



## Educating parents about the vaccination status of their children: A user-centered mobile application

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### ARTICLE INFO

#### Article history:

Received 22 July 2016

Received in revised form 6 January 2017

Accepted 8 January 2017

Available online 14 January 2017

#### Keywords:

Immunization  
Patient education  
Vaccination history  
Patient empowerment  
Mobile health  
Electronic health records

### ABSTRACT

Parents are often uncertain about the vaccination status of their children. In times of vaccine hesitancy, vaccination programs could benefit from active patient participation. The Vaccination App (VAccApp) was developed by the Vienna Vaccine Safety Initiative, enabling parents to learn about the vaccination status of their children, including 25 different routine, special indication and travel vaccines listed in the WHO Immunization Certificate of Vaccination (WHO-ICV). Between 2012 and 2014, the VAccApp was validated in a hospital-based quality management program in Berlin, Germany, in collaboration with the Robert Koch Institute. Parents of 178 children were asked to transfer the immunization data of their children from the WHO-ICV into the VAccApp. The respective WHO-ICV was photocopied for independent, professional data entry (gold standard). Demonstrating the *status quo* in vaccine information reporting, a Recall Group of 278 parents underwent structured interviews for verbal immunization histories, without the respective WHO-ICV. Only 9% of the Recall Group were able to provide a complete vaccination status; on average 39% of the questions were answered correctly. Using the WHO-ICV with the help of the VAccApp resulted in 62% of parents providing a complete vaccination status; on average 95% of the questions were answered correctly. After using the VAccApp, parents were more likely to remember key aspects of the vaccination history. User-friendly mobile applications empower parents to take a closer look at the vaccination record, thereby taking an active role in providing accurate vaccination histories. Parents may become motivated to ask informed questions and to keep vaccinations up-to-date.

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### 1. Introduction

The World Health Organization (WHO) recommends that each patient-physician encounter should be utilized to determine the patient's

vaccination status (Robert Koch Institute, 2014; Hutchins et al., 1993). In an effort to harmonize vaccination records for international travel, the WHO has issued the *International Certificate of Vaccination or Prophylaxis* (WHO-ICV), sometimes referred to as “the yellow card” (World Health Organization, 2005).

In many European countries, centralized vaccination registries are not available, but parents are maintaining a paper-based vaccination record for their children at home (UNICEF, 2016). In Germany, the WHO-ICV is used as the standard vaccination record, where any routine, special indication and travel vaccines are documented (UNICEF, 2016; National Vaccine Advisory Committee, 2003). Parents rushing their children to the emergency department (ED) however, often forget to bring the WHO-ICV with them (Goldstein et al., 1993). Pediatricians and surgeons may require the information in the acute care situation (Macken et al., 2013; Brown, 2012). In these instances, the parents will be asked to remember which vaccines have been administered to their children

*Abbreviations:* ED, emergency department; SOP, standard operating procedure; QM, quality management; RSV, respiratory syncytial virus; ViVi, Vienna Vaccine Safety Initiative; VAccApp, Vaccination App, a mobile application for vaccination histories; VPD, vaccine-preventable disease; WHO, World Health Organization; WHO-ICV, International Certificate of Vaccination, issued by the World Health Organization.

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(“parental recall”) (Williams et al., 2007). The most common answer during verbal immunization histories is that the children have received “the usual vaccines”. Further details are often inaccessible (Miles et al., 2013).

The European Centre for Disease Prevention and Control (ECDC) as well as the VENICE project keep track on vaccination rates in different EU member states (VENICE II Consortium, 2012; Lopalco and Carrillo, 2014). According to ECDC, German vaccination rates are lower than in many other European countries (VENICE II Consortium, 2011). A recent global survey of vaccine acceptance around the world revealed that Europe is in fact the WHO region with the lowest vaccine acceptance (Larson et al., 2016). Germany is one of the countries with significant issues in this area. As a result, vaccine-preventable diseases (VPD) are still posing a health risk to children in Germany today. For example, the prevalence of measles infections remained high during the past decade, despite the universal recommendation and availability of measles vaccines (Neuhauser et al., 2014). Disease outbreaks are the consequence (Robert Koch Institute, 2016; Opel et al., 2014).

The combat against VPD would benefit from empowered parents, who are able to provide detailed and accurate vaccination histories and who are in a position to interpret what has been documented in the vaccination record (Sabnis et al., 2003). Scientific studies assessing the ability of lay people to understand and report the content of a WHO-ICV however, are lacking (Maurer et al., 2014).

To enable parents to report accurate vaccination histories, the Vienna Vaccine Safety Initiative (ViVI) has developed a digital vaccine education and empowerment tool (VAccApp) to be used on smartphones or tablet computers (MacFadyen, 2014; Norman and Yip, 2012; Seeber et al., 2015). The VAccApp was designed to invite parents to take a look at the WHO-ICV and to engage in a virtual dialogue covering all aspects of vaccines administered to their children, thereby making parents an active partner in protecting their family. The development of this educational intervention was informed by the data gathered from a separate group of parents, who tried to remember the vaccination status of their child in the absence of a vaccination record (“Recall Group”).

