VaxInfo: An Online Service for Managing Immunization Records and Information

by

Olusesi Aliu

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Approved by:

DocuSigned by:
Kathryn Summers 12/15/2020
A10D371CA4EC43F...

Kathryn Summers, Thesis Advisor

DocuSigned by:
Greg Walsh 12/15/2020
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Greg Walsh, Committee Member

Abstract

This project aimed to develop an online service that allows individuals to access and manage their immunization records, as well as information on vaccines and the diseases they prevent. The proposed service sought to close an information gap by providing individuals access to their vaccination records stored in Immunization Information Systems (IIS). After reviewing the literature on data integration, a data architecture was proposed to connect disparate health information systems that contain and process vaccination records. Based on a literature review and comparative analysis of existing immunization applications, an interactive prototype of a web application was designed and tested with 18 participants. Usability testing showed that participants successfully completed most tasks but identified problems with the schedule feature of the application and with the status of individual vaccinations. Users offered suggestions for improving the app, most notably adding features/information to facilitate scheduling vaccination appointments, enabling direct sharing of records with doctors and schools, and simplifying the information presented in the schedule feature. Recommended next steps for implementing this service are to streamline the design and information presented in the schedule feature, conduct additional usability testing, complete a feasibility study of the proposed data architecture and make the business case for departments of health to create the service. The ongoing COVID-19 global pandemic and other recent disease outbreaks underscore the urgent need for this service.

Acknowledgments

I would like to thank my advisor, Dr. Kathryn Summers, for her guidance on this project and her instruction over the past three years. I would also like to thank my professors in the IDIA program for the training they provided, and my fellow students for contributing to my learning. Lastly, I would like to thank the participants who volunteered their time to provide valuable feedback on this project.

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Chapter 1: Introduction

With more than 70 million cases and 1.5 million deaths recorded as of December 2020, the COVID-19 global pandemic marks the latest chapter in humanity's ongoing war with pathogens (Dong, Du & Gardner, 2020). In this struggle, vaccines are our main weapon and have saved millions of lives from diseases such as polio, smallpox and measles. Yet we are still vulnerable. Globalization has made the world more interconnected and interdependent, but at the same time made it easier for diseases to spread widely and quickly. Urbanization has put people in closer contact with animal vectors, creating the conditions for new infectious diseases to emerge. On top of it all, growing skepticism about vaccines has led to declining vaccination rates, allowing diseases once eliminated from populations, such as measles, to revive.

In our ongoing battle against pathogens, data and information are key. They help public health officials monitor trends, spot outbreaks and contain the spread of disease. Considerable effort has gone into creating systems to collect this data, but there is a missing link: individuals are not empowered with vaccination data and information. Because immunization records are fragmented across different data systems and formats, it is difficult for individuals to know their vaccination status, which makes it harder for them to get recommended vaccines on the appropriate schedule. Individuals have a role to play in stopping the spread of disease, and public health interventions hinge on their involvement and compliance. Vaccination is most effective if a critical mass of the population receives vaccines. Providing immunization data and information to individuals can help ensure that this happens.

This project aims to address the information gap between individuals and health system data by creating an online service for patients to manage their immunization records and access information about vaccines and the diseases they prevent. The service will integrate data and information from various sources and provide access to them in a centralized space, in a format that is easy to understand and act on. It will also provide documentation of vaccination for travel, medical, academic and business purposes.

Within the current immunization data ecosystem, public health officials, and to a lesser extent healthcare providers, have access to patients' vaccination records through Immunization Information Systems (IIS) and Health Information Exchanges (HIE), but patients do not have access to these systems. Instead, patients must navigate a patchwork of platforms, portals and formats to retrieve their vaccination records. My research will directly address this problem, by bringing the data to the user. In doing so, this project will contribute to "meaningful use of interoperable electronic health records," which the U.S. federal government identified as a "critical national goal" in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act (Centers for Disease Control and Prevention, 2020). Making it easier to exchange health data between different information systems has clear benefits for epidemiological surveillance and public health interventions, and more generally can make healthcare delivery more efficient and effective. Existing immunization mobile applications focus primarily on providing information about vaccines and allowing people to manually record vaccinations they receive, but to date none of these apps gives patients access to the vaccination records that already exist within IIS and HIE. This project seeks to address this gap by designing a web-based application that allows people to request and manage their vaccination records.

This thesis is divided into four sections: i) literature review, ii) methods, iii) findings and iv) conclusion. The literature review discusses different approaches to data integration, as well as features of existing immunization applications. The methods section describes the steps taken to develop, test and document this service. The results section summarizes the outcomes of usability testing and implications for improving the design of the application. Lastly, the conclusion recommends next steps for improving the design and implementing this service.

Chapter 2: Literature Review

Patient immunization records are currently spread across various data systems (e.g. clinics, hospitals, health departments, schools) and formats (e.g. electronic medical records, health system databases, paper vaccination forms). This makes it difficult for individuals to access and keep track of their immunizations. A parent wondering whether their child's tetanus vaccinations are up to date likely must consult multiple sources to get a sure answer. The objective of my thesis project is to create a web-based service that allows people to easily access and manage immunization records in one place. In addition to securely storing records, the service will help individuals keep their vaccinations up to date, provide guidance about vaccinations for disease prevention and international travel, and provide documentation of required vaccinations for travel, employment, medical or other purposes. This service can be broken down into two components: a backend and front-end. The main challenge on the backend is integrating data from different systems to make it accessible to the user. The main challenge on the front-end is presenting this data in a way that users can understand and act on. This literature review is divided into two sections addressing the backend (data integration) and front-end (application) design.

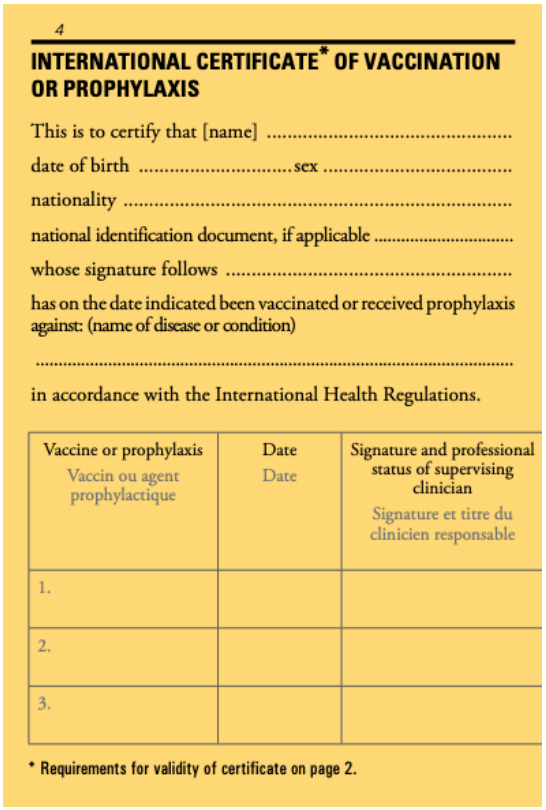
While immunization applications already exist, most of them either provide general information about vaccines or allow users to record and keep track of their vaccinations. To date, none of them provide the user access to already existing personal immunization records in IIS. Currently, healthcare providers and public health officials have access to records in IIS, but patients do not. This is the central problem my service aims to address. This project is particularly relevant given the ongoing global COVID-19 pandemic, and other recent outbreaks of vaccine-preventable diseases such as Ebola, Influenza, Polio and Measles. As scientists and public health officials work to prevent outbreaks, patients have a role to play. Providing them with access to their vaccination records, information about the benefits of immunization and documentation of vaccination, can help ensure that patients get required vaccines and that public health

officials are able to conduct epidemiological surveillance, ultimately lowering the prevalence of disease.

Data Integration

The technical challenge this project will need to overcome is one of data integration. Immunization records, like other medical records, exist in multiple data systems and formats, which reflect the fragmented development and deployment of health information systems over the past several decades. The landscape of immunization data comprises Immunization Information Systems (IIS), Health Information Exchanges (HIE), Electronic Health Records (EHR) and paper records.

IIS, also known as immunization registries, are centralized repositories of immunization records, which are fed by HIEs, EHRs and other sources. They are managed by health departments and operational in 49 states and 3 cities (Martin et al., 2015). IIS have been shown to increase vaccine coverage rates and decrease duplicate immunizations (Stevens et al., 2013). HIEs facilitate the sharing of health information between different healthcare providers, with the aim of "improving patient safety, care coordination, quality of care, work efficiency, and reducing healthcare cost and mortality" (Ahmed, 2018). Some are state-wide, while others are regional, private or a hybrid. Lastly, some immunization records are still stored in paper form. For example, the International Certificate of Vaccination or Prophylaxis (ICVP) is a World Health Organization-mandated paper form used to record vaccines required for travel to certain regions of the world (see Figure 1). Paper immunization records are less than ideal because they can easily be damaged, lost or forged and are more cumbersome to share. Combining immunization records from these different sources is challenging because they are not always interoperable: data is stored in different systems with different rules and formats. In the next section, I summarize the literature on approaches to integrating data housed in different information systems.



4

INTERNATIONAL CERTIFICATE* OF VACCINATION OR PROPHYLAXIS

This is to certify that [name] .....

date of birth .....sex .....

nationality .....

national identification document, if applicable .....

whose signature follows .....

has on the date indicated been vaccinated or received prophylaxis against: (name of disease or condition)

.....

in accordance with the International Health Regulations.

Vaccine or prophylaxis Vaccin ou agent prophylactique	Date Date	Signature and professional status of supervising clinician Signature et titre du clinicien responsable
1.		
2.		
3.		

* Requirements for validity of certificate on page 2.

Figure 1. International Certificate of Vaccination or Prophylaxis.

Data Integration Approaches

Patrick Ziegler and Klaus Dittrich use an architectural framework to classify different data integration approaches (2004). They outline different levels on which integration occurs, from the most abstract level – the user – to the least abstract – raw data. This framework is useful for the problem at hand and is described generally below. The middle levels of abstraction are particularly relevant to fragmented immunization data because they deal with applications and middleware, which are used to integrate data from dynamic and disparate information systems, such as those containing vaccination records.

At the level of the ***user***, data integration is essentially a manual process. The user interacts directly with data sources and must use different interfaces and query languages to find information. Additionally, users need to have detailed knowledge of the location,

logical representation, and semantics of different data sources. Manual data integration is usually done by data analysts in an ad-hoc fashion. One step below the user level, a ***Common User Interface*** approach presents unintegrated data from different sources in the same interface, such as in a dashboard. This still places the burden of integration on the user (Ziegler & Dittrich, 2004).

Further down, at the ***applications*** level, Michael Carey (2005) distinguishes two related integration approaches: Enterprise Application Integration (EAI) and Enterprise Information Integration (EII). According to Alon Halevy, EAI "facilitates hooking up applications to talk to each other", whereas EII "focuses on the data and querying it" (2005). Dina Bitton's definition of EII is similar, centering on the use of queries to collect data from multiple sources using an "integrated view" of these disparate sources (2005). Halevy describes this "integrated view" as a virtual schema or map of how data sources relate to each other. When a query is submitted which requires data from multiple sources, the system reformulates the query in terms that the individual data sources can understand, then pulls data from these sources and recombines them to answer the original query (Halevy, 2005). Halevy explains that because it involves the exchange of information, EAI can be used to update data and manage processes and workflows, which makes it a promising approach for integrating immunization data, as this data moves through different health information systems over time. EII, on the other hand, only allows you to read data through queries (Halevy, 2005). Ziegler & Dittrich highlight an important limitation of EAI; it becomes hard to manage as the number of applications grows, because differences in how these applications operate and treat data must be reconciled (2004).

The next level below the application level in Ziegler & Dittrich's framework is the ***middleware*** level, which is software that connects applications and their data sources to each other so that they can communicate and exchange data automatically (e.g. message-oriented middleware; 2004). Below middleware are the less abstract levels of data management and raw data itself. Ziegler & Dittrich explain that at the ***data management*** level, integration can be done through database management systems,

which is software that handles the storage, retrieval, and updating of data in a computer system (e.g. MySQL, Oracle; 2004).

Data warehouses are the main type of integration solution applied at this level, and data stores and marts are offshoots of warehouses. WH Inmon defines the data warehouse approach as one that involves extracting data from their original sources, transforming them to make them compatible with each other and loading them into a new location where they can be queried (1996). Data warehouses have data that is integrated, detailed, summarized, historical, and they also contain metadata. According to Inmon, the main advantage of warehouses is that they provide the fastest or most direct access to data, but the downside is that they lack adaptability - they are generally built once to support a specific set of data needs and if these needs change, then they must be reconfigured (1996). Ziegler & Dittrich also distinguish data stores, which are derived from data warehouses, the main difference being that the data are continuously refreshed, so they contain current information (2004). Inmon distinguishes data warehouses from data marts, which pull data from warehouses for specific departments/units in an organization (1996).

Lastly, the most concrete level in Ziegler & Dittrich's framework is the ***data*** itself; at this level, they argue, semantics are behind many of the challenges faced in integrating data (2004). They note that semantic heterogeneity between data sources can lead to data incompatibility, confusion, faulty analyses, and false conclusions (Ziegler & Dittrich, 2004). It follows then that integration solutions at this level can use metadata to clarify the meaning of data and relationships between data sources. But as they explain, even when metadata exist, some of the semantic meaning that helps users understand data is embodied in data models, conceptual schemas, program applications, and in the data itself (Ziegler & Dittrich, 2004). Ontologies address this challenge by providing a model of the domain/subject that the data is about and by making semantics explicit through references. Yet they note that even when ontologies exist, semantics are somewhat subjective, so concepts defined in an ontology might mean different things to different users in different contexts (Ziegler & Dittrich, 2004).

Arnon Rosenthal explains that formal semantics aims to resolve this subjectivity by developing mathematical models and programming languages to derive meaning from base concepts and relationships: the Web Ontology Language (OWL) and Resource Description Framework (RDF) are two such examples (Arnon Rosenthal, 2005). Lastly, Ziegler & Dittrich point out, semantics are not always static or standardized across data sources (2004). Semantic integration aims to solve this problem by integrating and automating metadata across data sources so that their meaning evolves with these sources. Rosenthal takes this a step further, with the notion of semantic management, which entails actively guiding semantic choices in ontologies and data systems, to preempt data integration issues (2005).

Table 1

Data Integration Framework

Level of Abstraction	**Integration Approach(es)**	**Description**
User	Manual Integration	Merge data from multiple sources ad-hoc
Interface	Common User Interface	Present unintegrated data from different sources in the same interface
Applications/Middleware	Enterprise Information Integration (EII)	Query data using virtual schema (integrated view) of disparate sources
	Enterprise Application Integration (EAI)	Connect applications to each other to exchange data
Data Management	Data Warehouse	Extract data from different sources, transform them to make them compatible and load them into a new location for querying
	Data Store	Continuously refresh data to stay current
	Data Mart	Pull data from data warehouse for specific department/unit in an organization
Data	Metadata	Clarify data and relationships between data sources
	Ontologies	Provide model of domain and make semantics explicit
	Formal Semantics	Model meaning mathematically
	Semantic Integration	Integrate and automate metadata
	Semantic Management	Actively guide semantic choices in ontologies and systems

Tradeoffs Between Data Integration Approaches

When considering different approaches to integrating data, there are tradeoffs in terms of cost, scalability, and performance (see Table 2). The data warehouse approach offers the best performance because it offers direct access to data, but it is hard to scale up because the warehouse must be configured for specific information needs in advance and any changes in these needs requires reconfiguration. This also makes warehouses potentially costly. The EII approach offers fairly good performance, depending on how complex the queries are and how different the data sources are. It is much more scalable than data warehouses because changes in information needs can be addressed by adjusting the query. This helps keep the costs down long-term. The EAI approach similarly offers reasonable performance but is not as scalable as EII because adding more applications and data sources makes the system harder to manage. Nevertheless, EAI can provide similar cost-savings in the long-run. A common user interface offers the advantage of being customizable and flexible because the changes are surface level and do not disturb the underlying configuration or flow of the data. However, developing dashboards and monitoring tools is an added cost, on top of maintaining the data systems that feed these tools. Though it is the least scalable solution, manual data integration offers the most flexibility because it is done on an ad-hoc basis and not bound by the inertia inherent in existing systems.

