treatment of a person in case of the occurrence of a vaccine reaction is possible as well. When implementing the application, it is important to enable the flexible use of the mobile vaccination card. In addition, specific conditions in the context of medical standards and data protection should be considered. Medical data are personal and therefore have to be kept in confidence. That is a key reason why an electronic vaccination card solution requires a high level of security mechanisms. The access to stored data may be possible via secure access and data should not be accessible on the electronic (mobile) device without protection. In addition to the encryption, data completeness and correctness must be ensured. Furthermore, access to the data by medical personal in emergency cases must be ensured. For the accuracy of the data the user needs support during the input of individual vaccinations. Finally, it should always be possible to read the data and the current vaccination status without medical knowledge.

The examination of the applications use cases so far has shown that currently many vaccines are administered unnecessarily (Bloom, Canning & Weston 2005). For example, a patient with a serious injury is vaccinated against tetanus again, because he does not carry his vaccination card along and thus, any examination of the vaccination cannot be carried out. On the one hand it is good that any health risks are avoided, but on the other hand, the patient is unnecessarily burdened with vaccines. Another example of the importance of a vaccination card is traveling to certain countries, which often requires a certificate of vaccination being carried along by the traveller. Finally, the possibility of an exceptional vaccine reaction or even a disease after a vaccination can be included. In both cases it is important to know the

vaccination quickly and whether the reaction is due to the vaccination in order to take appropriate countermeasures.

Based on these requirements, a design for a mobile vaccination card application was created (*Suggestion*). The problems of existing applications (conceptual and technical level) should be resolved in this design. For this reason, when opening the application a password is always requested to ensure the secure access to the stored data. Furthermore, when the application is closed any access to the data is blocked. The internal structure of the application is divided into a summary page (see Figure 3 left side), a detailed vaccination status (see Figure 3 right side), a calendar function and the settings page. On the summary page (see Figure 3 left side) the current vaccination status of the user is shown compactly. In addition, a photo of the user helps to immediately detect whose vaccination card is shown, since the administration of vaccination cards of family members is also possible. A specific user can administrate a various number of different vaccination cards (e.g. his own and those of his family members). The traffic light colors are used to show how long the protection provided by a vaccination against the appropriate infectious disease still persists (red = protection less than a month, yellow = protection more than one month and less than six months, green = protection more than six months). The buttons at the right top position next to the user's picture offer the possibility of accessing the help page of the application on which all components are described in detail. The user may also find behavioral evidence for unusual reactions to vaccines. The button "*Impfungen für Reisen*" provides access to a list of specific travel destinations. By choosing one destination the user gets a list of vaccinations that are recommended for this country. Via the "*Profil*" button the user can see all the information stored for the current vaccination card. This includes personal and medical data and, if specified, address, telephone numbers, family doctor and risk factors. In addition, there is the ability to switch between administrated vaccination cards or modify entries on the profile page. In the middle of the page the next three appointments are shown. By clicking on a specific appointment it is possible to access a detailed view of it (see Figure 4 right side). An appointment date includes the time of the vaccination, the affected infectious diseases and the vaccinating doctor. If an appointment date has not yet been arranged, it is seen as an indication of month and year within the list and can be completed by specifying the date and doctor.

