



## *Vienna Vaccine Safety Initiative*

### **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.

## Case Study (I)

The WHO recommends that each patient-physician encounter be used to check the immunization status of a patient, and to provide/plan catch-up vaccinations, if necessary.

The way immunizations are documented varies across Europe. In Germany, the vaccination record is a patient-held document. In the case of minors, it will remain in the hands of the parent or guardian. In the past, different types of paper-based records were in East and West Germany. Ever since the mid-late nineties, paediatricians in Germany are documenting routine childhood immunizations in the WHO International Certificate of Vaccination (WHO-ICV), also referred to as the 'yellow card'. The document is given to the parent after each vaccination visit. [Maurer et al. 2014]

As one can imagine, a paper record may get lost or destroyed. Parents, not always living in the same place, may lose track of its whereabouts. In times of stress, for example when rushing an ill child to the emergency room (ER), the record may not be available in time. At the same time, few parents remember off-hand which vaccines have been given to which one of their children and relatives. With vaccine hesitancy on the rise, it will be important to empower parents across Europe to be well-informed about the vaccination status of their children and to become active partners in health.

## Case Study (II)

Baseline assessments in a paediatric quality improvement (QI) program in Berlin, Germany in collaboration with the Robert Koch Institute revealed the following frontline challenges:

(a) Only 20% of parents taking their children to the ER for suspected meningitis or respiratory infections, i.e. potentially vaccine preventable causes, had remembered bringing the child's vaccination record with them.

(b) When asked which vaccines the child had received (the standard-of-care procedure at the time) the most common reply was "oh, the usual ones". Parents seemed unable to provide a detailed verbal immunization history and many did not think that they should.

We observed the process over several months and realized that, even if parents thought that their children's immunization status was "up to date", they did not know off-hand what this entailed. Early adopters among ER staff were concerned that they may be relying on inaccurate vaccination histories in their routine practice.

We conducted a systematic review of the literature and found that this concern is consistent with publications in Europe and North America. [Maurer et al. 2014] The review confirmed that so-called "verbal immunization histories" are unreliable with potentially negative consequences for quality of care. This situation may also impact vaccine pharmacovigilance: vaccine safety and effectiveness cannot be monitored unless the vaccination data are accurate. The typical information in ER discharge summaries may thus be of limited value. Routine ER records fail to discriminate whether the vaccination history was elicited from a parent's memory or from the actual WHO-ICV document.

## **Actions Proposed**

We developed the VAccApp, an avatar-based mobile application for parents, allowing them to understand and structure the information contained in the vaccination record of their child with ease. The VAccApp is designed to trigger questions and to awaken interest in the vaccination status of the children or other family members. A ‘traffic-light system’ was built into the App, allowing parents to indicate if they were uncertain about a specific vaccine, allowing them to go back to these questions during the next physician visit. The desired effect was to improve the quality of immunization histories solicited in acute care settings (parents always bring their phone with them, but often forget the paper records) and to empower parents to be better informed about the expected benefits of immunisation, i.e. the vaccine protection of their children. The VAccApp was conceptualized and designed during a pro-bono project with the School of Design Thinking in Potsdam, Germany, [Seeber et al. 2015] and subsequently validated in a “real-world” setting, as described in a separate publication [Seeber et al. 2017].

Future steps following the successful validation of the VAccApp in the clinical practice, include translation into multiple EU languages and development for both, android and iOS systems. Extended features will include confirmation of abstracted vaccination records by healthcare professionals, alignment of the vaccination status with immunization schedules across Europe, and links to WHO-approved information sources in various languages.

## Methodology

As part of an established QI Program for children with acute respiratory infections or meningitis in Berlin, vaccination records were solicited from all parents bringing their children to the ER.

Parents, who had *not* remembered to bring the vaccination record along to the ER, underwent structured interviews administered by QI staff regarding any immunizations received by the child. Parents were then asked to provide the WHO-ICV later.