Table 2

Comparing Data Integration Approaches

Integration Approach	Cost	Scalability	Performance
Data Warehouse	Reconfiguration potentially costly	Limited scalability	Best performance
Enterprise Information Integration (EII)	Lower costs in the long-term	Very scalable	Fairly good performance
Enterprise Application Integration (EAI)	Lower costs in the long-term	Less scalable than EII	Fairly good performance
Common User Interface	Added cost on top of existing data systems	Limited scalability	Performance depends on configuration

Manual Data Integration	Potentially costly in time	No scalability	Poor performance

Proposed Integration Approach

Ultimately, the best approach for data integration depends on the data that needs to be accessed and/or shared, the information systems and stakeholders involved, and the context of use. Given the standardized elements of immunization data (e.g. patient demographic information, vaccine type, vaccination date, vaccination provider, etc.), the fragmented information systems that house them, and the unique needs of different patient populations, the service proposed here will use a combination of different integration approaches to meet different design objectives. A Common User Interface can be used to combine data from disparate sources into a coherent picture of a patient's immunization history. The most critical integration will take place through applications and middleware, connecting health information systems to each other to query and exchange data. Data warehouses and stores can be used to create centralized repositories of unified records, while semantic integration at the level of the data itself can enhance the interoperability of all data and sources within the service.

In their proposal for a mobile-enhanced IIS, Wilson et al. schematize the flow of immunization data between different systems and stakeholders: data flows from EHRs and public health agencies into IIS (and vice-versa in the latter case), from IIS to researchers and patients, from patients to EHRs and public health officials (and vice versa in the latter case), and from immunization providers to patients (2016). The integration approaches described above will facilitate this flow of data, ensuring that "the same immunization data resides with the individual, their healthcare provider and public health officials at all times." (Wilson et al., 2016).

Immunization Application

Integrating immunization data spread across various information systems and stakeholders is only half the battle. Once the data is acquired, it must be presented to the end-user, in this case the patient. Existing immunization applications offer some

examples of how to approach the front-end design of this service. In their review of mobile immunization applications, Wilson et al. note that apps provide different functions, with a primary focus on vaccine-related information/education (i.e. FAQs, news, coverage statistics, storage, safety), while some enable vaccine tracking and others have patient and physician portals (2015). They point out barriers to use that might limit uptake, including physical (small screens, manual data entry), behavioral (hesitancy to share health information online), security (data privacy), and access barriers (syncing across platforms, operating systems, devices) (Wilson et al., 2015). The design of this service should address these barriers, by applying best practices and heuristics for human factors and ergonomics, health literacy, cyber security, and responsive design.

Three applications in particular provide a good starting point for developing this service, in terms of their interface design and information architecture: ReadyVax, Vaccines on the Go and CANImmunize (formerly known as ImmunizeCA). Bednarczyk et al. created **ReadyVax** to assess smartphone use to access information on vaccines and the diseases they prevent (2017). The app divides immunization information into four categories: vaccines, diseases, FAQs, and Resources. It also features a personal immunization tracker, as well as different portals for patients, providers and pharmacists. Initial results showed heightened interest by repeat users, with an average of 3.9 sessions per user, 5.4 screen views per session and 1 minute 53 seconds per session (Bednarczyk et al., 2017). Additional user research and testing of the application is planned. **Vaccines on the Go** is a similar immunization information app developed by the Children's Hospital of Philadelphia Vaccines Education Center. It provides information on vaccines, diseases, safety and the immune system. Instead of a personal immunization tracker, it provides a schedule of recommended vaccinations.

CANImmunize, developed by Wilson et al., is the most comprehensive application that exists, combining vaccine information with a personal immunization tracker (2015). Wilson et al. describe the three-phased approach taken to develop the application: the application is currently in the first phase, which establishes the unidirectional flow of information from the patient to IIS through manually entered

vaccination records (2015). The second phase enables the bidirectional flow of data between the application and IIS. Wilson et al. suggest two options for doing this: authenticated data from the IIS can be downloaded to the mobile app, or the mobile app can provide access to a mirror version of the IIS data, allowing for identification and correction of discrepancies, then subsequent updating of data (2015). The most effective approach likely depends on the mirrored version of IIS data architecture, for security reasons, despite the relative inefficiency this would involve. In the third phase, ancillary features are added to the application. These include tracking/reporting Adverse Events Following Immunization (AEFI), vaccination reminders, outbreak alerts, barcodes for immunization and AEFI reporting, as well as assessing vaccine effectiveness using lot numbers (Wilson et al., 2015). Using the Technology Acceptance Model of behavioral intention to use, Burgess et. al found that the convenience of digital record-keeping (as opposed to paper-records) and of information access contributed to the perceived utility of the app, while privacy and security concerns were not barriers to adoption (2016). Documentation of immunization was the most used app feature (47.6% of all sessions). Appointment and calendar features were used less often (9.5% of all sessions), and information even less so (4.9% of all sessions). Their study suggests that users consume vaccine-related information on the web and not just through the application, and that users are willing to share their immunization data with public health officials (Burgess et al., 2016).

Wilson et. al. (2016) present another use case for an immunization application: a virtual immunization record, which would complement the current standard of proof of immunization, the ICVP (see Figure 1). In contrast to the potential illegibility, misplacement, damage or forgery of paper records, Wilson et. al. outline several advantages offered by a virtual record: enhanced availability and reliability through cloud-based storage and syncing of immunization data; improved authenticity through digital authentication (e.g. key pairs, personal identification numbers, biometrics); notifications to locate providers and expiration reminders; lot-specific information which can reduce errors and facilitate vaccine safety surveillance and supply chain

management; and automated identification through barcode-enabled data transfer at borders/points of entry (2016). A virtual record is not without challenges, though. Among these, Wilson et al. note that a digital record would require a globally accepted mechanism for authentication, and data authentication would need to be possible offline in areas with limited internet access (2016).

As Wilson et al. point out, though existing mobile applications enable patients to manually record and report their immunization records to IIS, this only addresses one side of the needed bi-directional communication (2015). There should be a way for users to access already existing data in IIS. By allowing for bidirectional communication, applications can address critical immunization issues: improving record-keeping, facilitating logistics, disseminating information from public health officials, improving IIS data quality, facilitating program evaluation, harmonizing information between stakeholders, and reducing vaccine hesitancy (Wilson et al., 2015).

Conclusion

By creating a web application that allows patients to manage their immunization records, and access information on vaccines, this project addresses an information gap with significant implications for population health. Providing patients with this information can help improve vaccination coverage and lower disease prevalence. Creating this service will require integrating immunization data from IIS, HIE, EHRs and other sources, using different approaches at the user, interface, application, middleware, data management and data levels. In addition to data integration on the backend, this service will require a web application with automated record-keeping, a personalized schedule, general information, and other features. Existing applications such as ReadyVax, Vaccines on the Go, and CANImmunize provide a solid foundation to build on, including insights from web analytics and user research to inform design decisions for this service. The success of this service will ultimately be determined by its adoption and use over time. If successful, it will contribute to improved interoperability between health information systems, which in turn can improve health outcomes and lower costs.

Chapter 3: Methods

This project was implemented in several phases. First, a comparative analysis was completed to assess three existing applications for managing immunization records and accessing information about vaccines and diseases. The criteria used to analyze the applications include the target audience, service proposition, features and information content. By highlighting common features and content across existing applications, this comparison provided a starting point for developing the proposed service.

Table 3

Comparative Analysis: Audience, Service Proposition and Features

Application	**Audience**	**Service Proposition**	**Features**
CANImmunize	Patients (Canadian residents)	"securely stores your vaccination records and helps you get vaccinated on time"	Manage vaccination records Manage family's vaccination records Customized vaccination schedules Vaccination reminders Search vaccinations Recommended immunizations Vaccine education Kids activities Disease outbreak alerts/map
ReadyVax	Patients Providers Pharmacists	"Provides up-to-date information on vaccines and the diseases they prevent"	Vaccines & Diseases Alerts & Updates Personal Immunization Tracker Common Questions Resource Information
VaccinesOnTheGo	Patients Parents	"provide the public with information about the science, safety and importance of vaccines"	Vaccine and disease information Vaccine schedule Vaccine safety information Immune system information Educational video library Ways to connect Notepad

Table 4

Comparative Analysis: Information Content

Application	**Categories**	**Vaccine Information**	**Disease Information**
CANImmunize	Protecting Yourself & Those Around You For Kids! FAQs Pregnancy and Immunization Pain Management Travel Vaccinations Vaccine Fact Sheets Provincial Vaccination Schedules Further Readings	What are the benefits of this vaccine? Who should get this vaccine? What is the [vaccine name]?	What is [disease name]? What are the symptoms of [disease name]? How is it spread?
ReadyVax	Vaccines & Diseases Alerts & Updates Common Questions Resource Information	Overview Safety Who Should Get It Recommended Schedule Brand Information	*Unstructured paragraph with information on transmission pathways, symptoms, vaccine history, and disease prevalence/burden.*
VaccinesOnTheGo	Vaccines Schedule Safety Immune System Videos Connect	Vaccine Side Effects Special Considerations Reasons to get the Vaccine	Virus or Bacteria How it Spreads Level of Contagiousness Symptoms Typical Disease Timeline Possible Complications Other Things You Should Know

The comparative analysis was followed by a review of "Core Data Elements For IIS Functional Standards v4.0" on the Centers for Disease Control and Prevention website (CDC, 2019), as well as Health Level Seven (HL7) standards for exchanging vaccination data between information systems (HL7, 2018). These standards were used to create a high-level data architecture for the service using an Entity Relationship Diagram (ERD). This architecture informed subsequent design of the front end of the application, primarily by establishing limitations on information that the interface presents to the user.

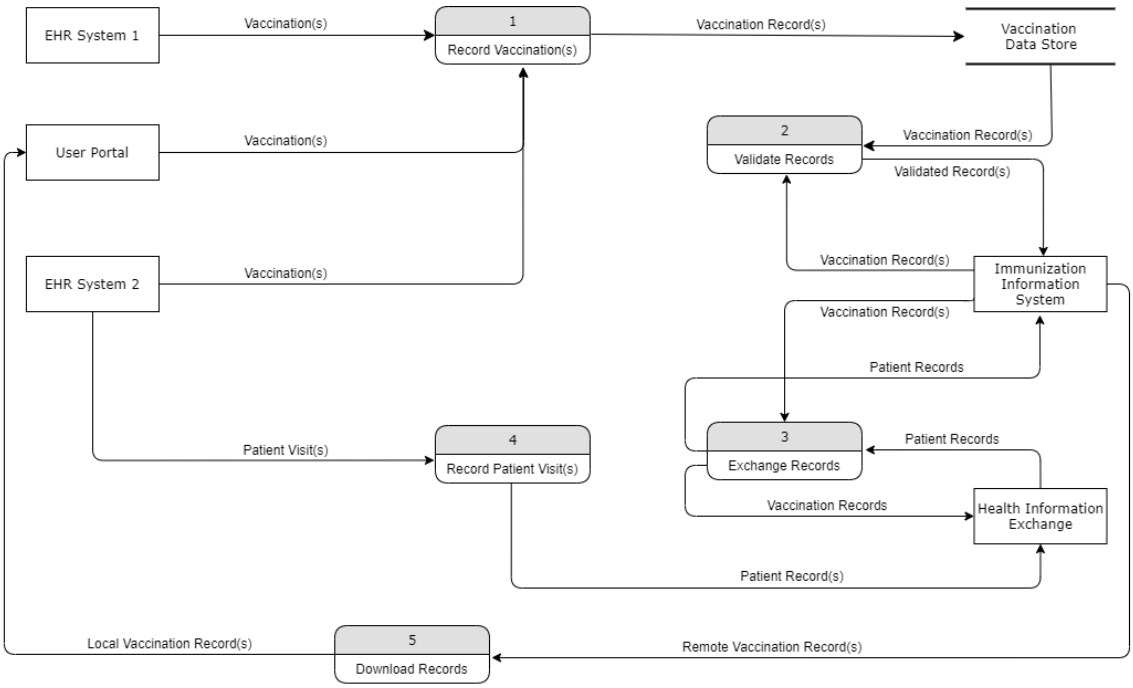


Figure 2. Data Architecture: Online Service for Managing Immunization Records.

After the data architecture, three user personas were created to represent the target audience for the service and to inform design decisions (see Figure 3 and Appendix E). The scenarios include demographic details and a summary of user goals, tasks, frustrations and technology use. A journey map was created for the parent persona; it outlines the steps this user group would take to use the service, describes their actions, thoughts and feelings as they do so, and highlights design insights and opportunities pertinent to each step of the journey (see Figures 4a and 4b). Based on the comparative analysis, data architecture, user personas and journey map, a prototype of the application was created, starting with a sitemap which outlined sections of the app and the navigation between sections (see Appendix F). Next, Sketch prototyping software was used to create screens of different sections and states within the app. These screens were reviewed to identify any problems. After this review, the screens were updated and linked together to make the prototype interactive.