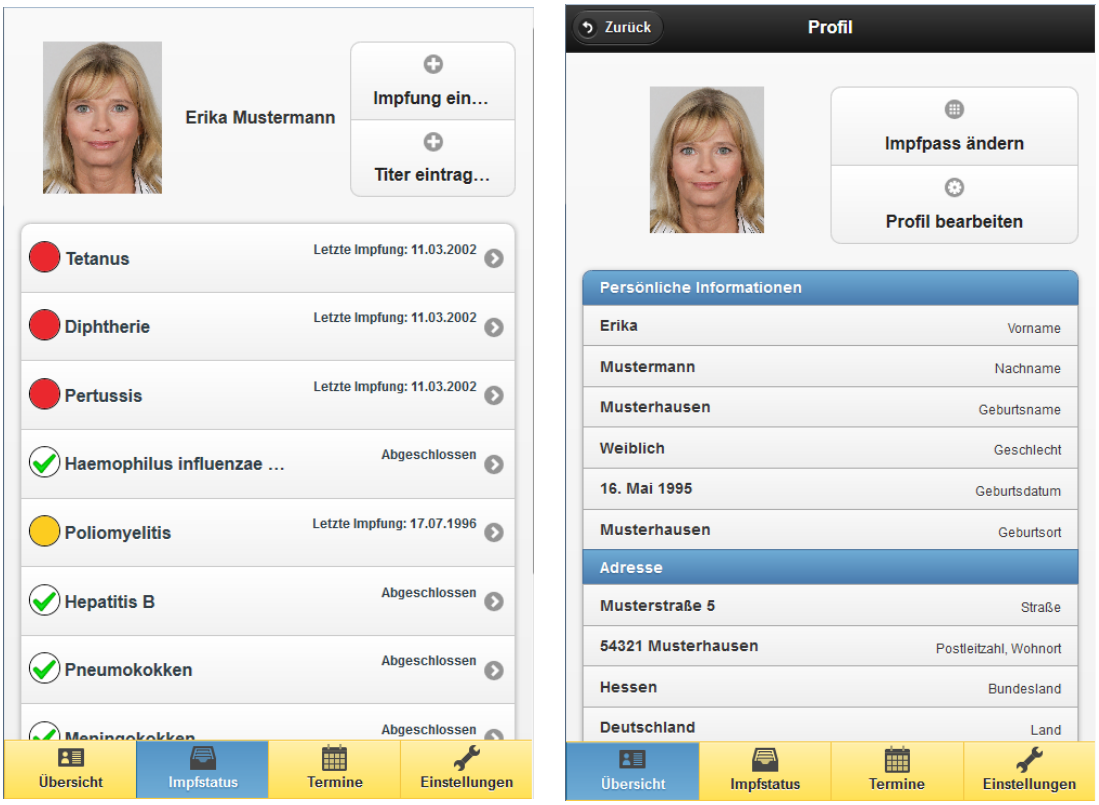

Figure 3: Summary page of the application (left side) and detailed vaccination status of the person (right side)

The second main view of the application is the vaccination status in detail (see Figure 3 right side). All previously performed immunizations are listed there, with the last vaccination for a specific disease highlighted with a corresponding color indicator. The green check mark is for a completed composite vaccination, where no further particular vaccinations are necessary. The other color indicators may be interpreted as described above. When an infectious disease is chosen, the details of the last vaccination with all statutory data are displayed and it is also possible to see a list of all vaccinations received against it. Furthermore, the application shows when the next vaccination is recommended. In general, the mobile vaccination card application follows the recommendations provided by the Robert Koch Institute in Germany and by the World Health Organization[34]. Via the button "*Impfung eintragen*" the user can insert new vaccinations to his vaccination card (see Figure 4 left side). The user is supported at the best during the insertion process by using the camera of the smartphone. This allows the recording of the vaccine's identification number and its batch number. Finally, after recording this data, it has to be checked for accuracy and is saved with the date and the details of the vaccinating physician.