The verbal immunization histories generated awareness of knowledge gaps among parents and additional insight into how parents are remembering different kinds of vaccination events. This feedback was leveraged to create a user-friendly mobile application. The reported validation project was thus designed to assess the *status quo* and to test a practical means for improving the *status quo* using a beta version of the VAccApp. We are presenting the results of a validation study testing the VAccApp in the typical user-group of parents waiting for their child to be seen at a pediatric emergency room in Berlin, Germany. To the author’s knowledge no similar educational tools have been developed so far. Different applications and text message services for appointment reminders have shown promising results in increasing the vaccination rate among users but did not test the knowledge of parents regarding the vaccination status of their children (Oyo-Ita et al., 2011; Stockwell et al., 2012; Wakadha et al., 2013).

## 2. Methods

### 2.1. Participants

The validation project was conducted from March 2012–August 2014 in the context of quality management (QM) programs at the Charité Department of Pediatrics in collaboration with the Robert Koch Institute in Berlin, Germany, as described previously (Rath et al., 2013; Chen et al., 2014; Karsch et al., 2015; Obermeier et al., 2016; Tief et al., 2016). Infants and children (0–18 years of age) presenting to the ED or hospitalized with suspected vaccine-preventable diseases (e.g. influenza-like illness or infections of the central nervous system) participated in QM programs approved by the institutional review board (IRB, EA24/008/10, EA2/161/11). Their parents were eligible for

VAccApp user-testing. Informed consent procedures were waived by the IRB for the purpose of quality improvement.

### 2.2. Standard operating procedure (SOP)

According to the QM SOP, vaccination records were solicited from all patients participating in the QM program. When the WHO-ICV was available, a photocopy was obtained for manual data entry into an anonymized PostgreSQL database, performed by an independent data entry professional, followed by double-entry verification (gold standard).

When vaccination records were *not* available (in approximately 74% of cases) trained QM staff conducted structured interviews, asking the parents about the vaccination status for every VPD separately (i.e. “Was your child ever vaccinated against rotavirus?” – Yes/No/I do not know). After completion of the interview, parents were asked to hand in the WHO-ICV later, for a photocopy and professional data entry (“Recall Group”).

From January 2014–August 2014, those parents who were fluent in German and who had brought their WHO-ICV with them, were invited to transfer the information (as they understood it) from the WHO-ICV into the VAccApp (“VAccApp Group”).

Professional data entry from the same vaccination record served as the gold standard for the quality of data obtained with the VAccApp. Likewise, the quality of data obtained from verbal immunization histories in the absence of a vaccination record was compared to the gold standard, i.e. professional data entry from a vaccination record later provided by the parents.

Both the structured interview as well as the VAccApp solicited the same basic information regarding 25 different vaccine types.

The VAccApp also contained a brief pre/post testing feature, assessing potential short-term learning effects resulting from VAccApp utilization: Initially, participants were asked to remember off-record, whether their child had ever received any of three commonly used childhood immunizations. The same question was repeated immediately after VAccApp utilization. The pre/post testing had to be completed without consulting the WHO-ICV or the VAccApp.

After using the VAccApp, parents were also invited to provide a feedback regarding the mobile application itself, using a standard instrument, the so-called System Usability Scale (Brooke, 1996; Bangor et al., 2008). The System Usability Score consists of ten statements (e.g. “I felt very confident using the app”), which are judged by the user on a five point Likert scale. Scores are reported ranging from 0 (“worst imaginable”) to 100 (“best imaginable”) (Brooke, 1996; Bangor et al., 2008).

### 2.3. VAccApp design

The VAccApp was designed to help parents understand the vaccination record of their children. The mobile application was developed by ViVI, a Berlin-based vaccine safety think tank and non-profit organization, in collaboration with the School of Design Thinking in Potsdam, Germany (Seeber et al., 2015). Design Thinking is an innovation technique first taught at Stanford University with a strong focus on user-centeredness and interdisciplinary thought processes (MacFadyen, 2014). The visual language of the VAccApp is non-threatening and playful, using graphical representations of health care practitioners and vaccine recipients (avatars) keeping the user engaged.

For the purposes of the QM program, the VAccApp beta version was provided on Google Nexus 7 Tablets™ as a mobile application for Android systems (Seeber et al., 2015). During the evaluation period, the VAccApp remained on the tablet computers provided by QM staff. Parents entered the requested information autonomously and anonymously while waiting for their child to be seen by a doctor.

When using the VAccApp, parents were instructed to open the vaccination record and to look up any of the requested information in the

WHO-ICV. The questions in the App were presented by avatars representing either a physician or a nurse, asking for example “Is your child vaccinated against tetanus?” (Fig. 1)

After the initial yes/no/unknown response, the avatar assisted the user in localizing pertinent information in the WHO-ICV and on product labels. Parents could also enter the name and number of immunizations received, including booster vaccinations, batch numbers, and vaccination dates. The queries were repeated for every vaccine type separately (named after the respective VPD), including special indication and travel vaccines.

