

A Health IT-Empowered Integrated Platform for Secure Vaccine Data Management and Intelligent Visual Analytics and Reporting

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Abstract: Health IT (HIT) and big data analysis have been applied to a community-oriented COVID-19 vaccination program (RapidVax). The HIT platform enables security data collection, enforces data quality and rule validations, preserves privacy through strict data access control with HIPAA compliance and secure VPN, customizes interactive user interfaces, empowers outcome visualization, and generates intelligent reporting. The RapidVax program has adopted the HIT platform for ninety-five vaccination events in thirty geographically separated communities. Our study demonstrated the significance of health IT tools, and automated program generated in this study to help manage a public health problem such as the COVID-19 pandemic. The health IT tools developed in this study provided an essential piece of critical infrastructure which supported our clinicians to run the vaccination task efficiently.

1 INTRODUCTION

COVID-19 is a novel form of coronavirus disease caused by a respiratory virus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus spreads through respiratory droplets and airborne particles. As of October 2nd, 2021, there are 219 million cases observed globally, out of which 4.55 million patients died from COVID-19. In the US, as of October 2nd, 2021, there are 43.6 million cases, out of which 700,000 died from COVID-19 (Covid in the U.S.: Latest Map and Case Count - The New York Times). COVID-19 infection causes flu like symptoms such as fever, chills, cough, shortness of breath, fatigue, muscle ache, body ache, headache, and loss of taste (Mizrahi, 2020).

Vaccination is a simple, safe, and effective way to enhance immunity for disease prevention (prophylactic vaccine) or treatments (therapeutic vaccine) (Bloom, 2017). Studies have shown that vaccines have made great advances in public health and improved human health through preventing diseases. To date, no treatment planning has

demonstrated effectiveness for treating COVID 19 infections due to the susceptible mutations of the virus (DeRoo, 2020). Scientists worldwide have been working on developing vaccines against COVID 19 virus for the past 16 to 18 months. In the US, the first vaccine was given On December 18, 2020, vaccine for the prevention of COVID-19. Currently the US Food and Drug Administration (FDA) has only approved three of the COVID 19 vaccines that include Pfizer-BioNTech, Moderna, and Janssen/J&J, for use in the US. (Gee, 2021; Oliver, 2020, 2021).

At the Temple University College of Public Health (TU CPH), we developed a LEAN protocol, for Rapid Vaccination. We coined (RapidVax) to vaccinate essential faculty, staff, and students at Temple University's College of Public Health, in November/December 2020. The provision of vaccinations was essential to keeping students in the clinical field to meet the stringent educational requirements of clinical programs such as nursing, physical therapy in during the COVID-19 pandemic. We developed an interprofessional team of licensed

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clinical faculty and students and conducted a proof-of-concept test of the RapidVax protocol in February 2021. To further satisfy our community's needs for vaccine delivery in Philadelphia, we partnered with the Philadelphia Housing Authority (PHA) (the 4th largest public housing authority in the US) to vaccinate their essential workers and their community partners, providing excellent customer service no lines. In partnership with PHA we held over 80 vaccine clinics in senior public housing and accomplished our joint goal of offering vaccination to every senior in Philadelphia Public Housing by the end of April 2020. Our mobile team has also reached out to local communities, especially underserved neighbourhood's, to deliver vaccines efficiently and quickly. To date, the RapidVax program has hosted more than 100 community-based events in 30 geographically separated communities. In order to successfully implement our program, we have developed health IT strategies to effectively register people for vaccination electronically, determine the number of people who will visit for vaccinations on a particular date, document their vaccine series (dose one and dose two) information, report vaccination to the city health department and schedule follow-up appointments. Hence, the objectives of this study are as follows.

- Develop health IT processes to capture patient information, registration, reporting and scheduling of appointments electronically.
- Develop methods to preserve data confidentiality, and patient privacy as the collected data contains Personal Identifiable Information (PII).
- Create data quality matrices (completeness and concordance) to perform timely data quality checks.
- Develop computational programs to generate accurate individual and summary reports required by the Philadelphia Department of Public Health (PDPH) and other groups, including individual vaccine information, daily summary, weekly reports, monthly updates, and geospatial distributions.
- To analyse the heterogeneous patient information, clinical variables, vaccination events, vaccine types, and other factors for evidence-based decision making.
- To create a website and a dashboard to visualize the vaccination information for public.

2 METHODS

Our approach consisted of the following steps. First, we designed an online form using emergency use authorization (EUA) guidelines from the FDA to register patients for vaccines, documenting patient specific information, risk of adverse effects of vaccines, obtaining consent and dose 1 and dose 2 specific information, and booster dose information (*COVID-19 Vaccination Clinical and Professional Resources | CDC, n.d.*). Second, we developed a method to de-identify datasets to preserve patients' privacy and confidentiality. Next, we developed data quality matrices to ensure high accuracy and quality of the collected data. Lastly, we created an automated algorithm to generate reports for the city and for the internal usage. We created two databases to store patient information and automated reporting and generated a dashboard for data visualization. See Figure 1 for overall workflow of this project. We describe each step-in detail below.