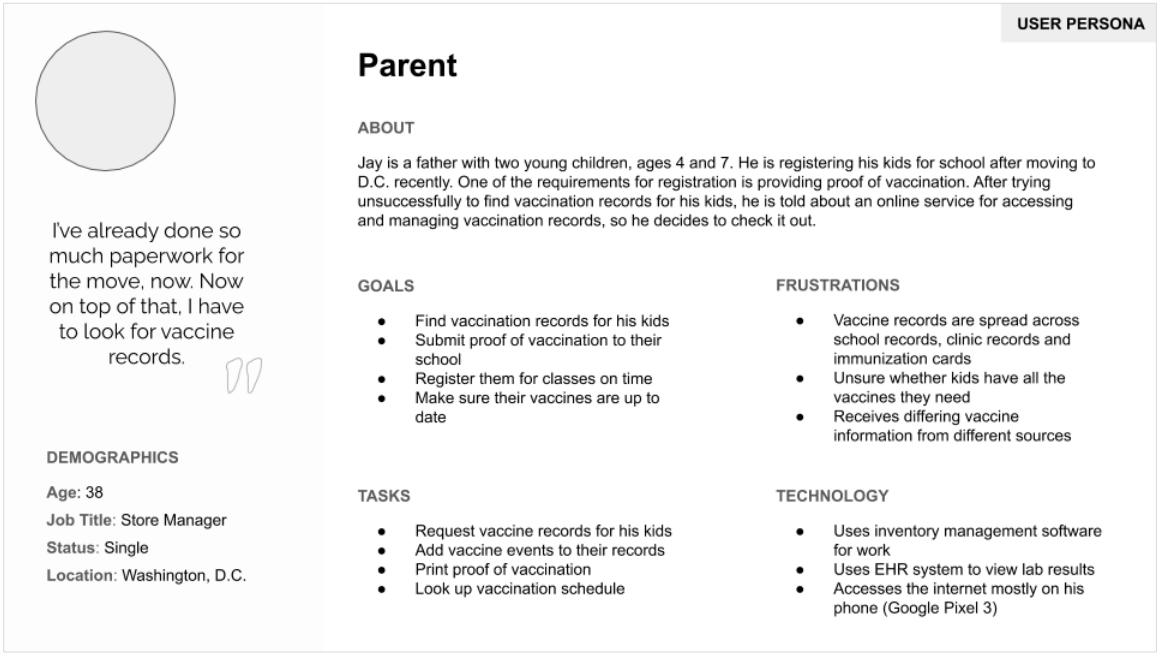


Figure 3. User Persona (Parent)

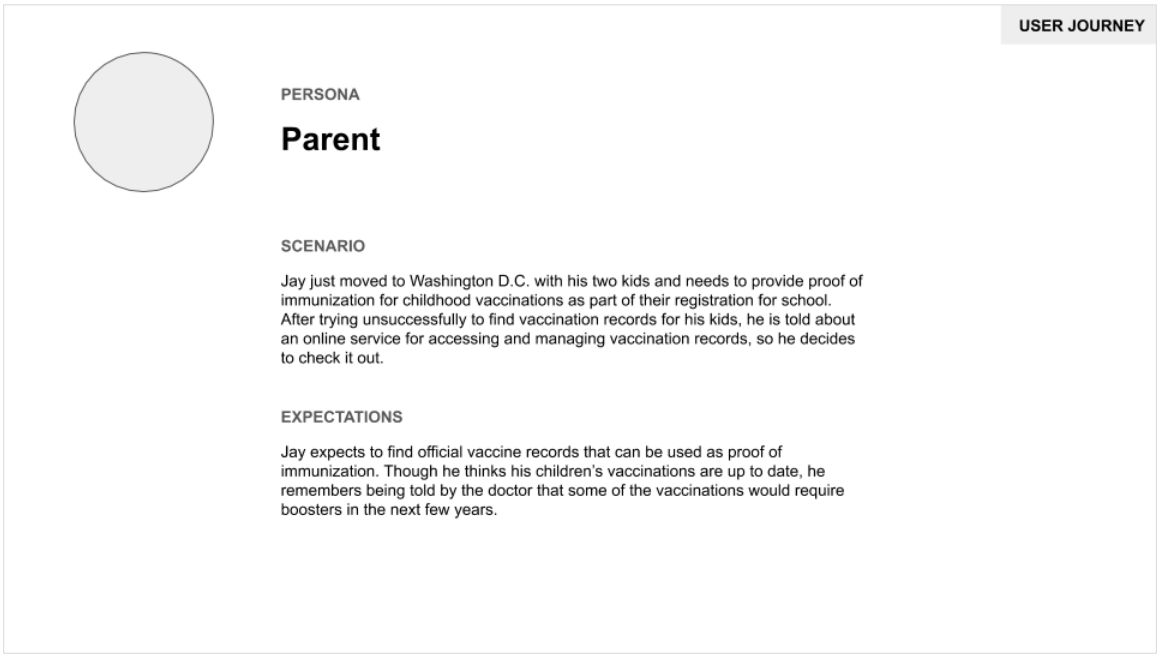


Figure 4a. Journey Map Scenario for Parent

USER JOURNEY

	Sign up	Request records	View records	Add records	Search information
DOING	See digital ad Visit website Create account	Log in Give consent Request records Track request status Receive records	Log in Go to Records Browse or search by date/disease/vaccine	Log in Go to Records Enter vaccine event information Submit records	Log in Browse diseases Browse vaccines Browse travel
THINKING	How long will this take? Why do you need my personal information?	What am I consenting to? How long will this take? Where are my records coming from?	What was this vaccine for? Do I need a booster?	What do these words mean? Where are these records going?	Can I trust this information? What do these words mean?
FEELING	Overwhelmed by searching for records Skeptical about finding records online	Uneasy about providing consent Anxious about receiving records	Impatient to find record Unsure about correct record	Confused by terminology	Curious about vaccine efficacy/safety
INSIGHTS	Trustworthiness and ease are critical from the get-go	Explain process and provide context	Make browsing/search as easy and efficient as possible	Apply form design best practices	Make medical information accessible
OPPORTUNITIES	Integrate with other health apps List affiliations Highlight compliance	Create chatbot Send status updates	Use metadata to enhance searchability Voice-enabled search Proof of vaccination	Provide prompts Use autofill Validation in-the-moment	Pull from reputable sources Use plain language, images and video

Figure 4b. Journey Map for Parent

This interactive prototype was used to complete three rounds of usability testing, with updates to the prototype after the first two rounds based on feedback from participants about their experience while completing the test. Six individuals were recruited in each round of testing, for a total of 18 participants (17 female, 1 male). They ranged in age from 25 to 56 (mean = 37). Participants were contacted by email and asked to fill out and sign an informed consent form approved by the University of Baltimore Institutional Review Board (see Appendix D). Participants were recruited based on their previous experiences receiving vaccinations. For the second round of testing, participants were recruited based on the fact that they had small children who routinely receive childhood vaccinations. Participants' children ranged in age from 7 months to 4 years. The tests were conducted remotely using Zoom video conferencing software. Participants were sent a link to the interactive prototype, hosted on Sketch cloud. Each test was recorded using Zoom; participants were asked to share their screens and turn off their cameras prior to recording so that their faces would not be included in the recording.

A standardized testing script and note taking template were used for each test (see Appendix C). The test began with an introduction explaining the overall purpose and outline of the test, and participants were asked for permission to record the session. On average, the tests lasted 38 minutes. All participants completed their tests, though Participant 12 and Participant 13 had to complete their tests in two separate sessions because of technical difficulties with Sketch cloud. Because these tests were interrupted either before or after the task scenarios (the main portion of the test), the results were considered to be valid, as the interruptions did not interfere with participants' completion of these tasks. Each test consisted of four tasks, which varied slightly for the second round of testing, but were otherwise consistent. This variation was necessitated by the fact that participants in round 2 represented a different user group (parents of small children) than rounds 1 and 3, and so required slightly different tasks to reflect their use case (i.e. managing their children's vaccination records as opposed to their own records).

Table 5

Usability Task Scenarios

Round 1	**Scenarios**
Task 1	Sign up
Task 2	Request vaccination records
Task 3	View vaccination records
Task 4	Check vaccination schedule
Round 2	**Scenarios**
Task 1	Add child to profile and request records
Task 2	View child's vaccination records
Task 3	Check child's vaccination schedule
Task 4	Download child's vaccination schedule
Round 3	**Scenarios**
Task 1	Sign up
Task 2	Request vaccination records
Task 3	View vaccination records
Task 4	Check vaccination schedule

During the test, participants were asked to complete the tasks and "think out loud" as they did so, providing insight into their expectations, points of confusion, difficulties and questions. For each session, the note taking template was used to record whether the participant easily completed the task (2), completed it with difficulty or with help (1), or did not complete the task at all (0). Additional observations of participants and comments by participants were also recorded. After each task, participants were asked to rate the task in terms of ease/difficulty, selecting 1 of 5 options: very easy (VE), somewhat easy (SE), neutral (N), somewhat difficult (SD) or very difficult (VD). They were then asked if anything was confusing or unclear. After completing all tasks, participants were asked about their overall experience using the prototype and if they had any recommendations or suggestions.

After the tests were completed, transcripts of the recordings were made using Otter.ai speech to text transcription software. Video recordings of the tests were reviewed to verify/identify problems or points of confusion participants encountered while completing the tasks. The recordings were also used to chart the navigation path users took as they completed tasks (i.e. which screens they visited and in which order). These user flows were analyzed to identify deviations from ideal or common paths, which could be indicative of confusion or problems users faced with the application interface. Once problems and points of confusion were identified, they were compared across users (within each round of testing) to identify those that were most frequent. Suggestions and recommendations from users were similarly analyzed for frequency of occurrence. The results of this analysis are presented next in the findings section.

Chapter 4: Findings

Round 1 Test Results

During the first round of testing, all six participants easily completed Task 3 (View vaccination records), while four participants easily completed Task 1 (Sign up) and Task 2 (Request vaccination records). Only one participant easily completed task 4 (Check vaccination schedule). Overall, participant's ratings of the ease of the tasks mirrored their completion rates, with five participants rating Task 3 as 'very easy,' and four participants rating Tasks 1 and 2 as 'very easy.' Two participants rated Task 4 as 'very easy' - one who easily completed it and one who did not complete it.

Table 6

Round 1 Test Results

	Task 1: Sign up		**Task 2: Request vaccination records**		**Task 3: View vaccination records**		**Task 4: Check vaccination schedule**	
Participants	Task Outcome	User Rating	Task Outcome	User Rating	Task Outcome	User Rating	Task Outcome	User Rating
P0	2	VE	1	VE	2	VE	0	VE
P1	2	VE	2	VE	2	VE	2	VE
P2	2	VE	2	SE	2	VE	0	SE
P3	2	VE	2	VE	2	VE	0	SE
P4	0	N	1	SE	2	SE	1	SE
P5	1	SE	2	VE	2	VE	0	SE

While completing the tasks, participants expressed confusion about two aspects of VaxInfo: its operating model and the status of their vaccinations. Although the homepage of the prototype outlined steps for using the service under the heading of 'How it works,' participants were unclear about who they were submitting a request to and where their vaccination records would come from. Participant's confusion might have stemmed from their assumption that healthcare providers would be the ones sending their vaccination records. Participant 4 wondered, "Once you click that, does it take you to your doctor's place? What if you have several [doctors] and really it's up to them to submit those

records?" Participant 0 on the other hand was confused about VaxInfo's data brokering role, stating, "I don't think I was completely clear on what VaxInfo was doing between someone with all my health records and me. I didn't completely understand that I was supposed to request from VaxInfo, which already had information." Participant 2's lack of understanding prompted her to question the utility of the VaxInfo service, saying, "Where is this info coming from? And is it a source different than a source that I could access myself?" Based on participants' comments, it seems that they lacked a critical piece of information, which is the basis of the VaxInfo service: records of past vaccinations they received are reported into IIS that state and local health departments manage. Furthermore, VaxInfo's role as a go-between requesting records from these systems on their behalf was not sufficiently clear, hence their questions about who they were requesting records from and where the requests were going.

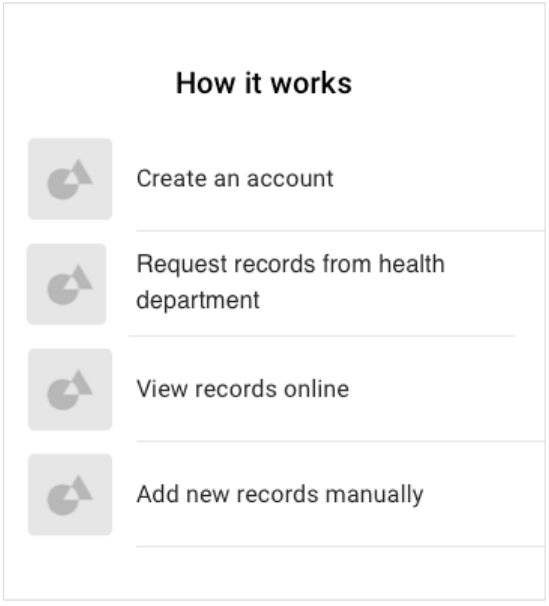


Figure 5. How it Works: Step-by-Step Guide for Using the VaxInfo Application.

The other points of confusion shared by participants revolved around the status of their vaccinations, which they tried to discern from the icons and dates listed next to vaccine names. In the first version of the prototype, icons were only used to highlight

missing vaccinations, but Participant 0 suggested that seeing icons next to all vaccinations would be more reassuring, saying, “I think I would feel a little bit safer if I had a little checkmark saying these vaccinations are okay or up to date.” Participant 1 was unsure whether the dates on the View Records page (see Figure 6) signaled when a vaccination was previously received or when it was due to be received. Similarly, Participant 3 was confused by the fact that only the Tdap vaccination had a warning symbol and wondered why similar warnings or expiration dates were not displayed for other vaccinations.

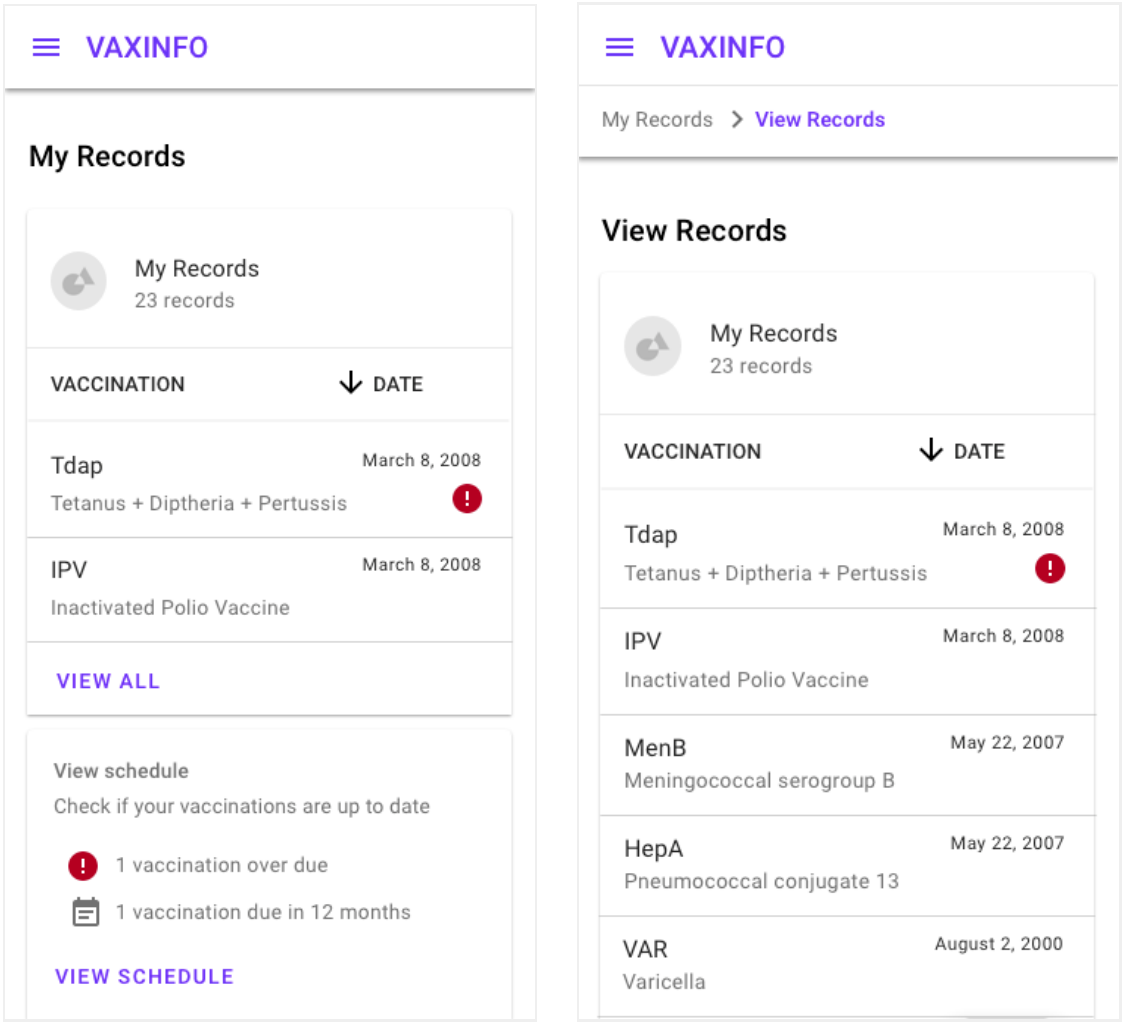


Figure 6. My Records and View Records Pages.