#### 2.4. Statistical analysis

Descriptive analyses were executed using Microsoft Excel 14.0.7 and basic statistical analyses with IBM SPSS Statistics 22.

Table 1 illustrates the demographic characteristics of patients participating in the VAccApp Group compared to the Recall Group. *P*-values were computed using the Whitney *U* test and the Chi-square test to assess whether the groups were significantly different from each other.

Responses from the structured interview and VAccApp entries were both compared to gold standard, i.e. professional data entry from photocopies of the respective WHO-ICV. Bivariate statistical analysis was performed, assessing the percentage of parents able to provide a complete vaccination history (i.e. with 25/25 correct answers) in either group (VAccApp and Recall Group).

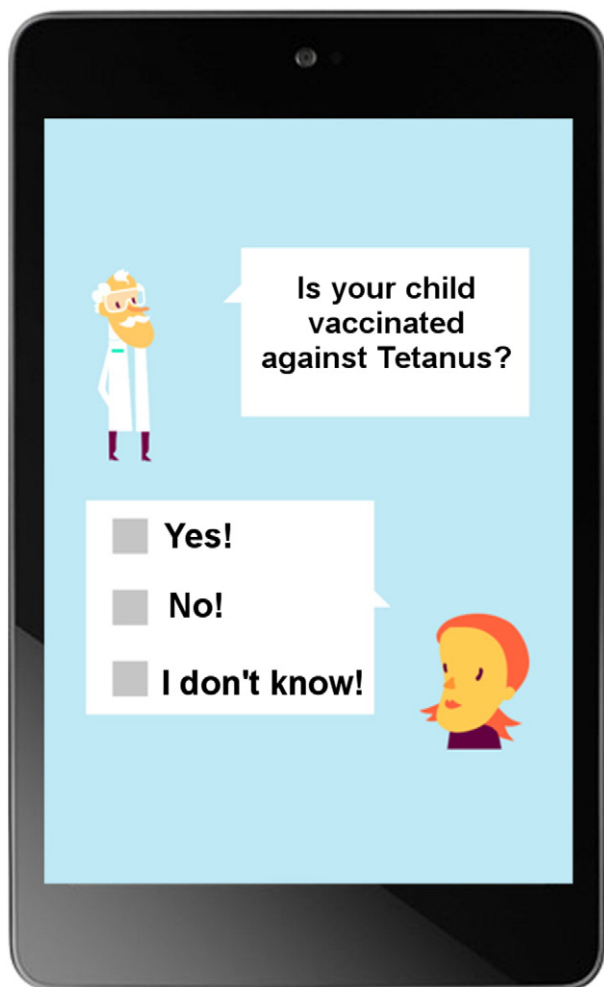


Fig. 1. Example of the VAccApp user interface.

**Table 1**  
Participant characteristics.

Patient characteristics	VAccApp Group	Recall Group	<i>p</i> -Value
Age of the child (mean in months) range	38.7 (2180)	82.1 (2216)	<0.001
Gender (% male)	56.2	49.3	0.151
First or second generation international migrant (%)	51.1	52.9	0.708
Race (%)			
Caucasian or White	83.1	75.2	<b>0.046</b>
Middle Eastern or North African	10.1	13.7	0.254
African American or Black	2.2	3.2	0.529
Asian	2.2	2.5	0.838
Native Hawaiian or other Pacific Islander	0.0	0.4	0.399
Other	0.6	0.7	0.898
Unidentified	1.7	4.3	0.129
Ethnicity (%)			
Hispanic or Latino	1.1	0.7	0.651
Non-Hispanic or Latino	96.6	92.1	0.051
Other	1.1	2.2	0.385
Unidentified	1.1	5.0	0.027
Number of individuals living in household (mean)	3.7	3.9	0.140
Birth rank of the child among siblings (mean)	1.6	1.7	0.501

Baseline characteristics of patients in the VAccApp Group ( $n = 178$ ) compared to the Recall Group ( $n = 278$ ). *p*-Values were computed using the Whitney *U* test and the Chi-square test to assess whether the groups were significantly different from each other. Boldface indicates statistical significance ( $p < 0.05$ ). The evaluation project was conducted between 2012 and 2014 in Berlin, Germany.

Overall accuracy rates were expressed as the percentage of the 25 vaccine questions in the VAccApp or structured interview, which a parent had been able to answer correctly.

In addition, vaccine-specific accuracy rates were computed for each vaccine type separately, and expressed as the proportion of parents providing accurate responses with either the VAccApp or during structured interviews.

For the pre/post testing, the percentage of accurate responses before and after VAccApp utilization was compared using the Chi-square test.

### 3. Results

#### 3.1. Baseline characteristics

464 parents had initially brought the vaccination record with them. Of these, 178 parents participated in the program, completing the user-testing of the VAccApp (VAccApp Group). Ten parents declined participation. The remaining 276 parents were unable to participate in the user-testing due to lack of time or language skills.