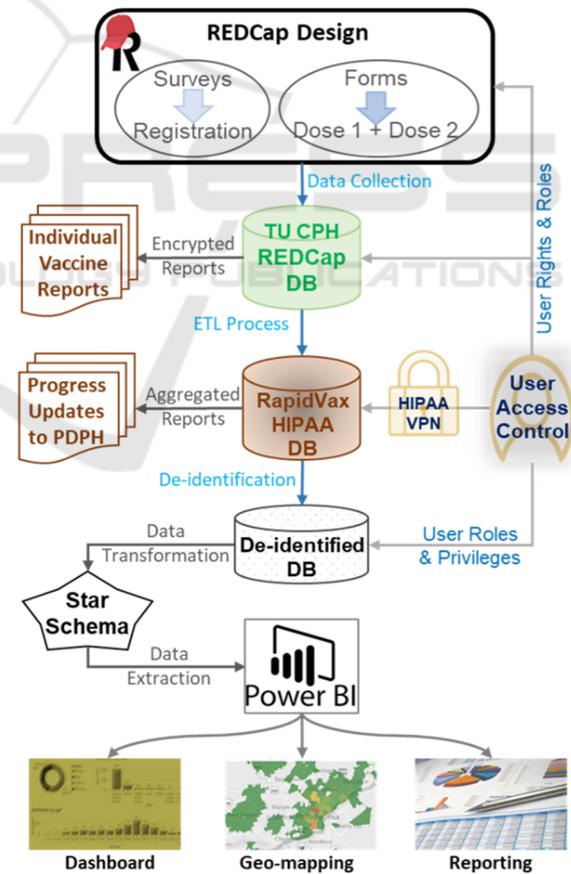


Figure 1: The integrated RapidVax platform and secure data workflow.

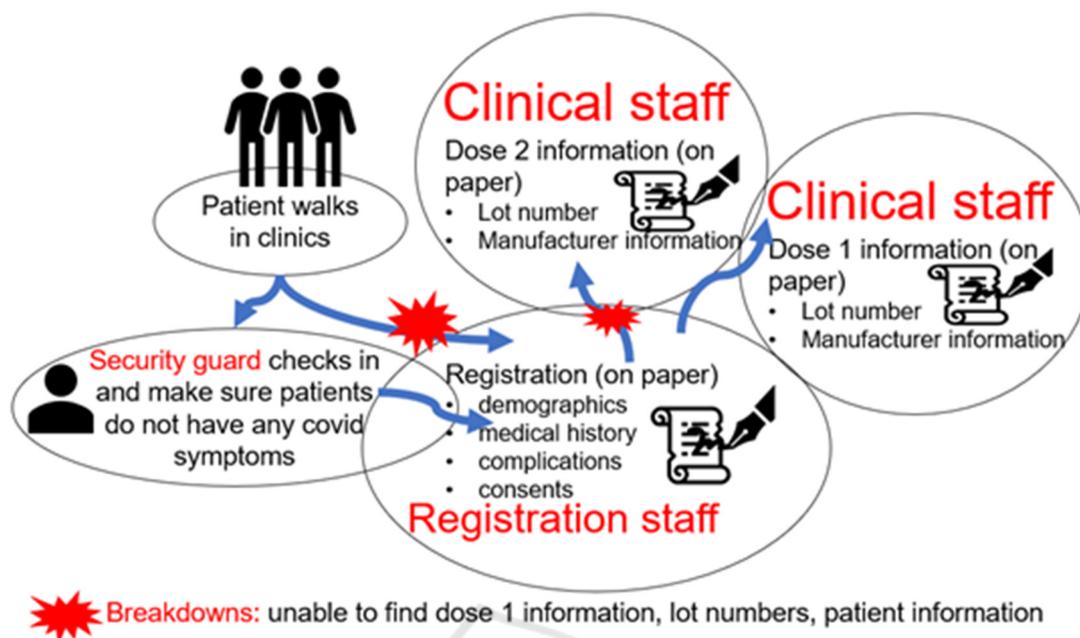


Figure 2: Contextual inquiry to determine the vaccination workflow in RapidVax clinics.

2.1 Observation of Vaccination Clinics using the Contextual Inquiry Method

First, using the contextual inquiry method, three researchers (HW, SVS, LAF) visited the community and clinic-based vaccination sites (site 1) in person for at least five times. One of the researchers and clinicians (SVS) is an Associate Dean for Clinical Affairs at TU CPH. SVS has visited vaccination sites at least 15 times to collect the workflow information. Contextual inquiry is a type of ethnographic field study that involves in-depth observation and interviews of a small sample of users to gain a robust understanding of work practices and behaviours (Wixon, 1996). As demonstrated in Figure 2, typically, patients walk in the clinics and are checked by the security guards. Security guards initially performed the COVID-19 symptom screenings to identify anyone who might be infected with COVID. If patients have symptoms, then they are sent back, and no vaccination is given. If the individual has no covid symptoms, they proceed to the registration table. Individuals have the option to register via a URL before they get to the vaccination site. If this is the case the individual is checked in and consented for the vaccine. If the individual did not register ahead of time, they are asked to complete a registration form which includes their demographic information and the consent. The consent is reviewed by a trained