During the first round of testing, participants were the least successful with Task 4 (Check vaccination schedule). Analysis of the navigation pathways users took during this task reveals the challenge: only users who navigated to the My Schedule section of the prototype successfully completed it, and most users (four out of six) never made it to this part of the prototype. Participants were probably oblivious to the My Schedule section of the prototype because the View Schedule button leading to this section of the app could only be seen if the participants scrolled down on the My Records page (see Figure 6). This was compounded by the fact that there was no direct path to the My Schedule section from the View Records page (see Figure 6), which most participants visited during this task. Lastly, as discussed in later findings, the terminology used might not have registered with participants, as some participants in the second and third rounds of testing thought 'schedule' referred to upcoming appointments for vaccinations.

Based on the results of the first round of testing, changes were made to improve participants' success with checking their personalized vaccination schedule. Additionally, in preparation for the slightly different tasks in the second round of testing, changes were made to the My Children section of the app. The specific changes are detailed below:

- *My Records*: the My Records page was regrouped to move the View Schedule link higher on the page so that it is visible when the user lands on the page, without the need to scroll down. This resulted in the elimination of the View Schedule card, which contained information about overdue and upcoming vaccinations. However, because that information was also on the records summary card at the top of the page (albeit in a different format), this was deemed an appropriate tradeoff to make it easier for users to find their personalized vaccination schedules. See Appendix A, Figure A1.
- *View Records*: given the high success rate of participants on Task 3 (View vaccination records) the only changes made on this page were to 1) change the title of the page to All Records, so that users understood it to contain a comprehensive list of their records and 2) add a View Schedule button which

takes the user to their personalized vaccination schedule. See Appendix A, Figure A2.

- *Vaccination Records*: as with the All Records page, the primary change on pages for individual vaccination records (e.g. Tdap) was the addition of a View Schedule button at the top of the page. Filled/unfilled green circles were also added to the overview section to indicate where each vaccination falls within a sequence of recommended doses. See Appendix A, Figure A3.
- *Vaccination Schedule*: details were added to the vaccination schedule page, including an explicit statement on the status of each vaccination (i.e. whether the vaccination has been received and when it was received), a link to the vaccination record page for vaccinations that have been received, a brief description of who/when the vaccine is recommended for, and a link to more information. An All Records button was also added to the top of the personalized vaccination schedule page to provide the user quick access to a different view of their records. See Appendix A, Figure A4.
- *Request Records*: the form for requesting records was adapted for parents requesting records on behalf of their children. The form consists of a two-step process: 1) adding a child to an account and 2) providing consent for VaxInfo to request records for the child. Including both steps in the same form but making them distinct leaves parents the option to manually add records before, after, or instead of requesting the records through VaxInfo, thereby supporting multiple use scenarios. See Appendix A, Figure A5.
- *My Children*: in addition to adapting the form for requesting records, pages were added to the My Children section of the app, starting from the My Children page, which contains summary cards of records for the account holder's child(ren). Further down the hierarchy in this section are pages for each child which mirror those of the account holder; the individual child's homepage (Mya in this fictional scenario) mirrors the parent's My Records page. Similarly, the Mya's Records page mirrors the parent's All Records page. The changes outlined above for the

My Records and All Records page were also made in the My Children section. See Appendix A, Figure A6.

- *Download Records*: pages were added for the download feature of the VaxInfo app. The download wizard employs the same layout and iconography as the All Records page to facilitate quick comprehension and completion of this important task. See Appendix A, Figure A7.

Round 2 Test Results

The second round of testing featured similar tasks but focused on a different user group: parents with children who need to keep track and provide documentation of their children's vaccinations for schools, daycares and other purposes. All participants easily completed Task 1 (Add child to profile and request records), while four participants easily completed Task 3 (Check child's vaccination schedule) and Task 4 (Download child's vaccination records). Only two participants easily completed Task 2 (View child's vaccination records). In general, participants' ratings of the tasks reflected completion rates. Most participants who completed tasks with difficulty or help rated those tasks as somewhat easy or somewhat difficult and most participants who completed tasks easily rated those tasks as very easy.

Table 7

Round 2 Test Results

	Task 1: Add child to profile and request records		**Task 2: View child's vaccination records**		**Task 3: Check child's vaccination schedule**		**Task 4: Download child's vaccination records**	
Participants	Task Outcome	User Rating	Task Outcome	User Rating	Task Outcome	User Rating	Task Outcome	User Rating
P6	2	VE	2	VE	0	SD	0	SD
P7	2	VE	1	SE	2	SE	2	VE
P8	2	VE	2	SE	2	VE	2	VE
P9	2	SE	1	SE	0	VE	2	VE
P10	2	VE	1	SE	2	VE	0	VD
P11	2	VE	1	SE	2	SE	2	VE

Participants' comments while completing the tasks point to a few issues, some of which are unique to their use case (managing their children's vaccination records). While completing Task 1 (Add child to profile and request records), three participants voiced concerns about privacy and suggested that they would need assurances that their children's medical records were safeguarded. According to Participant 6, "The challenge is...concerns about privacy here...because all of these are obviously pretty sensitive records, and because our doctor's office has made such a big deal about not sharing this even directly with the parent over email." As in the first round of testing, four participants had questions about VaxInfo's operating model, including who requests were submitted to and whether there was an associated fee. These questions reinforce the need to educate users on the immunization data landscape, specifically situating VaxInfo between users and their existing records in IIS.

Participants encountered three primary points of confusion while completing Task 2 (View child's vaccination records). First, two participants said they were confused by the summary card for their child on the My Children page; they were unsure whether clicking on the View button would take them to the same place as clicking elsewhere on the card (Figure 7). However, the prominence of the two buttons on the card – View and Add – provided a strong enough call to action that this momentary hesitation did not prevent any participants from completing the task. Nevertheless, participants' confusion suggests that clickability on this page – that is, what should be clicked and what should not be – could be made clearer. Second, after clicking the View button and landing on the page summarizing their fictional child's records, two participants were unsure why the MMR, VAR and IIV vaccination records were previewed (see Figure 7). Initially, participants assumed that these records were the most recently received, but later realized that these vaccinations required action. The confusion was probably tied to the header above these records; the date label and arrow next to it suggest that the records are sorted chronologically, which is the case, but there is no explicit cue indicating that these vaccinations require the user to take action. In the absence of such a cue, the users assumed these vaccines were simply the most recent. Third, similar to the first round of

testing, two participants were unsure of the status of vaccinations that did not have a warning icon next to them, and they suggested that a status label would be helpful.

Participants faced similar issues while completing Task 3 (Check child's vaccination schedule). Three participants said they were unclear about the exact status of vaccinations, including which vaccinations were up to date and which were missing, as well as the extent to which missing vaccinations were overdue. Two participants said they would also like to know the source of information on vaccines and vaccination schedules. While completing Task 4 (Download child's vaccination records) three participants noted that the records would need to be verified by a doctor in order for schools to accept them as valid. As participants suggested, coupled with the source of information, providing official verification would lend credibility to the VaxInfo application. Lastly, two participants suggested that sending records to schools directly from the app would be more convenient, as opposed to downloading them and having to take additional steps to email or print them.

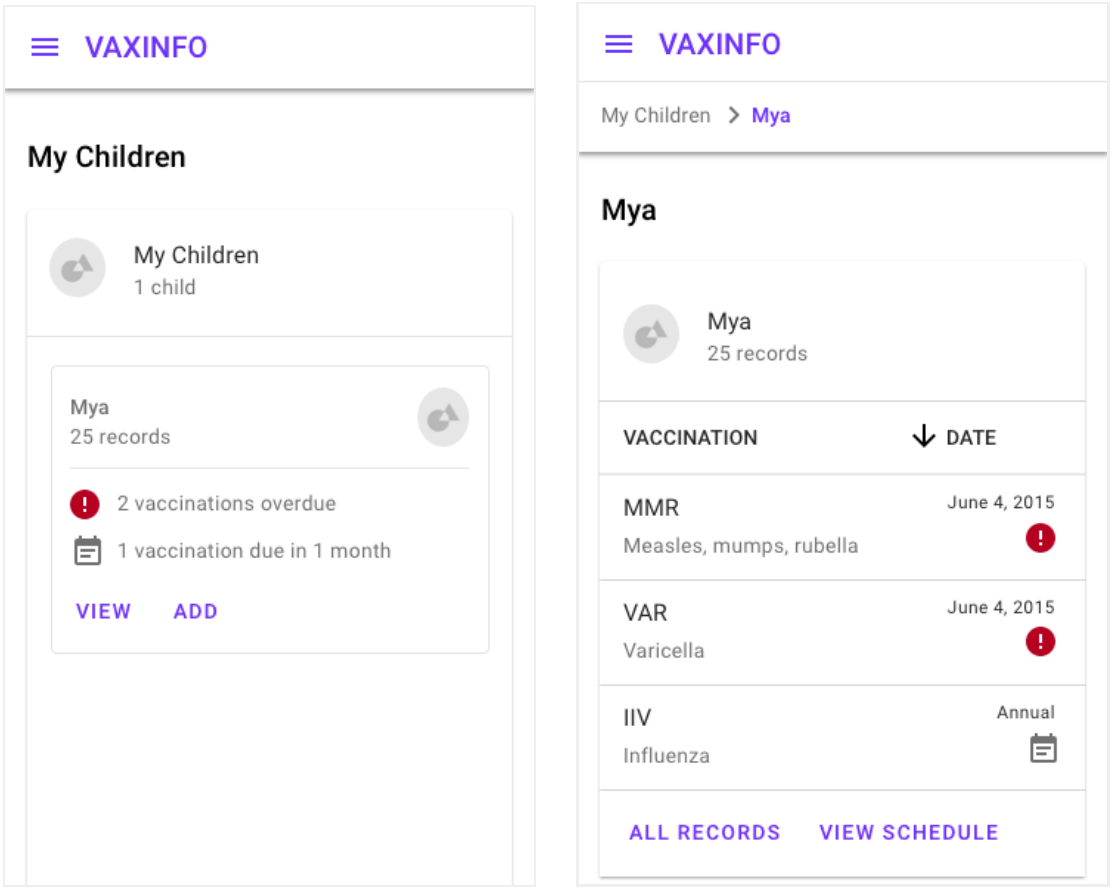


Figure 7. My Children and Mya.

Based on results from the second round of testing, changes were made to the request form and the My Records page. Vaccine and disease information pages were also created to increase the fidelity of the prototype. The specific changes are described below:

- *Request Records*: in order to address privacy concerns and clarify VaxInfo's operating model, language was added to the request form. The language explains that users authorize VaxInfo to request records on their behalf from local/state health departments. It also states that users' vaccination records are stored in IIS, which vaccine providers report into, and which are managed by health departments. The language assures users that VaxInfo does not share their records with any third parties. See Appendix B, Figure B1.

- *My Records*: to clarify why the My Records summary card shows the Tetanus (Tdap) and Influenza (IIV) vaccinations, explicit status labels – Overdue and Upcoming – were added, indicating that these vaccinations required action. In the case of the overdue vaccination, the Overdue label replaced the date that the last dose was received. In the case of the annual flu vaccine, the Upcoming label replaced an Annual label which participants found ambiguous. Though the header row was unchanged, the sort arrow was removed from the date column to eliminate confusion about these being merely the most recent vaccination records. Keeping the column titles the same ensured consistency between the summary and the full list of all records. See Appendix B, Figure B2.
- *My Children*: No changes were made to the summary card on the My Children page. Although participants were unsure whether to click on the View button or elsewhere on the card, the prominence of the two buttons on the card – View and Add – provided a strong enough call to action that this momentary hesitation did not prevent any users from completing the task. See Appendix B, Figure B3.
- *All Records*: though participants suggested adding status icons to all vaccinations on the All Records page to differentiate those that required action from those that did not, this change was not made after the second round of testing, for fear of overloading the vaccination records with information and reducing their scanability. However, a search bar was added to the top of the All Records page to allow users to look up vaccinations more quickly. See Figure B3.
- *Vaccine Information*: to increase the fidelity of the prototype, Vaccine Information pages were created and linked to vaccination records in the My Schedule section of the app. They were also linked to Disease Information pages. The CDC's Vaccine Information Statements was cited as the source of information on these pages. Due to the technical limitations of the Sketch Cloud, these pages were not included in the third round of testing. See Appendix B, Figure B4.

- *Disease Information*: disease-specific pages were created and linked to vaccination records in the My Records section of the app. These Disease Information pages were also linked to Vaccine Information pages. The Children's Hospital of Philadelphia Vaccine Education Center was cited as the source of information on these pages. Due to the technical limitations of the Sketch Cloud, these pages were not included in the third round of testing. See Appendix B, Figure B5.

Round 3 Test Results

For the third round of testing, participants completed the same tasks as the first round. Overall, performance on the tasks improved from the first round. Five participants easily completed Task 1 (Sign up), compared to four in round 1. All six participants easily completed Task 2 (Request vaccination records), compared to four in round 1. As in round 1, all six participants easily completed Task 3 (View vaccination records). Two participants easily completed Task 4 (Check vaccination schedule), up from one participant in round 1; however, it is clear that this task needs further improvement. Participant's ratings of the tasks varied somewhat. Ratings for Task 1 (Sign up) and Task 2 (Request vaccination records) reflected the completion rates, with all participants rating those tasks as somewhat easy or very easy. Ratings for Task 3 (View vaccination records) ranged from neutral to very easy, while ratings for Task 4 (Check vaccination schedule) ranged from somewhat difficult to very easy.

Table 8

Round 3 Test Results

	Task 1: Sign up		**Task 2: Request vaccination records**		**Task 3: View vaccination records**		**Task 4: Check vaccination schedule**	
Participants	Task Outcome	User Rating	Task Outcome	User Rating	Task Outcome	User Rating	Task Outcome	User Rating
P12	2	SE	1	SE	2	N	0	SD
P13	2	SE	2	VE	2	VE	0	SE
P14	1	SE	2	VE	2	VE	2	VE
P15	2	VE	2	VE	2	VE	1	VE
P16	2	SE	1	VE	2	N	0	VE
P17	2	VE	2	VE	2	SE	2	VE

Participants raised new issues with the sign-up process during the last round of testing, and they encountered problems with checking their vaccination schedule, as in earlier rounds of testing. While completing Task 1 (Sign up), three participants said that they were unsure what step to take after completing the sign-up form. They expected either a message on the page confirming their account activation or a button allowing them to sign in immediately. Participants faced the most problems with Task 4 (Check vaccination schedule). To begin with, three participants were unsure what 'View Schedule' meant. Participants 12 and 14 thought it referred to making an appointment to receive a vaccination. This, coupled with similar comments from Participant 7 in the second round of testing and participants' overall poorer performance on this task, suggests the need for different terminology to describe this feature of the app.

Participants also cited problems with the age ranges on the My Schedule page; two participants said they thought the age ranges required too much clicking to see their vaccination records, and one participant was unsure whether the age ranges corresponded to her age (see Figure 8). Taken together, these observations point to a more fundamental issue with this section of the application. While organizing vaccination records by age provides markers for parents tracking their child's routine vaccinations, Participant 16 noted that as an adult, information about childhood vaccinations she already received is extraneous. For adults using VaxInfo, the most useful information to have under 'My

Schedule' is likely to be action oriented. Participant 15 echoed this sentiment, saying, "So that way, the My Schedule really keeps it to the minimal information you need...whether it's overdue, whether that's something you need to do coming up."

As for individual vaccination records, participants were not sure how to interpret the icons in terms of their vaccination status. Participant 17 wondered, "I'm not sure what this little green circle means. And the empty circle...the green means I'm good to go. Yeah, but I don't know what the empty one means." Though the filled/unfilled circles provide a way to indicate both whether a vaccination has been received and where it falls within a sequence of doses, some additional detail would provide users more clarity about how to interpret this icon. Lastly, two participants said they wished the app facilitated taking action on their missing vaccinations – either by providing information about where to get vaccinated, or by allowing them to schedule an appointment from within the app. The former could feasibly be integrated into the app, but the latter would be more challenging to implement.