A total of 278 parents did not have the vaccination record initially but were able to provide it at a later time (Recall Group) for comparison between parental recall and the same gold standard (professional data entry).

The composition of the VAccApp Group and the Recall Group is described in detail in Table 1. The two groups differed significantly with respect to mean patient age and ethnicity: children in the VAccApp Group were younger, and more participants in the VAccApp Group identified as Caucasian ( $p < 0.001$  and  $p = 0.048$ , respectively). The remaining baseline characteristics were comparable between groups.

#### 3.2. Overall and vaccine-specific accuracy rates in the Recall Group

Having no WHO-ICV at hand, 9.0% of parents in the Recall Group provided a complete and fully accurate vaccination status (responding to 25/25 questions correctly). On average, 39.2% of the questions were answered correctly. Additional detail was not requested in the Recall Group. The majority of parents in the Recall Group (82.7%) indicated that their children were up-to-date on recommended immunizations, but when asked to respond to vaccine-specific questions, 41.7% parents responded with “I do not know” to at least 24 out of 25 vaccine

**Table 2**  
Vaccine-specific accuracy rates in the Recall Group.

	Vaccine type	Accurate responses in the Recall Group (%)
Routine childhood vaccines	Tetanus	41.01
	Diphtheria	35.97
	Polio	35.25
	Pertussis	35.25
	Haemophilus influenzae type b	29.86
	Hepatitis B	31.29
	Mumps	39.21
	Measles	39.21
	Rubella	38.85
	Pneumococcus	24.10
	Meningococcus	23.74
	Varicella	30.94
	Rotavirus	38.13
Special indication vaccines or passive immunization	Human papilloma virus	43.53
	Influenza	69.06
	Hepatitis A	38.85
	Tick-born encephalitis	42.81
	RSV (palivizumab)	43.17
	Tuberculosis	41.01
	Typhoid fever	42.45
	Yellow fever	42.09
	Rabies	42.81
	Cholera	42.81
	Japanese encephalitis	42.81
	Small pox	42.09

Vaccine-specific accuracy rates describe the percentage of parents providing accurate vaccine-specific responses by recall only, i.e. without the vaccination record at hand ( $n = 278$ ). Professional data entry from the original vaccination record served as gold standard. RSV = respiratory syncytial virus (passive immunization).

questions. Accuracy rates varied by vaccine type (Table 2) and ranged from 23.7% for meningococcal vaccine to 69.1% for influenza.

### 3.3. Overall accuracy rates and vaccine-specific accuracy rates in the VAccApp Group

With the help of the VAccApp and the vaccination record, 61.8% of participants were able to provide a fully accurate vaccination status. An average of 24/25 (95.2%) accurate responses was achieved. When asked to provide additional detail, such as the number of vaccine doses administered and the dates of administration, accuracy rates declined progressively, but 25% of VAccApp users were able to provide all additional detail accurately. Vaccine-specific accuracy rates ranged from 85.4% for meningococcal vaccine to 100% for special indication and travel vaccines such as cholera, typhoid fever, rabies and Japanese encephalitis vaccines (Table 3).

### 3.4. Learning effects and usability score

The pre/post testing revealed a significant short-term learning effect as illustrated in Fig. 2.

Prior to VAccApp utilization and without looking at the WHO-ICV, 24.7% of parents (44/178) were able to answer all three sample questions correctly, compared to 63.5% after VAccApp utilization ( $p < 0.0001$ ). System Usability Scores ranged from 35 to the maximum score of 100, with an average score of 69.6 (Table 4).

## 4. Discussion

Vaccines are powerful tools for disease prevention (Cherian and Okwo-Bele, 2014). With vaccine hesitancy on the rise, parents are seeking reliable information helping them to distinguish fact from fiction (Downs et al., 2008; Strelitz et al., 2015). The active involvement of