3 http://www.rki.de/DE/Content/Infekt/Impfen/impfen_node.html

4 http://www.who.int/immunization/policy/immunization_tables/en/

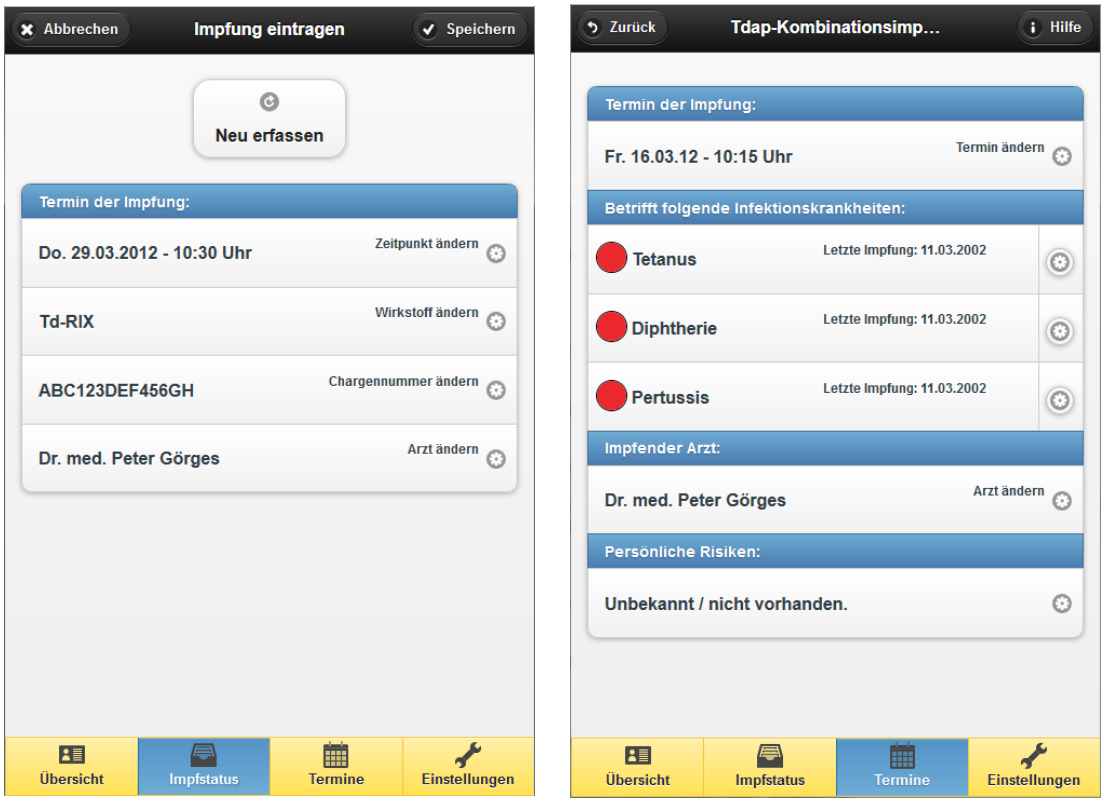

Figure 4: Insertion of a a new vaccination to the application (left side) and detailed view of an appointment for a vaccination (right side)

The appointment page is an image of the calendar of the phone, which only shows the vaccinations. This integration can be changed in the settings. The mobile vaccination card application is not limited for the use in certain countries such as the electronic certificate of vaccination in Switzerland[5]. The design allows its operation anywhere in the world. Furthermore, in the settings menu it is possible to make backups of the data or to generate an image of the vaccination card, which can be sent to another mobile device. Thus, the transfer of the vaccination card to a child can be realized when it has reached majority age. Using this concept, a first version of a prototype for a mobile vaccination card application was implemented.

6 Prototypical implementation for mobile devices

After presenting the first two steps of the Design Research Cycle by creating awareness for a real world problem and discussing a possible solution for this problem, a concrete development was conducted by designing and implementing a first prototype. This prototype was implemented with jQuery Mobile and PhoneGap to allow a cross-platform development. Thus, the same functionality can be made accessible on many current mobile devices, regardless of their operating systems. By doing so, a better evaluation of the prototype during

5 http://www.viavac.ch/

the Design Research evaluation process is possible. The first prototype is intended as a patient version, in which the patient can deposit his vaccinations. Another version with special views for medical personal or doctors is designed in a future step of the development process (*Development*). The prototype is based on a client-server model with minimal data storage on the client side. On the mobile device only the pre-vaccination and the information about the user themself is stored. In a future version of the application, this information will be received from a server too. The recommendations for necessary travel vaccinations are retrieved from a central server. However, no permanent internet connection is necessary because the recommendations are cached and updated at regular intervals (*Artifact*).

7 Conclusion and outlook

In this paper we have used a design science approach to the design and prototyping of a vaccination card application for mobile devices. Following the identification of requirements and analysis of the capability of existing products the concept for an applications was developed. In addition we present a prototypical implementation for mobile devices.

This first prototype can be seen as a proof of concept for a mobile vaccination card application. The next step will be an evaluation with possible users from different demographic backgrounds to get detailed information about the prototype and the conceptual design. This way, the gathered information will be analyzed, structured and prepared to build the foundation for a new re-designing development cycle. Due to the cross-platform approach the prototype could be provided for other operating systems in the following stages of development. Further development measures are outsourcing the user profiles and the complete data of a user's vaccination card in a database on a central server (backend system). In the future, the entire project could be stored centrally on the server of a specialized service provider in electronic health care that would also ensure the privacy compliance. A detailed discussion of the security and privacy aspects together with a possible design concept was left out in this paper and will be realized and implemented in a future version of the prototype.

In a further step, a prototypical version for medical personal or doctors will be realized, which allows the vaccinating doctors to enter vaccinations for the patient. This version is currently planned as a web service and maybe has a connection to the practice management software of the doctors to allow a better integration into the existing IT service landscape. For these further steps, a system that allows the identification of physicians and grants the appropriate permissions for entries and changes to vaccination cards is needed. The future use of the electronic identity card or the electronic health card for unique identification of medical personal is investigated under this aspect. A partnership with a leading software provider in this market segment is already initiated. In addition, in a separate research project, legal conditions and sustainable business models of such mobile health care applications are examined. This project also includes the integration into a comprehensive mobile health management system, which can provide the end user a lot more personally configurable mobile health services.

The meta-goal of all those services is the "*empowerment of the patient*" which assumes that a higher self-responsibility for all personal health issues forms a basic building block for

sustainable welfare of a society (Lau 2002; Lenert 2009; Salmon & Hall 2004). The mobile vaccination certificate is classified as one further component of this eco-system. Developing numerous applications which help to give the patient more power over his medical data in methodic design research cycles can help answering the underlying research questions paving the way to reach that goal.

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