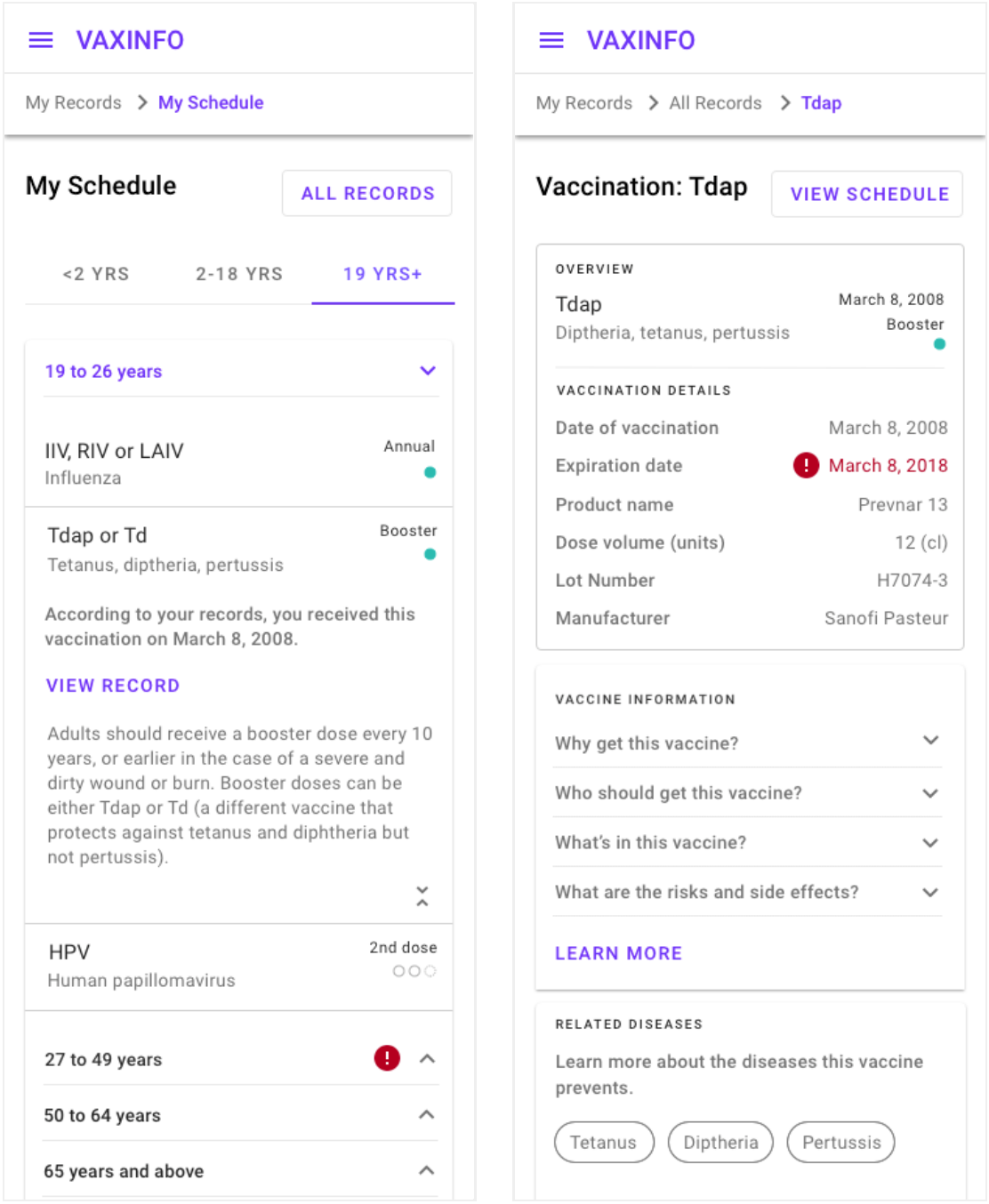


Figure 8. My Schedule and Tdap Vaccination Pages.

Based on results from the third round of testing, changes for the next version of the prototype will primarily focus on the schedule feature to more clearly communicate

this section of the app, simplify the interface, prioritize the most important information and facilitate user action based on this information. Changes will also be made to the iconography and labeling of individual vaccination records, as well as changes to help users complete the sign-up process. Specific changes are detailed below:

- *View Schedule*: to eliminate confusion about what the schedule section of the app contains, the button label and page title for this section will be changed from View Schedule and My Schedule, respectively, to My Timeline. The word 'timeline' more accurately describes this section of the app, which displays previously received vaccinations and upcoming vaccinations in chronological order.
- *My Schedule*: to simplify the schedule interface for adult users of the app, earlier sections of the vaccination schedule (i.e. <2 years and 2-18 years) will be collapsed, and vaccination records within these age categories will be organized by disease, showing the sequence of vaccine doses received for each disease. This topical organizational scheme better addresses adult users' goal of ensuring that required doses have been received. It eliminates the need to click on individual sub-sections (e.g. 1 month, 2 month, 4 months, etc.) to view vaccination records but still provides access to a comprehensive immunization history. In addition, the default view for adult users who visit this section of the app will be the window of time that corresponds to their age. For example, a 30-year old would be taken to the section showing recommended vaccinations for ages 27-49. The forward-looking sub-sections would retain the current chronological organizational scheme, providing a way to track overdue and upcoming vaccinations.
- *Scheduling Vaccinations*: to help users take action on overdue and upcoming vaccinations, a link to information about where to get vaccines will be added to the schedule section of the app, under entries for overdue vaccinations. Links will also be added to the Vaccine Information section of individual vaccination records and vaccine information pages. The links will take users to the U.S. Department of Health and Human Services vaccines.gov webpage on where to get

vaccines: https://www.vaccines.gov/get-vaccinated/where. The webpage features a VaccineFinder map, as well as links to state departments of health.

- *Vaccination Records*: to make the status of individual vaccinations clearer, the iconography will be updated and coupled with the use of color. All entries on the All Records page will have a written status indicator (Overdue, Upcoming, or the date of vaccination for vaccines that have been received). These written indicators will have corresponding colors (red, orange and green, respectively) and icons (an exclamation point, a calendar and a checkmark, respectively). To eliminate confusion about the vaccine dose icons (●●○), explanatory text will be added to the dose number (i.e., "2nd of 3 doses").
- *Sign Up*: to help users complete the sign-up process, explicit instructions will be added to the sign-up confirmation page, asking users to first confirm their account by clicking on the link emailed to them, then returning to the website to log in.

Suggestions

In addition to describing problems they encountered while completing the tasks, participants offered suggestions of improvements or additional features for the VaxInfo application. The most common suggestions pertained to scheduling vaccinations. Eight participants said they would like the application to help them take steps to get vaccinated, by providing a direct link to their doctor's office, contact information for their doctor's office, or information about where vaccines are offered. Two participants suggested that appointments made from the app could even be linked to their calendars. These suggestions make sense, since scheduling an appointment for an overdue or upcoming vaccination is a natural next step along the user journey.

Five participants suggested options for sharing vaccination records, in addition to downloading them. Some of these suggestions reflect participants' partial understanding of the VaxInfo operating model. For example, Participant 6 suggested that a link could be established between doctors and schools to ensure that records are transmitted and verified. In fact, VaxInfo would allow users to request these records from IIS and submit

them directly to schools, without needing to involve their doctors. However, providing a way for participants to share and request records with their doctor's EHR system offers the benefit of data triangulation, which could potentially improve data quality. What is clear from Participant's 6 comments is that the current process of providing proof of vaccination for school registration is cumbersome and could be improved by VaxInfo: "This is useful, especially for school registration every year, it's a huge hassle...And if I could do this online, instead of having to make appointments physically to go in, have them sign a piece of paper, pay them in person, and then bring it over in person to my school, that would be really helpful." Participant 1, who previously worked at a school, shed light on these challenges from a different perspective: "And then on the school's end it's really difficult when you have like a bunch of disparate sources or papers, just records that are electronic or paper or copied or whatever, trying to get those kind of aggregated for each student and getting that into each student record...I know that it's a really difficult process...for parents and school administrators." Given that most public and private schools require proof of childhood vaccinations for enrollment, enabling parents to submit records to schools from the VaxInfo app would alleviate a major pain point. This would require schools to accept these records, which could be achieved by engaging public health and education officials to agree on or adapt verification processes and data standards. Because all concerned stakeholders have a shared interest in streamlining and safeguarding immunization record-keeping, there is room for cooperation.

While browsing the My Schedule section of the application, four participants suggested simplifying and reducing the amount of information presented. Participants 15 and 16 commented that they would not need to see records for previously completed vaccinations in this section, but rather would prefer to see immediately relevant and actionable information about overdue or upcoming vaccinations. Participants 12 and 16 found it difficult to navigate the My Schedule section because it required too much clicking to see records under different age ranges (see Figure 8). In describing their challenges with interpreting the status of individual vaccinations, participants suggested three different ways to convey this information: labels (e.g. 'received,' 'overdue'),

checkmarks for vaccinations that were received (in addition to the red warning icons used for overdue vaccinations), and a three-color scheme (i.e. red = overdue, yellow = upcoming, green = received). Lastly, three participants suggested adding more color to the VaxInfo interface, to make it more engaging and increase visual interest.

Summary

Through three rounds of testing and two intervening rounds of design changes, participants were generally successful in completing the tasks, with the exception of checking their vaccination schedules. In each round of testing, this task had the lowest completion rate. After the first round of testing, navigation changes to the VaxInfo interface improved the discoverability of the schedule section, while information changes improved its usability for parents managing their child's vaccination records. However, the third round of testing revealed deficiencies in its usability for adults who are not tracking routine vaccinations and are more concerned with overdue and upcoming vaccinations, which are less frequent. To prevent the information overload bemoaned by participants in the third round of testing, the schedule interface will be changed to display past vaccinations in a condensed format (grouped by disease) for adult users.

Overall, participants' ratings of the ease of tasks mirrored the completion rates, with easily completed tasks receiving more favorable ratings than tasks that were completed with difficulty or help, or that were not completed at all. Participants encountered problems with different aspects of the application across the three rounds of testing. The most commonly cited issues were confusion about the operating model of VaxInfo (who requests are submitted to and where the data come from), the status of individual vaccinations, and the amount of information presented in the My Schedule section of the app. Participants suggested additional features to help users schedule vaccinations and share records, as well as changes to streamline the My Schedule section and make the status of vaccinations easier to understand.

Chapter 5: Conclusion

This project aimed to develop an online service that allows individuals to manage their immunization records and access information about vaccines and the diseases they prevent. Drawing on different integration approaches, a data architecture was proposed, linking IIS, HIE, EHRs and patients. Next, an interactive prototype of a web application was designed, combining features and information content from three existing immunization applications. Usability testing identified problems with the application interface, particularly in the schedule section of the application and with regard to the status of individual vaccinations. Users offered suggestions for improving the app, most notably adding features/information to facilitate scheduling vaccination appointments, enabling direct sharing of records with doctors and schools, and – for adult users – simplifying the information presented in the schedule section of the application.

Limitations

Though the usability testing provided valuable insights about the core functions of this service, it did not allow for investigation of all features. Due to the limited capacity of the Sketch cloud platform, the sections of the application on vaccine and disease information (see Figures B4 and B5) were not tested, nor was the section for travel vaccines. Given that multiple users indicated they would find this information and these features useful, further testing that includes them would be beneficial. The challenges with using Sketch cloud for remote usability testing could be circumvented by different prototyping software and/or plug-ins.

Next Steps

The recommended next step in developing this service would be to update the prototype and then conduct additional usability testing. Based on the findings and limitations of testing discussed earlier, design updates should focus on the ‘My Schedule’ section of the app, the vaccine and disease information, and the travel vaccine section. Testing for the My Schedule section should aim to identify a combination of iconography, language, navigation and information architecture that alerts users to

overdue and upcoming vaccinations as a first priority, and as a second priority gives them an understanding of their vaccination history (i.e. what vaccines were received and when), without overwhelming them with too much information. Achieving this will require testing and/or combining different organizational schemes (e.g. chronological, topical, etc.) and tailoring default views to user goals. Testing for the vaccine and disease information sections should focus on users' understanding and trust of medical information, while testing for the travel vaccine section should focus on searching and browsing relevant vaccines depending on travel destinations. Once the core functions of the application have been designed and thoroughly tested, additional features and content can be tested, including information for scheduling vaccination appointments, and options for sharing records with third parties such as doctors and schools, for verification purposes. Lastly, in addition to the front-end of the application, the proposed back-end data architecture should be evaluated. This could be done by conducting a feasibility study of data and system requirements, based on existing IIS and HIEs.

After this is done, the next step towards implementation would be to create a software requirements specification document which describes the overall system and data architecture, data dictionary, features, user class characteristics, use case reports and diagrams, constraints, assumptions and dependencies, and user, hardware, communications and software interface requirements. This software specification step is critical to ensure interoperability with existing health information systems. Finally, the service could be pitched to local and state governments, making the business case for why it should be created.

The COVID-19 pandemic, which has taken a devastating toll on health systems, economies and societies, demonstrates the urgent need for this service. As the world anxiously awaits the approval and mass distribution of vaccines against the SARS-CoV-2 virus, significant hurdles remain. Leading vaccine candidates will require multiple doses, and epidemiological models suggest that a significant portion of the population must be vaccinated to achieve herd immunity (Anderson et al., 2020). These conditions underscore the need for ways to manage and access vaccination records. Individuals

might need to show proof of vaccination against COVID-19 to return to work or travel, and public health officials will need records to monitor levels of immunization among the population. With the possibility of the disease becoming endemic (Shaman & Galanti, 2020), vaccination against SARS-CoV-2 could become routine, making it even more critical to develop a service that allows individuals to manage their vaccination records.