**Table 3**  
Vaccine-specific accuracy rates in the VAccApp Group.

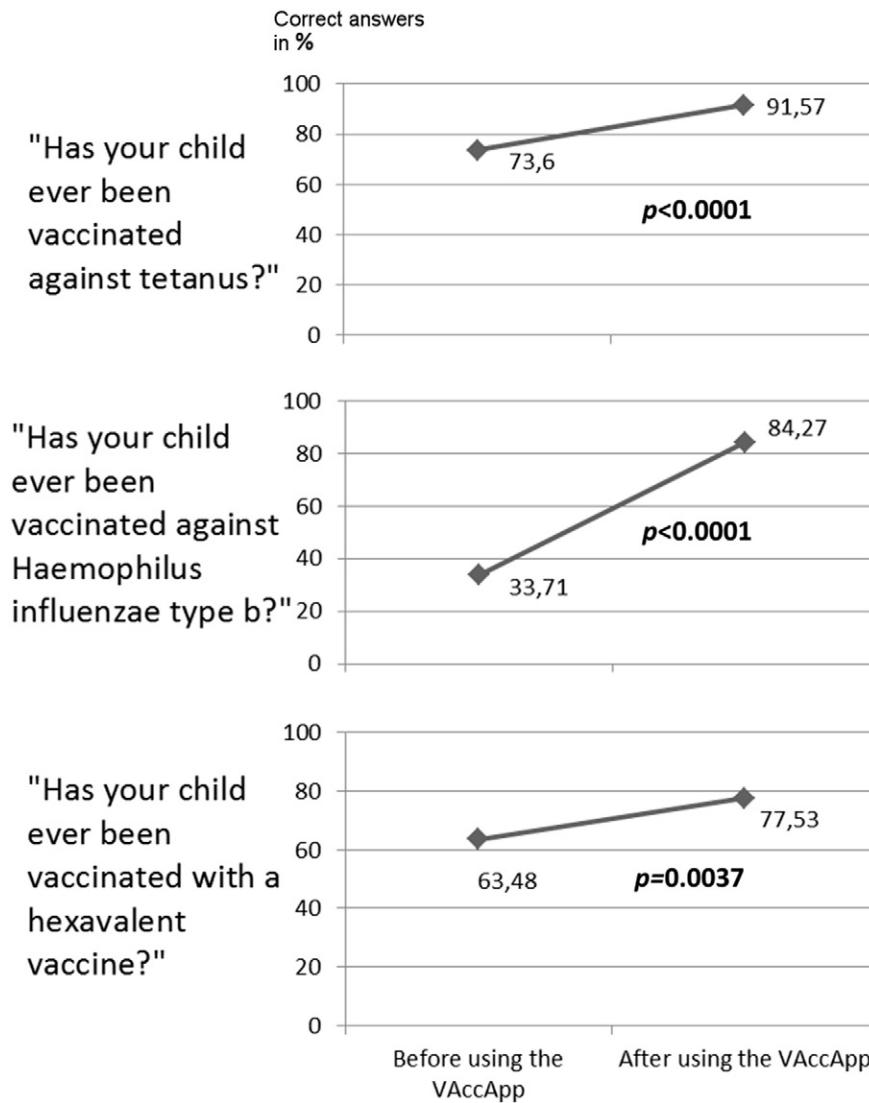
	Vaccine type	Accurate responses in the VAccApp Group (%)
Routine childhood vaccines	Tetanus	96.07
	Diphtheria	94.38
	Polio	93.82
	Pertussis	93.82
	Haemophilus influenzae type b	91.01
	Hepatitis B	93.82
	Mumps	89.89
	Measles	91.01
	Rubella	92.13
	Pneumococcus	90.45
	Meningococcus	85.39
	Varicella	91.57
	Rotavirus	97.75
Special indication vaccines or passive immunization	Human papilloma virus	99.44
	Influenza	93.26
	Hepatitis A	97.19
	Tick-born encephalitis	98.88
	RSV (palivizumab)	96.07
	Tuberculosis	98.31
	Typhoid fever	100.00
	Yellow fever	99.44
	Rabies	100.00
	Cholera	100.00
	Japanese encephalitis	100.00
	Small pox	99.44

Vaccine-specific accuracy rates describe the percentage of parents providing accurate vaccine-specific responses when entering data from the original vaccination record into the VAccApp ( $n = 178$ ). Professional data entry from the original vaccination record served as gold standard. RSV = respiratory syncytial virus (passive immunization).

parents in matters of vaccine prevention may contribute towards restoring trust (Oyo-Ita et al., 2011; Fadda et al., 2015; Odone et al., 2015). Many parents have difficulties recalling the vaccination status of their child, which was shown by several studies earlier and confirmed by the current evaluation (Miles et al., 2013; McVicar, 2013). Parents need encouragement and support when keeping track of the vaccination record of their children (Thorpe et al., 2016; Varkey et al., 2010). This may be particularly important in larger families with many children (Byington et al., 2015; Monto et al., 2014; Pearce et al., 2015; Amin et al., 2013; Oliveira et al., 2014). Current vaccination records however, are not designed to be used or understood by lay people.

Technical innovation may help parents to understand the vaccination status of their children. The VAccApp guides parents through the paper record allowing them to store the data for themselves in an easily accessible format. In this validation study, the App was user-tested by parents who were waiting for their child to be seen at an academic children's hospital in Germany. Use of the VAccApp motivated parents to take a closer look at the vaccination record of their children, often for the first time. It may be encouraging to doctors and patients alike, that VAccApp users were able to complete 95% of vaccine questions in the App correctly. A total of 62% responded to 100% of the questions correctly, thereby providing a complete and accurate vaccination history. These results indicate that with the help of the WHO-ICV and the VAccApp, the majority of parents are able to understand and interpret the vaccination history of their children accurately.

The reported validation project aims to test the functionality and feasibility of the VAccApp in a typical user group, with the limitation of a convenience sample derived from a single center. The QM project was not designed or powered to assess differences between subpopulations. It is possible that parents who remembered to bring the vaccination records to the emergency room also showed a greater interest in keeping their child's vaccinations up to date. Using the VAccApp will always require a minimum level of interest in the topic of vaccines and



**Fig. 2.** Pre/post testing illustrating short-term learning effects. Short-term learning effects are illustrated before and immediately after use of the VAccApp: pre/post testing questions are displayed separately with regards to tetanus, *Haemophilus influenzae* type b, and hexavalent vaccine.