Parents, who *had* brought the WHO-ICV with them, were asked to use the time in the ER waiting room to take a closer look at the child's WHO-ICV and to enter the immunization information via VAccApp. The information was compared to the information entered by a professional data entry staff from an anonymized copy of the same vaccination record.

The VAccApp beta version was provided on Google Nexus 7 Tablets™ as a mobile application for Android systems. The VAccApp remained on the tablet computers provided by QI staff. Parents entered the requested information autonomously and anonymously while waiting for their child to be seen by a doctor.

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

## Results (I)

The detailed results of the validation project are published in Public Health Reports, Seeber et al, 2017: “Educating parents about the vaccination status of their children: A user-centered mobile application.”

Power analysis revealed a minimum participant number of 150. From January 2014–August 2014, a total of 178 parents participated in the program, completing the user testing of the App (VAccApp Group). 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).

Accuracy rates with immunization histories provided via VAccApp (VAccApp Group) were compared to professional digital data entry into a database. Similarly, in the Recall Group, the *status-quo* (verbal immunization histories) was compared to professional data entry from the same patient’s immunization card. The stated QI goal was a 50% improvement in the accuracy of immunisation data provided to the physician during the ER visit through VAccApp use.

Vaccine information was solicited individually to assess differences in awareness of specific vaccines/ vaccine components.

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. 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 24/25 vaccine questions.

## Results (II)

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.[Tables 2 and 3 in Seeber et al. 2017]

Parents were also asked to participate in answering a subset of sample questions before looking at the WHO-ICV and VAccApp, and once again after data abstraction was completed. For the pre/post testing before and after use of the VAccApp, the percentage of accurate responses before and after VAccApp utilization was compared using the Chi-square test.

The pre/post testing revealed a significant short-term learning effect [Figure 2 in Seeber et al. 2017]. 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 in Seeber et al. 2017]

## **Conclusions (I)**

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. The App was user-tested by parents 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.

### **Relevance**

The impact of introducing VAccApp use in the ER was significant: The workflow was improved. Parents welcomed the ability to do something useful for their child while waiting, taking control of the situation. Parents were less impatient while waiting, yielding higher quality information and asking targeted questions during the subsequent physician encounter.

### **Effectiveness**

Usability testing (using a standard System Usability Test) revealed that parents found the App easy to use. The quality of the vaccination data reported to the physician was significantly improved. Parents took an active role in keeping track of the immunizations administered to their children. School-aged children and adolescent ER patients observed and supported their parents' use of the App, gaining interest in their vaccination status.



## **Conclusions (II)**

### **Transferability**

The VAccApp provides a low-cost/high impact tool that will encourage parents to take an active role in tracking their child's vaccination status, thereby improving vaccine acceptance. Next steps include translation of the VAccApp into multiple European languages and allowing users to compare adult and paediatric immunisations to the respective national schedule.

### **Sustainability**

The validated VAccApp will require regular updates and tech support. Additional optional features will be included, allowing parents to choose if they wish to abstract all vaccination histories in their family, whether they wish to seek verification by a healthcare professional and/or the ability to store the information in a secure cloud system.

### **Intersectional Collaboration**

The innovation team at the School of Design Thinking included young students from mathematics, social sciences, history, IT and design. The ViVI Think Tank, which developed the project further, is by definition interdisciplinary. The validation project required clinical and IT staff working hand in hand in prototyping and multiple iterations of the VAccApp. A data entry team was responsible for the abstraction of immunization records into a database, under supervision of a project coordinator. Data analysis was supervised by a bioinformatics specialist. Two National Reference Centres at the Robert Koch Institute were involved in the planning of the overall QI Program and in the analysis and interpretation of the data.

### **Innovation and Creativity**

The VAccApp is the first user-centered and scientifically validated digital tool empowering parents to take charge in keeping the vaccination status up-to-date.

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