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Appendices

Appendix A: Changes Made to the VaxInfo Prototype after First Round of Testing

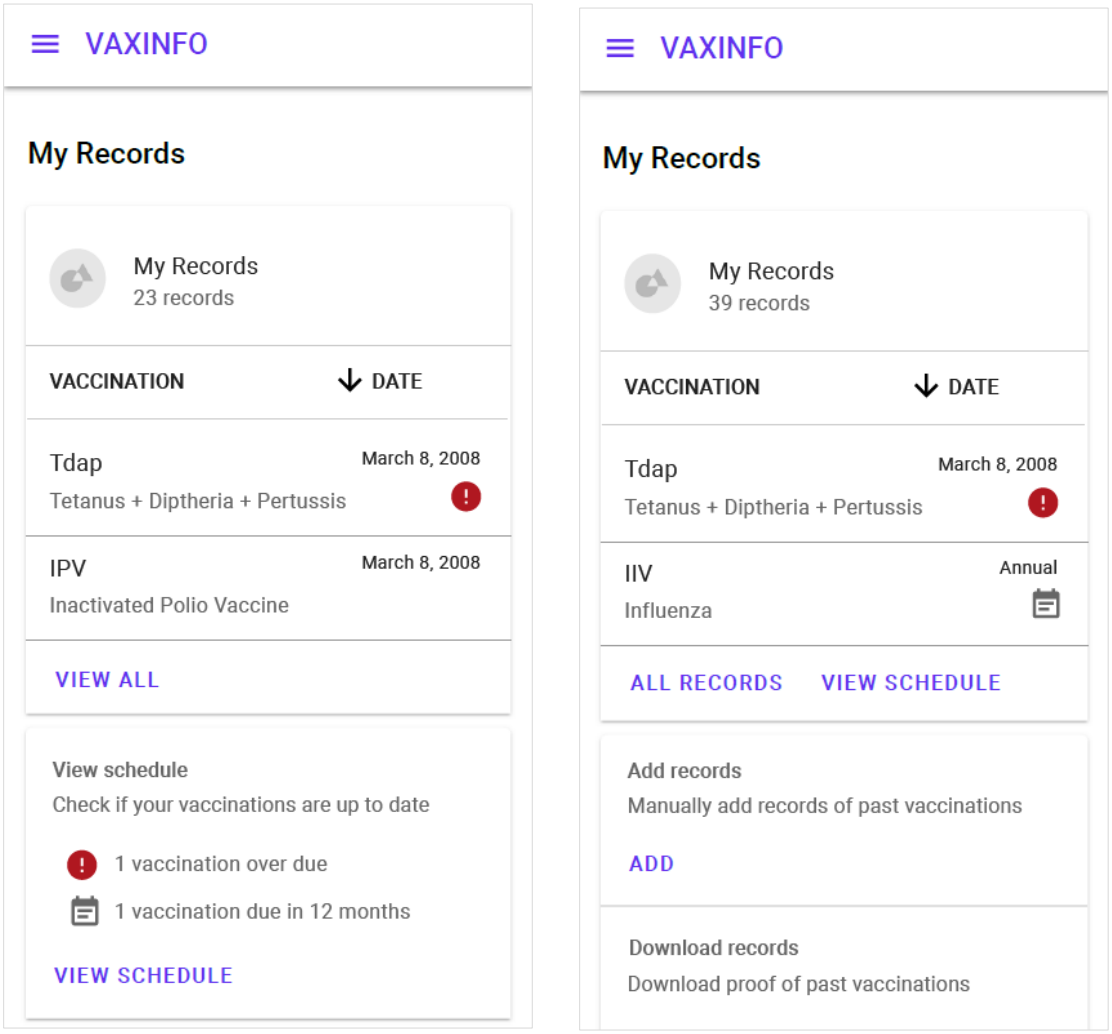

Figure A1. Changes to My Records after Round 1 Tests.

The My Records page was regrouped to move the View Schedule button higher on the page.

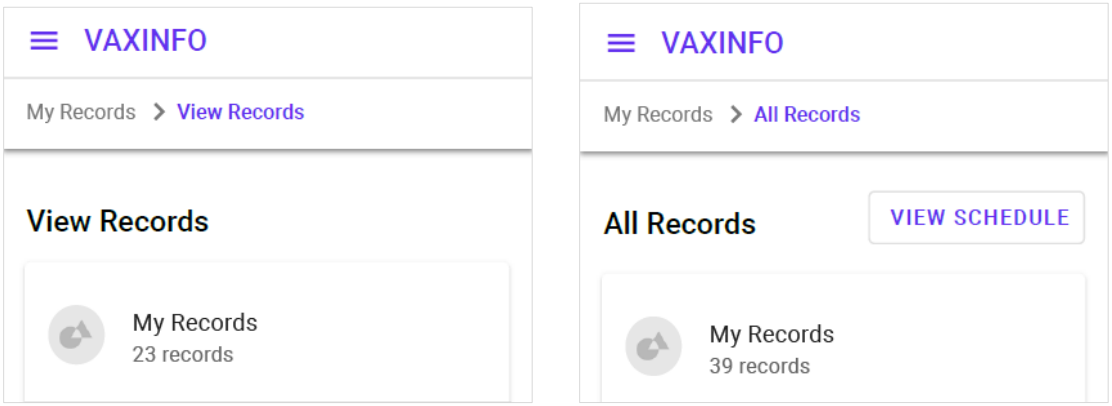

Figure A2. Changes to View Records after Round 1 Tests.

The title of this page was changed from View Records to All Records, and a View Schedule button was added.

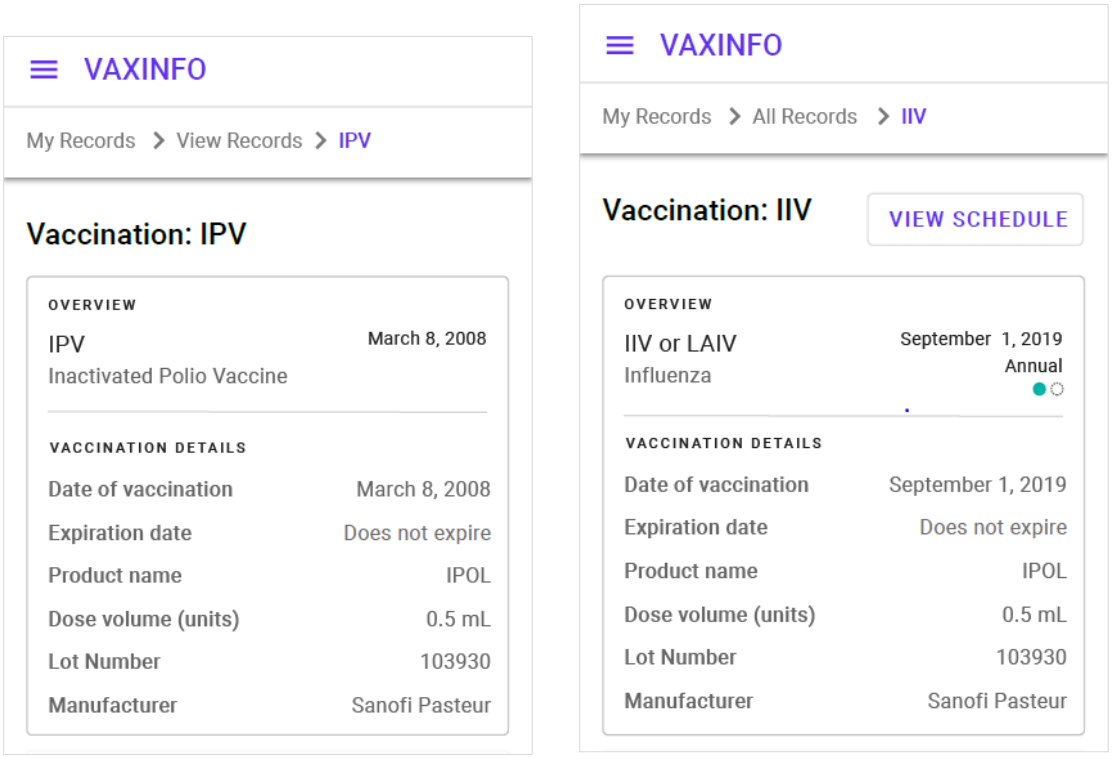

Figure A3. Changes to Vaccination Records after Round 1 Tests.

A View Schedule button was added to the top of vaccination record pages. Filled/unfilled green circles were also added to the overview section to indicate where each vaccination falls within a sequence of recommended doses.

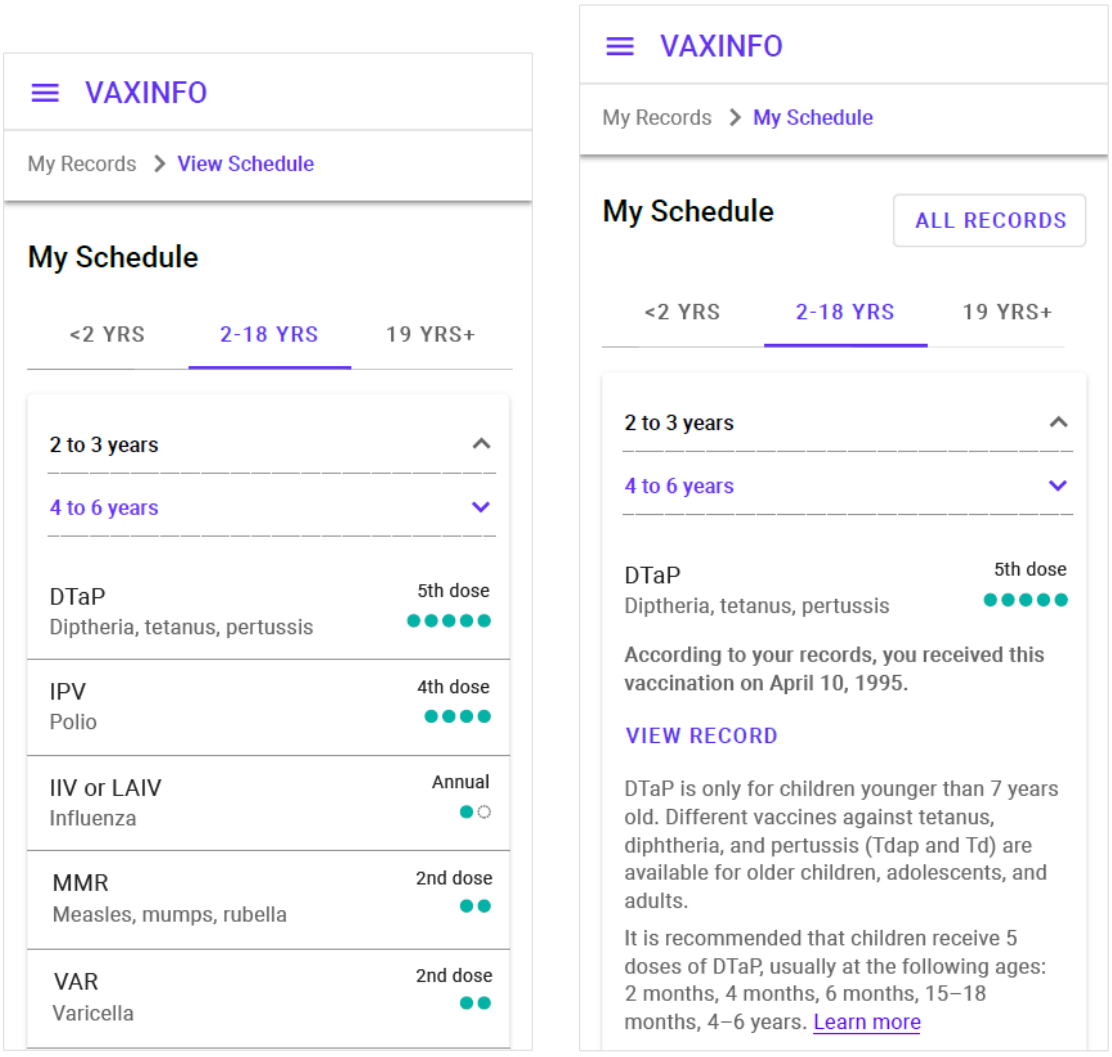

Figure A4. Changes to Vaccination Schedule after Round 1 Tests.

Additional details were added to the vaccination schedule page, including an explicit statement on the status of each vaccination, a link to the vaccination record page for vaccinations that have been received, a brief description of who/when the vaccine is recommended for, and a link to more information. An All Records button was also added to the top of the personalized vaccination schedule page.

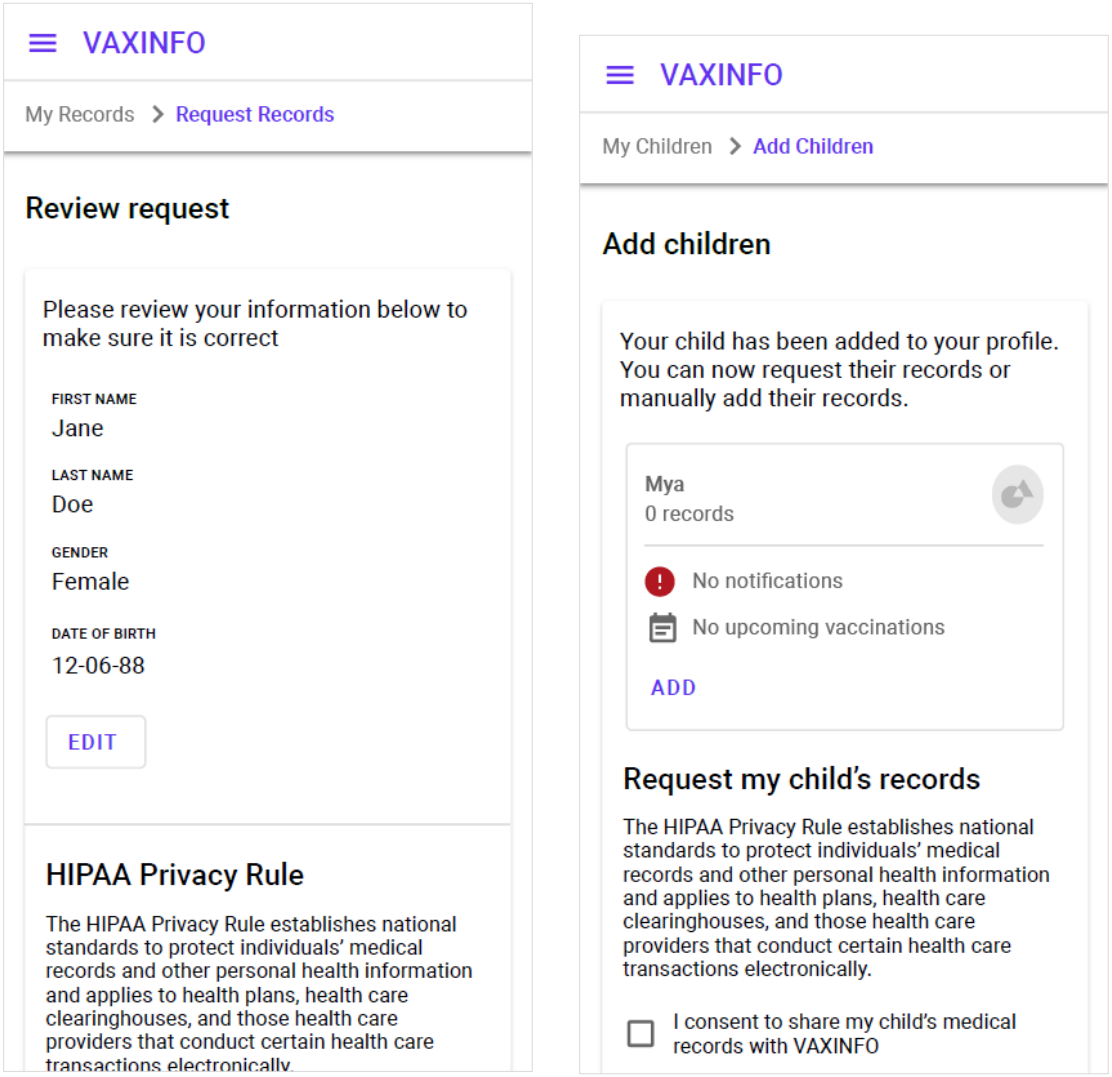

Figure A5. Changes to Request Records after Round 1 Tests.

The form for requesting records was adapted for parents requesting records on behalf of their children. This form consists of a two-step process: 1) adding a child to an account and 2) providing consent for VaxInfo to request records for the child.

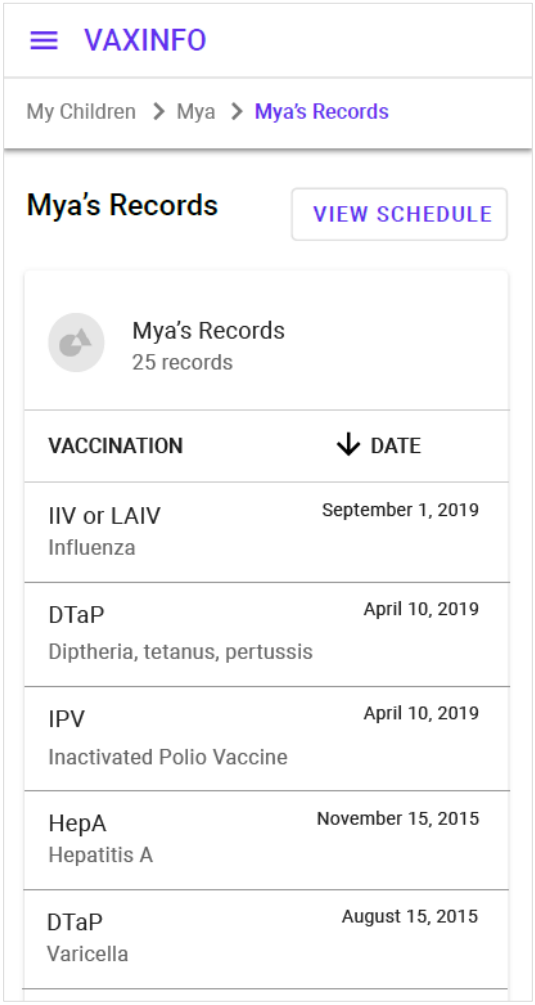

Figure A6. Changes to My Children after Round 1 Tests.