**Table 4**  
Results of the system usability assessment.

System Usability Scale	Mean value on Likert scale (1-strongly disagree; 5-strongly agree)
#1: I think that I would like to use this app frequently.	3.57
#2: I found the app unnecessarily complex.	2.29
#3: I thought the app was easy to use.	3.89
#4: I think that I would need the support of a technical person to be able to use this app.	1.87
#5: I found the various functions in this app were well integrated.	3.70
#6: I thought there was too much inconsistency in this app.	2.03
#7: I would imagine that most people would learn to use this app very quickly.	3.41
#8: I found the app very cumbersome to use.	2.48
#9: I felt very confident using the app.	3.74
#10: I needed to learn a lot of things before I could get going with this app.	1.81

After using the VAccApp for the first time, users were asked to assess the usability of the VAccApp, using the System Usability Scale (Brooke, 1996; Bangor et al., 2008). The assessment resulted in an overall System Usability Score of 69.5 out of possible 100 points, individual scores ranging between 35 and 100.

immunization. The VAccApp was decisively *not* designed as a substitute vaccination record, but as a helpful tool and encouragement for parents to take an active part in keeping their children healthy. Since the validation study was embedded in a QM program, randomization was not possible. Evidently, those parents who did not bring the vaccination record with them, could not have been asked to enter data from an absent vaccination record. Instead, they proceeded with verbal immunization histories as per standard of care.

The goal of this study was to study the ability of parents to understand the content of a standard vaccination record with the help of a mobile application. The results were compared to professional data entry into a standard clinical database using a copy of the same vaccination record.

The Recall Group served as a reminder that the quality of the information gained with verbal immunization histories (which are common practice) is in fact, very low. Minor demographic differences were observed: VAccApp users had younger children on average compared to the Recall Group. Younger children are vaccinated frequently, thus parents may be more likely to remember bringing the vaccination record with them to a doctor's visit.

The VAccApp can provide an important service with reminders for booster immunizations and motivating parents to remain well informed

about the vaccination status of their children. The visual clues of the App help parents to see where they are in the process, to keep appointments and to prevent unnecessary delays in immunizations (Hofstetter et al., 2015; Jordan et al., 2015; Uddin et al., 2016; Schlumberger et al., 2015). At the same time parents generate important information to be

stored on their smartphones, which may be helpful at any time when the vaccination record may not be at hand. In the future, it will be important to engage older children and adolescents to learn more about their own health and vaccination status. Future studies evaluating the VAccApp in schools or adolescent clinics are currently being developed.

4 Certificate of **vaccinations\*** against:      Certificat de **vaccinations\*** contre:  
 Bescheinigung über **Schutzimpfungen\*** gegen:

Date Datum	Polio- myelitis (oral) Polio- myélite	Diph- theria Diph- térie Diph- therie	Tetanus Tétanos	Pertussis Coque- luche	Haemophilus influenzae b (HIB)	Signature and stamp of physician Signature et cachet du médecin Unterschrift und Stempel des Arztes
19. 11. 93	X				0	DM Martinus Leipzig Kinderarzt
	30123 A		27 3071		30043	
04. 1. 94	X					Leipzig Kinderarzt
18. 1. 94			26 001 B			
23. 02. 94						Leipzig Poliklinik Metzdammstr. 1 05500 Mendota DM Martinus Kinderarzt
13. 12. 94	X		310 X - 21			
16. 1. 95						Leipzig Kinderarzt
			310 15 - 17		HIB-DPT	

\* Show by „x” in the appropriate column(s) the vaccination(s) performed and/or give the vaccine dose. Invalidate unused spaces by „Ø”.  
 Indiquer par «x» les vaccinations dans la colonne relative ou inscrire la dose appliquée. Annuler les espaces en blanc par «Ø».  
 Impfungen in betreffender Spalte ankreuzen oder Impfdosis eintragen. Freie horizontale Spalten ungültig machen durch „Ø”.

Immuneisation against – Immunisation contre – Schutzimpfung gegen

Date Datum	Measles Rougeole Masern	Parotitis Parotite Mumps	Rubella Rubéole Röteln	Signature Unterschrift
13. 12. 94	MHR	074011A (Vax)		DM Martinus Leipzig Kinderarzt
45. 06. 2004		27. 07. 04 MHR		

Immuneisation of prepubertal girls (10th–14th year) against rubella and women taking oral contraceptives  
 Immunisation de fillettes prépubères (âge de 10–14 ans) et de femmes sous contraception orale  
 Impfung gegen Röteln für Mädchen vor der Pubertät (10.–14. Lebensjahr) und Frauen unter kontrazeptivem Schutz

Date Datum	Vaccine and dosis Vaccin et dose Impfstoff und Dosis	Signature Unterschrift

Rubella antibody assays: a) 10 weeks or more after immunization    b) Immunization omitted because of existing immunity  
 Dosage d'anticorps anti-rubéoliques: a) 10 semaines ou plus après l'immunisation    b) Immunisation omis à cause d'une immunité préexistante satisfaisante  
 Röteln-Antikörper-Bestimmungen: a) 10 Wochen oder mehr nach Impfung    b) Impfung unterblieb, weil Immunität bestand.