Pages were added to the My Children section of the app, starting from the My Children page (see Figure 7). Further down the hierarchy in this section, the individual child's homepage mirrors the parent's My Records page (see Figure 6) and the Mya's Records page (see above) mirrors the parent's All Records page (see Figure A2).

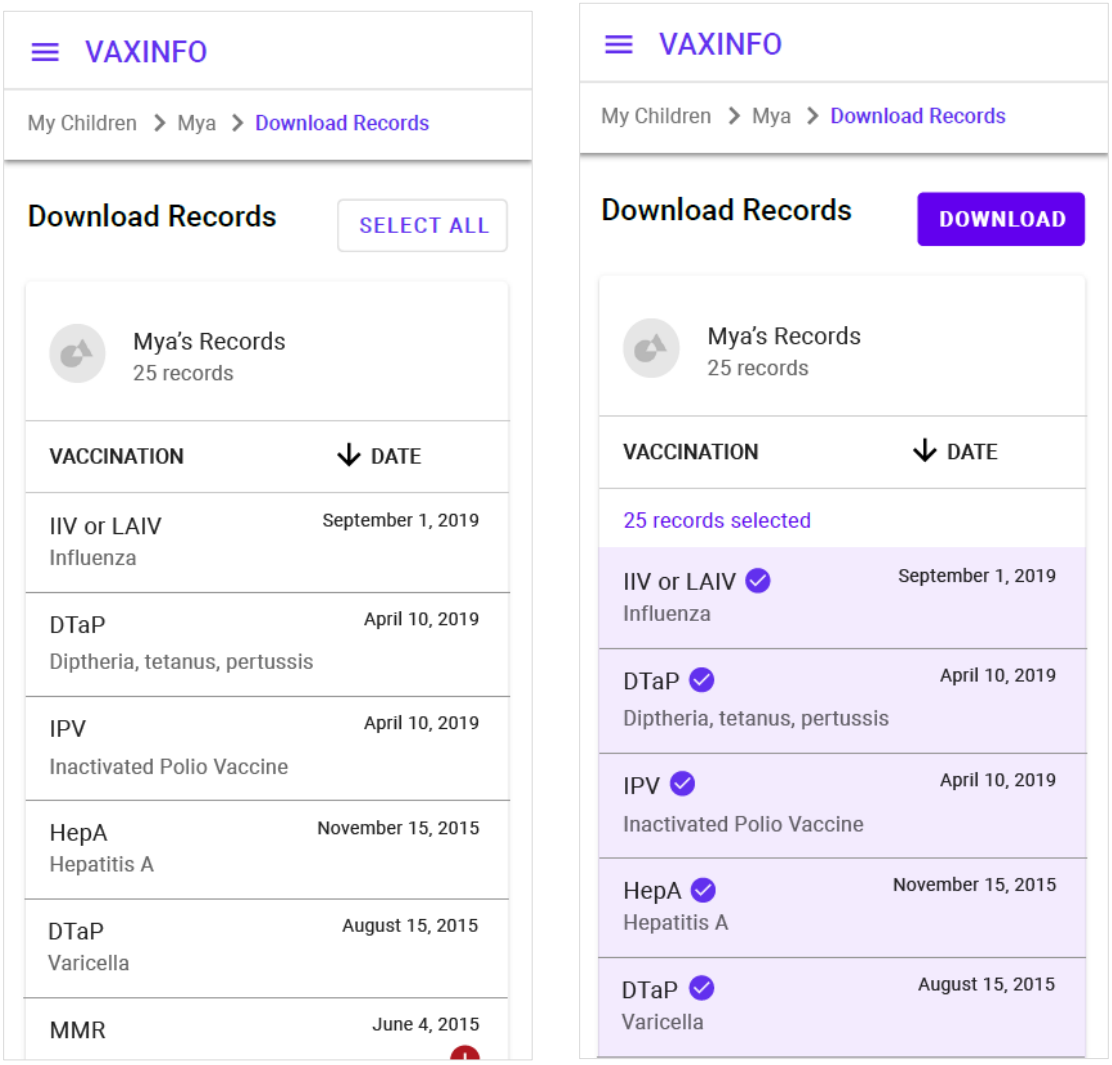

Figure A7. Download Records

Pages were added for the download feature of the VaxInfo app. The download wizard employs the same layout and iconography as the All Records page to facilitate quick comprehension and completion of this important task.

Appendix B: Changes Made to the VaxInfo Prototype after the Second Round of Testing

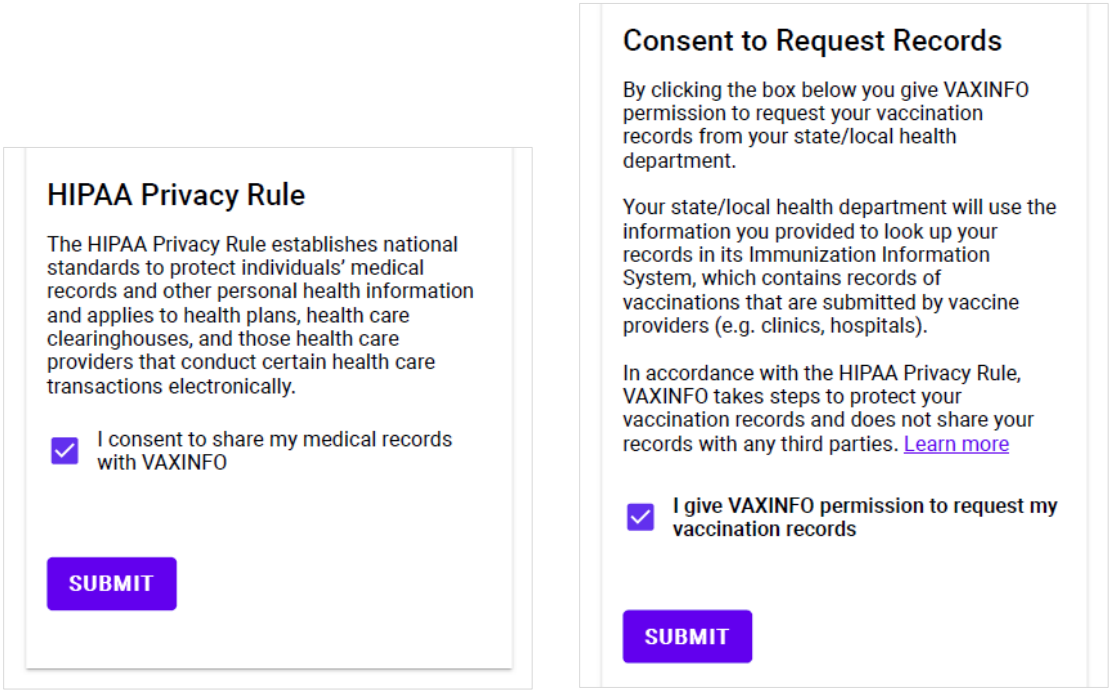

Figure B1. Changes to Request Records after Round 2 Tests.

Language was added to the request form to address privacy concerns and clarify VaxInfo's operating model.

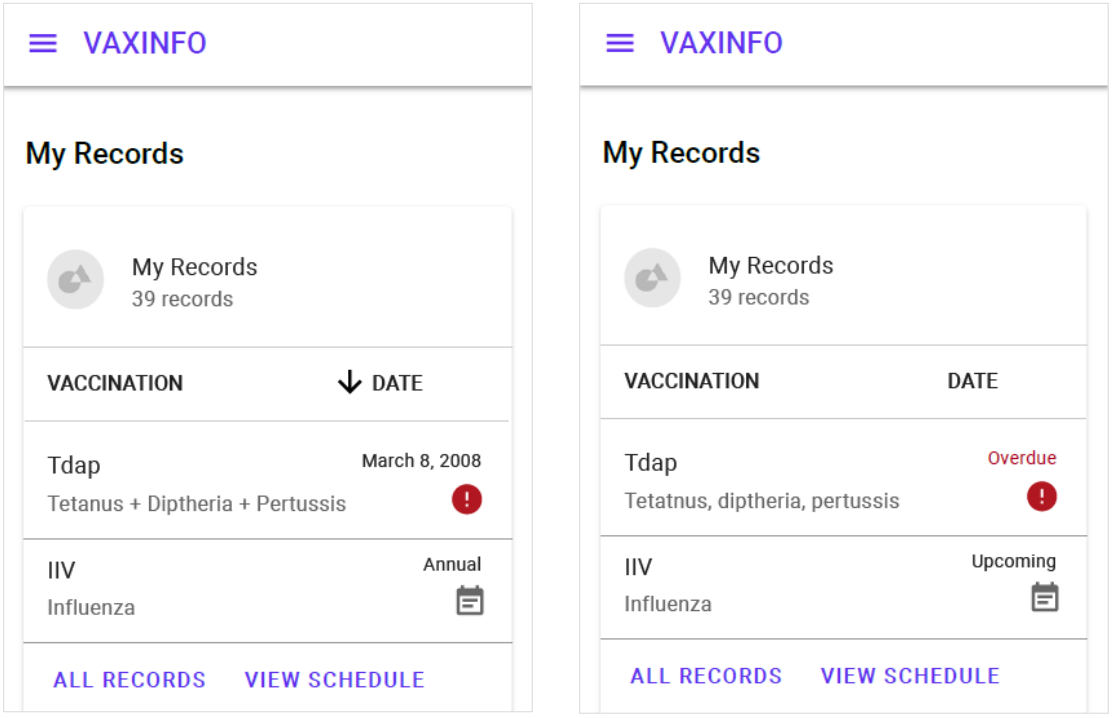

Figure B2. Changes to My Records after Round 2 Tests.

Status labels were added to the to the My Records summary card, and the sort arrow was removed from the date column.

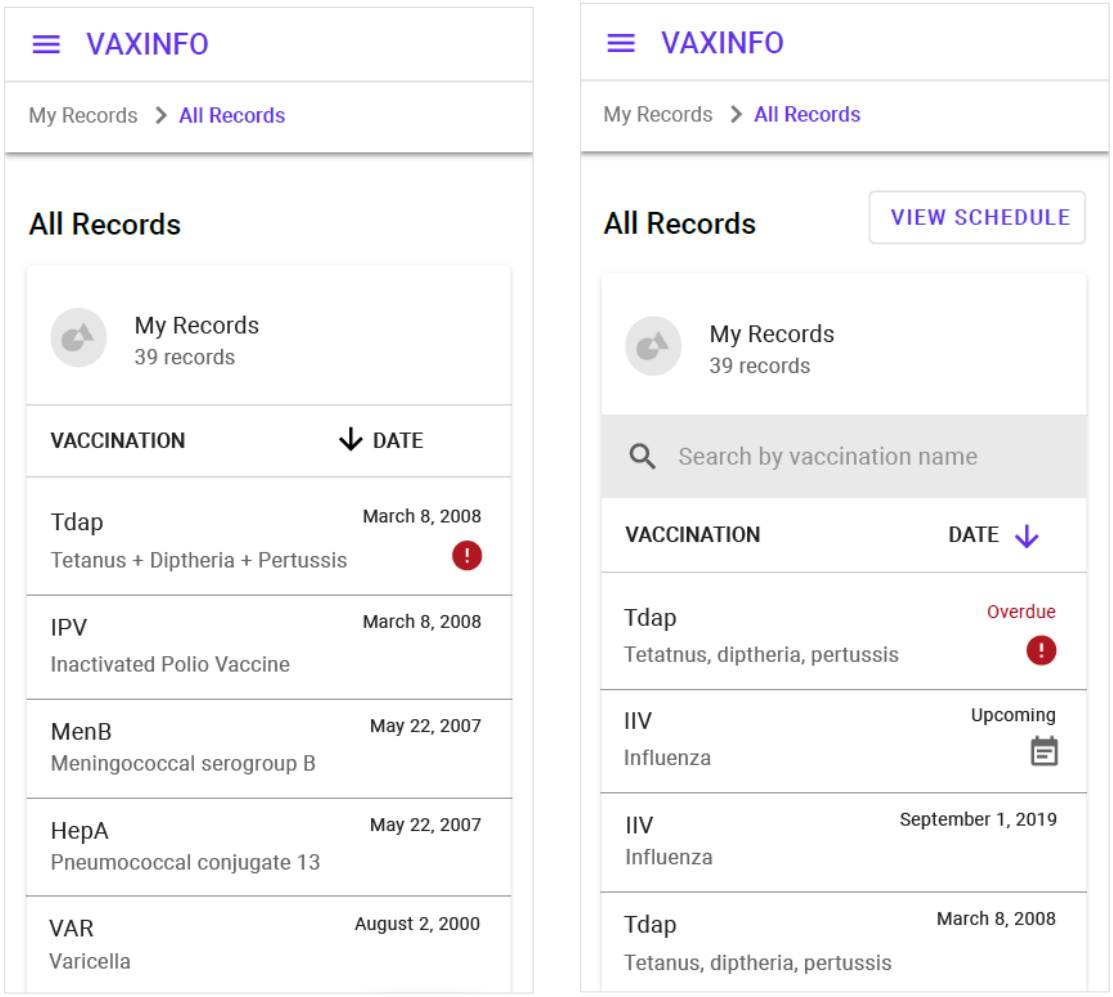

Figure B3. Changes to All Records after Round 2 Tests.

A search bar was added to the top of the All Records page.

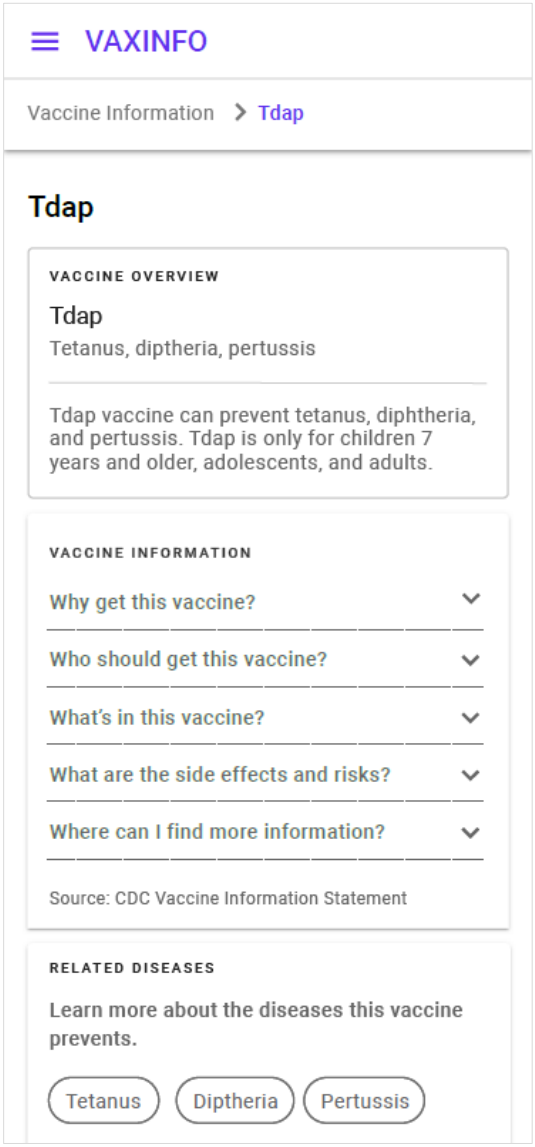

Figure B4. Vaccine Information Page.