Date Datum	Methods Méthodes Methode(n)	Titers or sim. Titres or sim. Titer o. ä.	Signature Unterschrift
a)			
b)			

Fig. 3. The WHO International Certificate of Vaccination or Prophylaxis (WHO-ICV). Routine childhood vaccines (such as poliomyelitis vaccine) are presented in a matrix format (a). Other vaccinations (such as hepatitis A vaccine) are documented in a list format (b), which appears to be more difficult for parents to read.

Vaccinations against influenza (FIV) Vaccinations contre la grippe Schutzimpfungen gegen Influenza (Grippe)			
Date Datum	Vaccine Vaccin Impfstoff	Dose Dosis	Signature of physician Signature du médecin Unterschrift des Arztes

Other vaccinations Autres vaccinations Weitere Schutzimpfungen, z. B. gegen Typhus abdom. (Typhoid fever, Fièvre typhoïde), Cholera, Pneumococcosis, FSME, Tollwut (Rabies, Rage), Meningitis u. a.			
Date Datum	Kind of vaccination Manière de vaccination Art der Impfung	Dose Dosis	Signature Unterschrift
4.11. 2004	Twinrix Kinder Ch.-B.: HAB29689 16102	0,5 ml	Dr. med. Rathe O.
2.12. 2004	Twinrix® PEDIATRIC Lotter: HAB29689 Schadl.: 04-2006	0,5 ml	Dr. med. Rathe O.
6.4. 2006	Twinrix® KIDNER Ch.-B.: AHAB039CK	0,5 ml	Dr. med. Rathe O.
14.10. 2006	NeisVac-C® Ch.-B.: Bexser verwendet bis VN904389 06/2009	0,5 ml	Dr. med. Arztin für Allge- und Ne-
26.7. 2008	GARDASIL® Ch.-B.: NH17630	0,5 ml	Dr. med.
26.5. 2009	Gardasil® FA f. All Ch.-B.: NH41920 Verwendbar bis: 09.2010	0,5 ml	gemeinmedizin/Naturheilverfahren/ Homöopathie
12.11. 2009	GARDASIL® Ch.-B.: NH38490	0,5 ml	

Fig. 3 (continued).

Additional multi-center validation studies assessing differences in various settings, geographic regions and population strata, are planned. For those using regular telephones rather than smartphones, the VAccApp could be made available online for password-protected data entry via short message service or public computers.

While it would always be recommended for parents to bring the vaccination record to the hospital, this was the case in only 26% of parents in our setting. In Europe, parents may not be aware of their responsibility in this regard, unless their pediatrician has encouraged them to get involved in keeping vaccinations up-to-date.

In our validation setting, parents in the Recall Group were most likely to remember travel and special indication vaccines. This may be due to the fact that “exotic” vaccines require active decision-making on behalf of the parent, for example prior to taking a vacation in an exotic destination (Bouder, 2015; Grimaldi-Bensouda et al., 2013; Daum et al., 1995; Betsch et al., 2012; Hagen et al., 2008).

If the vaccination status was requested consistently during every doctor's visit, parents would grow accustomed to taking the vaccination record with them, including in stressful situations. This is evident from the ability of parents to remember the tetanus vaccination status better than other routine childhood vaccines, possibly due to the ‘positive reinforcement’ and frequent questioning by surgeons (Hagen et al., 2008). Parents in this validation setting responded to vaccine-related questions while waiting for their children to be seen in the pediatric ED. This is also the “natural” setting where immunization data are relevant and when parents are likely to be motivated to learn about the vaccines protecting their children.

In many countries including in the US, the responsibility of maintaining vaccination records remains with the physician, the school system, or public health institutions, as would be the case with national or regional vaccination registries (Miles et al., 2013; Maurer et al., 2014;

Dombkowski et al., 2014). Parents who are interested to create their own, portable vaccination record for their children, may take photos of the vaccination record to keep it in their smartphones.

While the accuracy of vaccination data may be higher with this approach, the VAccApp project was intentionally designed to empower parents to keep track of vaccinations in their family and to ask clarifying questions during the doctor's visit, rather than delegating the entire task to the healthcare provider (Seeber et al., 2015).

The design of the VAccApp was a strength, as it was assessed by parents in the System Usability Survey. This may be due to an appealing user surface and the interaction with avatars. Completing the record in the VAccApp for the first time can be time consuming, as it required around 30 min. The time may be readily available and well-spent during waiting hours in the ED. Future vaccinations can be added later within a few minutes. Parents will be able to create one vaccine and risk factor profile per child, which can be linked through a common login for the entire family. Currently, the VAccApp assesses the vaccination status for 25 different vaccines, updates will be necessary for newly recommended vaccines. The VAccApp is available in German language, and translation into multiple additional languages is underway. The VAccApp will also need to be adjusted to accommodate different vaccination schedules across Europe and beyond.

The VAccApp validation provides useful insight on how the accuracy rate of 62% could be improved further: Routine childhood vaccination data are usually provided in a matrix format in the WHO-ICV (Fig. 3a), which appeared self-explanatory to most parents. Pages in the WHO-ICV where vaccines were listed individually (meningococcal vaccines for example, see Fig. 3b; Table 3) were more likely to induce errors.

Additional guidance may be helpful. Future versions will provide “need clarification” signifiers reminding the parent to ask clarifying questions during upcoming physician visits, thereby improving data

quality over time (Hostetter and Klein, 2016). The learning effect with the initial version of the *VAccApp* showed promise for future developments.

The *VAccApp* is in full compliance with Clinical Data Interchange Standards Consortium (CDISC) data standards, including the Clinical Data Acquisition Standards Harmonization (CDASH), the Biomedical Research Integrated Domain Group (BRIDG) Model and the Study Data Tabulation Model (SDTM), thereby meeting regulatory requirements (Maurer et al., 2014; Souza et al., 2007; Fridsma et al., 2008; Hill et al., 2015; Censi et al., 2015). This will be useful if *VAccApp* entries are used in clinical trials, as well as safety and effectiveness studies. It also ensures Health Insurance Portability and Accountability Act (HIPAA) compliance and data interoperability (Maurer et al., 2014; Free et al., 2013; Brown et al., 2014; Atkinson et al., 2015; Gates Foundation, 2016). Eventually, the user should be able to choose whether data are stored locally on the personal device or saved in a cloud system, if so desired (Burgess et al., 2016).

Several vaccine-related mobile applications are under development, e.g. the “Vaccine Record for Travellers” in Australia (Mills, 2016), “ImmunizeCA” in Canada (Canadian Public Health Association, 2016; Wilson et al., 2015; Atkinson et al., 2016), and “myViavac” in Switzerland (Stiftung meineimpfungen, 2016). The majority of these applications issue reminders for immunization appointments (e.g. “Save The Date” (NSW Ministry of Health, 2016), “Vaximate” (Pfizer Australia, 2016)), or provide vaccine information (e.g. “Shots Immunizations” (Society of Teachers of Family Medicine (STFM), 2016), “Vaccines on the go” (Vaccine Education Center at The Children’s Hospital of Philadelphia (VEC), 2016)).

The *VAccApp* has an entirely different focus and represents the first user-centered education and empowerment tool allowing parents to understand the content of the vaccination record in addition to storing the data in a safe place. Well-informed parents who support and maintain vaccination records will have an improved sense of control and the ratification of playing an active role in keeping their children healthy (Fadda et al., 2015; Thorpe et al., 2016; Varkey et al., 2010; Kundi et al., 2015). Parents, who have an active interest in vaccinations, will likely encourage their peers to do the same, thereby improving public knowledge and appreciation of immunization programs (Yeung et al., 2016; Gargano et al., 2015).

## 5. Conclusions

Informed parents are more likely to appreciate the benefits of vaccines. With patient-reported outcomes becoming increasingly relevant to regulators, user-centered mobile applications may help to shift the attention to the vaccine recipient. The learning effect of digital vaccination apps could be further improved by providing additional feedback-loops for vaccine follow-ups this generating additional data sources for the monitoring of vaccine safety in real-time (Lindemann et al., 2016; Panatto et al., 2016). With children and adolescents representing the next generation of parents and caretakers, it will be important to develop age-appropriate forms of vaccine communication (Lee et al., 2016). Digital vaccination records will be easily accessible to adolescents and young adults, who rarely seek physician appointments (Stockwell et al., 2012; Wakadha et al., 2013; Johnson et al., 2008; Kharbanda et al., 2011; Castano et al., 2013; Amicizia et al., 2013). Innovative visual language, based on gender and ethnic equality, is key to patient-driven vaccine communication.

## Contributions

Conceived and designed the project: BR with SB, SD, and BS. Contributed to data acquisition: LS, PO, XC, KK, SM, and FT. Analyzed and managed the data: LS, TC, and CH. Wrote first draft of the manuscript: LS. Contributed to the writing of the manuscript: BR, PO, and TC.

All authors reviewed and approved the final version of the manuscript.

## Financial & competing interests

The authors have no conflicts of interest to declare. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. No writing assistance was utilized in the production of this manuscript.

## Acknowledgments

The authors thank the Vienna Vaccine Safety Initiative for providing the *VAccApp* for the validation study. The authors are grateful for the support by Profs. Christoph Meinel and Uli Weinberg and the School of Design Thinking at the Hasso Platter Institute in Potsdam, Germany. They also thank Maria Klokow and Andreas Raetz for supporting IT and data entry.

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