Vaccine Information pages were created and linked to vaccination records in the My Schedule section and to Disease Information pages.

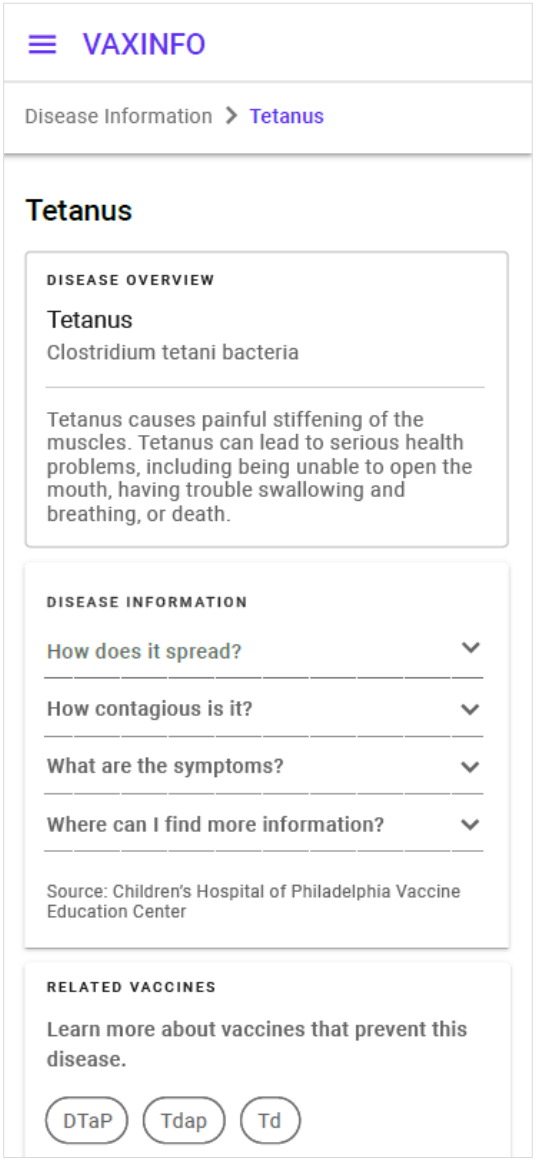

Figure B5. Disease Information Page.

Disease Information pages were created and linked to vaccination records in the My Records section and to Vaccine Information pages.

Appendix C: VaxInfo Usability Testing Script

Introduction

Hello, my name is Sesi Aliu, and I'm going to walk you through today's session. As I mentioned over email, I am developing an online service that allows people to manage their immunization records and access information about vaccines and the diseases they prevent.

I'd like to begin by thanking you for making time to participate in this project. Your feedback is valuable and will help me improve the design of this service. Just to confirm, I'd like to keep this session to 60 minutes or less. Does that still work for you?

Great. If you need a break or to stop at any time, please let me know.

During this session, I'll start by asking a few background questions about you, your use of technology and your immunization records. I won't ask you to share these records. Later on, I'll ask you to share your screen and complete a few tasks using a prototype of the website/application I'm designing.

Please be aware that there are no wrong answers. In fact, this is probably the one place today where you don't have to worry about making mistakes! As you go about using the website/application, I'll ask you to think aloud as much as possible: to describe what you're looking at and what you're trying to do. This will be a big help.

Also, please don't worry that you're going to hurt my feelings. I'm doing this to improve the website/application, so I need to hear your honest reactions.

If you have any questions as we go along, just ask. I may not be able to answer them right away, since I'm interested in what people do when they don't have someone sitting next to them to help. But if you still have any questions when we're done, I'll try to answer them then.

With your permission, I'd like to record this session. The recording will only be used to help me figure out how to improve the website/application, and it won't be seen by anyone except me and my thesis advisor. Recording this session also helps me, because I don't have to take as many notes! Do I have your permission to record this session?

Finally, I want to confirm that you've received and had a chance to review the consent form? Do you agree to the terms of the consent form?

Great. Do you have any questions for me at this time?

Warm up

- Before we take a look at the website/application, I'd like to hear a little bit about you:
- What type of phone do you use? Computer?
- Approximately how many hours a day do you spend on your phone? Computer?
- When was your last vaccination, including the flu vaccine?
- What is the next vaccination you expect to get, including the flu, coronavirus and any vaccines required for travel?
- Where are your vaccination records currently stored? Primary care physician? At home?
- How far back do these records go?

- What formats are they in? Paper? Electronic?
- How would you go about accessing them?

Setup screen sharing

OK, great. We're done with the questions, and we can start looking at the website. The first thing I'd like you to do is open the prototype using the link I sent you. Next, share your screen by clicking "Share screen" in the bottom panel of the Zoom window. Then click on the prototype window.

To start, please look at this page and tell me what you make of it: what are your first impressions? You can scroll if you want to, but don't click on anything just yet.

Scenarios for Rounds 1 and 3 Tests

Thanks. Now I'm going to ask you to respond to the following few scenarios. I'm going to read each scenario out loud.

Scenario 1: Sign up

During your last visit, your doctor said that you might need to get a tetanus booster if you haven't had one in the last 10 years. He recommends VAXINFO, a website where you can track your vaccinations.

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenario 2: Request vaccination records

Let's say that you receive a confirmation email and then you return to the website.

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenario 3: View vaccination records

Let's say that you receive a notification that your records are available, so you head to the website to check them out.

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenario 4: Check vaccination schedule

You remember that your doctor said to see if you need a booster for tetanus. Can you tell if there are any other vaccinations you need so you can get them all at the same time?

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenarios for Round 2 Tests (Parents)

Thanks. Now I'm going to ask you to respond to the following few scenarios. I'm going to read each scenario out loud.

Scenario 1: Add child to profile and request records

You are registering your 6-year old for school and need to make sure her vaccinations are up to date. You already use VAXINFO to manage your vaccination records and would like to do the same for her.

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenario 2: View child's vaccination records

Let's say that you receive a confirmation that your child's records are now available, so you head back to the website. What was your child's most recent vaccination?

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenario 3: Check child's vaccination schedule

Are your child's vaccinations up to date?

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Scenario 4: Download child's vaccination records

How can you prove to the school that your child has received vaccinations?

Pathway(s)	Success	Notes/Observations
	0 Not completed 1 Completed with difficulty or help 2 Easily completed	

- How would you rate this task: very easy, somewhat easy, neutral, somewhat difficult, very difficult?
- Was anything confusing or unclear?

Follow up

Great, we're finished with the bulk of the test. You mentioned [something they said out loud] earlier and I didn't want to jump in at that time. Can you say more about that?

Wrap up

- What was your overall impression of the website?
- What did you like most about the website?
- What did you like least?
- Do you have any recommendations for improvement?
- Is there anything else that you would want to be able to do on this website?

Thank you so much for your time.

Appendix D: VaxInfo Usability Testing Consent Form

Consent Form for Participation in Research Activities

This form is for participating in usability testing for the VAXINFO service.

Introduction/Purpose

I am being asked to participate in usability testing for a research project. The purpose of this project is to develop an online service that allows patients to manage their vaccination records and access information about vaccines and the diseases they prevent.

I am being asked to volunteer because of my experience looking up immunization records for myself or members of my family. My involvement in this study will begin when I agree to participate and will continue until I complete the usability testing. About 15-20 persons will be invited to participate.

Procedures

As a participant in this study, I will be asked to remotely test an interactive prototype of a website and application for immunization records, while my computer/phone screen is recorded, and my voice is audio recorded via Zoom.

As part of the test, I will be asked to look up and enter fictional vaccination records, and search for factual information about vaccines and the diseases they prevent. I will be asked to complete this test remotely. My participation in this study will last for about 1 hour. No personal identifying information will be collected during the session.

Risks and Benefits

My participation in this study does not involve any significant risks and I have been informed that my participation in this research will not benefit me personally but may benefit individuals who would like to keep track of their vaccination records and public health officials in their efforts to monitor and prevent disease outbreaks.

Confidentiality

Any information learned and collected from this study in which I might be identified will remain confidential and will be disclosed ONLY if I give permission. All information and recordings collected in this study will be stored on the investigator’s password-protected computer hard-drive and in a password-protected Google Drive folder. Only the investigator and members of the research team will have access to these records. If information learned from this study is published, I will not be identified by name.

Audio and video recordings from this study will be stored on the investigator’s password-protected computer hard-drive and in a password-protected Google Drive folder. The recordings will be retained for two years after the completion of the study, and then deleted.

By signing this form, however, I allow the research study investigator to make my records available to the University of Baltimore Institutional Review Board (IRB) and regulatory agencies as required to do so by law.

Consenting to participate in this research also indicates my agreement that all information collected from me individually may be used by current and future researchers in such a fashion that my personal identity will be protected. Such use will include sharing anonymous information with other researchers for checking the accuracy of study findings and for future approved research that has the potential for improving human knowledge.

Check if images or video are recorded during the research study:
- Yes, I give permission for video recording of my screen
- No, I do not give permission for video recording of my screen

Check if voice recordings are used during the research study:
- Yes, I give permission for audio recording of my voice
- No, I do not give permission for audio recording of my voice

Sponsor of the Research

This research project is for a master's thesis.

Compensation/Costs

My participation in this study will involve no cost to me. I will not be paid or reimbursed for my participation in this study.

Contacts and Questions

The principal investigator(s), Sesi Aliu, has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions, I can contact Sesi Aliu at olusesi.aliu@ubalt.edu or 202-294-4562.

For questions about rights as a participant in this research study, contact the UB IRB Coordinator: 410-837-4057, irb@ubalt.edu.

Voluntary Participation

I have been informed that my participation in this research study is voluntary and that I am free to withdraw or discontinue participation at any time.

I will be given a copy of this consent form to keep.

Signature for Consent

The above-named investigator has answered my questions and I agree to be a research participant in this study. By signing this consent form, I am acknowledging that I am at least 18 years of age.

Participant's Name

_____

Participant's Signature
Typing your name in the space below serves as your signature.
_____

Date (mm/dd/yy)
_____

Investigator's Signature

Sesi Aliu

Contact Info

Sesi Aliu
Interaction Design & Information Architecture
Division of Science, Information Arts and Technologies
University of Baltimore
olusesi.aliu@ubalt.edu
202-294-4562

Appendix E: User Personas and Journey Maps

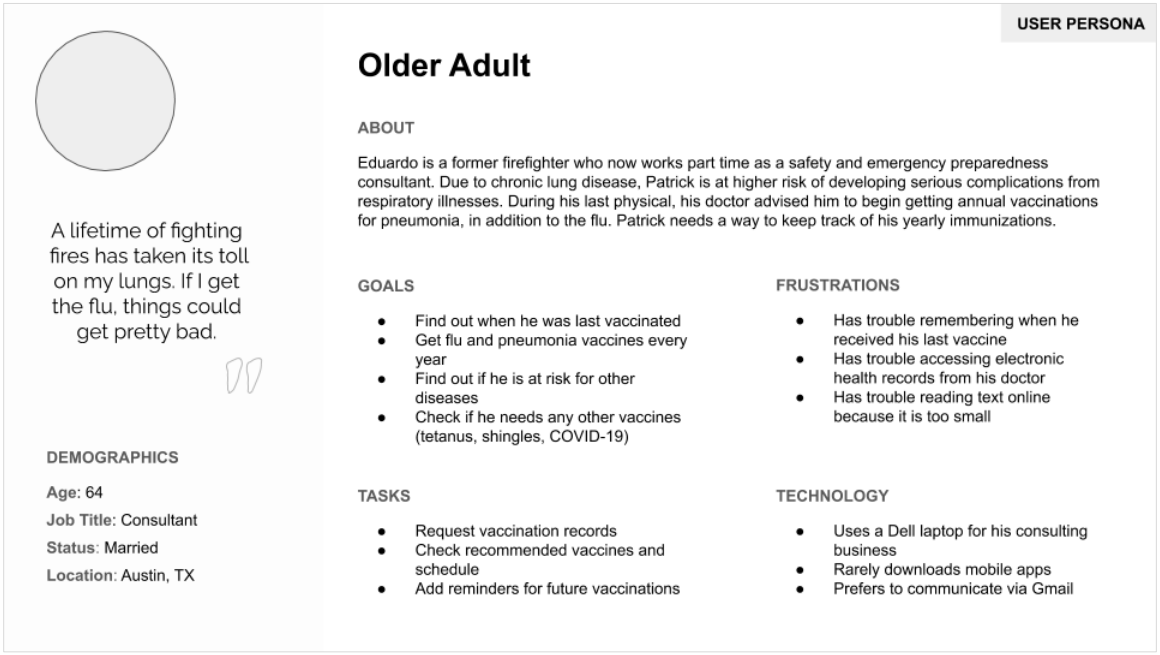

Figure E1: User Persona for an Older Adult.

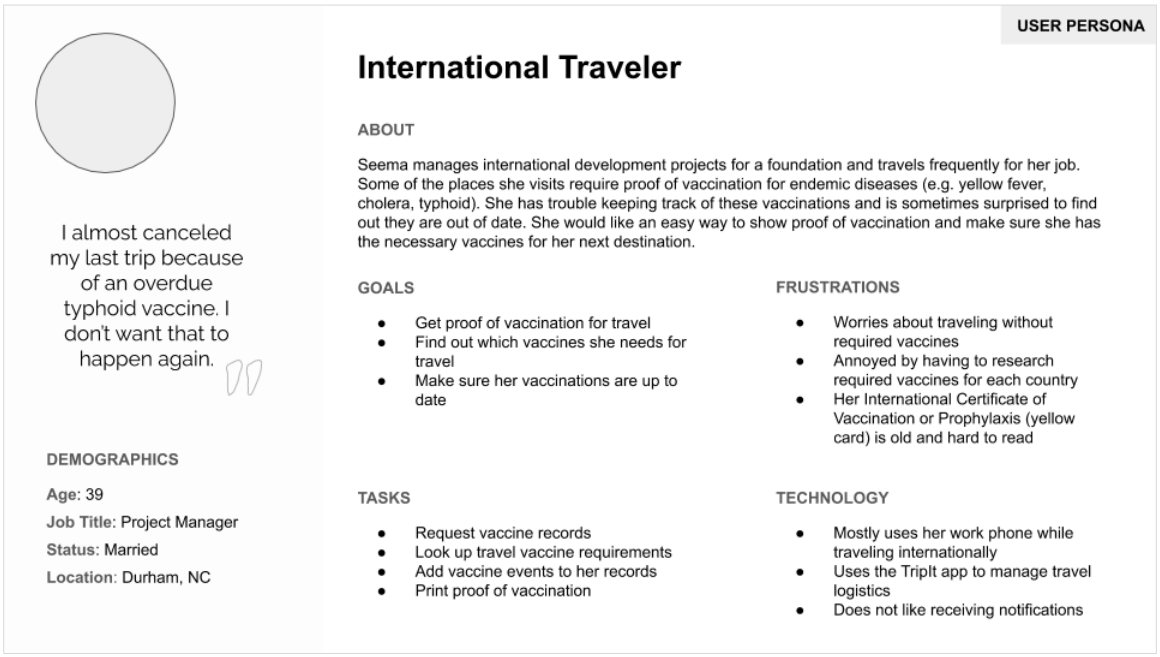

Figure E2: User Persona for an International Traveler.

Appendix F: VaxInfo Application Site Map