member of the vaccination staff. These steps were observed when the contextual inquiry was done, registration staff used paper for registration. If an individual is coming for the first dose of vaccine, the person gets the first dose. The patient is given a completed Centers for Disease Control and Prevention (CDC) handwritten card that confirms that they received the vaccination, date of vaccination, type, manufacturer of vaccination, and lot number. If the patient has already received the first dose, they are asked for their CDC card at the time of registration to verify which vaccine they received and to validate the time interval between dose 1 and 2. Upon retrieval of this information, the second dose of vaccination is given. The individual's CDC card is updated with the second dose of the vaccine confirming their vaccination date and time, dose number, manufacturer, and lot number.

While conducting the contextual inquiry, we found several breakdowns. For instance, many times, patients will forget their cards to confirm their previous dose information. As a result, it was very time-consuming for the registration and clinical staff to find their information through paper records. In addition, sometimes the records were missing, and, in these cases, the team had to register the patients and rely on patient information. Often, patients provide different names (e.g., Joe instead of Joseph), which also hinder in finding reports of these patients.

2.2 Information System to Document Patient Information

After conducting the contextual inquiry, we designed electronic forms to collect individual’s demographic information, consent and vaccine information. We created these forms in REDCap. REDCap is a secure web application for building and managing online surveys and databases which was designed by Vanderbilt University (Harris, 2019). We collected patients’ basic demographic information in the patient registration form, such as email address, first name, last name, gender, date of birth, address, city, state, zip code, race, ethnicity, and primary language. While providing dose one and two vaccinations, we collected information as demonstrated in Table 1. We followed EUA / FDA COVID 19 guidelines to collect patient information. We collected this information on

Table 1: Dose 1 and Dose 2 information collection in REDCap.

Participant information and registration number
Vaccination type (Moderna, Pfizer, Janssen)
Manufacturer (ModernaTx,Inc, Pfizer-BioNTech, Janssen)
Lot number (open-ended)
Vaccine admin site (left arm, right arm)
Vaccine route admin (open-ended)
Dose number (open-ended)
Vaccine series complete (Yes, No)
Vaccination refusal (Yes, No)
Sickness/fever/being treated for acute illness (Yes, No)
Prior vaccination in the last 14 days (Yes, No)
Testing positive for Covid-19 in the past 14 days (Yes, No)
Cosmetic implants such as lip or breast (Yes, No)
History of Guillain bureau syndrome
Women younger than 50 years old should be aware of the rate risk of blood clots with low platelets after vaccination and that other Covid-19 vaccines are available (Janssen only). The individual is asked to confirm they choose to receive the vaccine.
Consent: I understand that there is no Vaccine Information Statement (VIS) available for the vaccine I am receiving today. I have reviewed the Fact Sheet provided about the vaccine I am to receive. I understand the benefits and risks of vaccination and I voluntarily assume full responsible for reactions that may result. I understand that I should remain in the vaccine administration area for 15 minutes of observation after receiving the vaccine.

the CPH server that is used for further processing in the following steps. Typically, registration staff have access to the REDCap and are responsible for the data collection. We designed surveys and forms with rules to check potential data entry errors, validate input information accuracy (such as age limits or parent signature for minors), and guarantee that the required data elements are provided. We also ensure data privacy with access control, password protection, and encryption for data collection and transfer.

2.3 HIPAA Servers and Data De-identifications

We established two servers: 1) the HIPAA server and 2) non-HIPAA server. The HIPAA-protected database housing the fully identifiable data can only be reached via a HIPAA Virtual Private Network (VPN), enforcing a secure demarcation between the fully identifiable data. The de-identified data is being used at the data consumption layer in the non-HIPAA server for Power BI Dashboards on the webserver. Privacy preservation is also considered for statistical analysis.

2.4 Comprehensive Data Fabric

We combined existing data delivery approaches with innovative use of data integration and preparation as part of the data operations process. The RapidVax Data Fabric includes the Data Source Layer (DSL, bottom in Figure 3), Data Integration Layer (DIL, middle), and Data Consumption Layer (DCL, top). The DSL use Health IT standards and policy, tools, operational databases, VPNs, and cloud data stores. The DIL prepares data with an iterative and agile process for finding, combining, cleaning, transforming, and sharing curated datasets. This layer will merge data, identify anomalies and patterns, and review and improve data quality in a repeatable fashion with a faster time to delivery. The DCL refreshes the PowerBI Dashboard to ingest the latest data, perform integrative analysis, geo-mapping information, and visualize outcomes.

The RapidVax data catalogue starts with DSL, including individual and collective REDCap projects. The identifiable data is imported to a MySQL HIPAA- protected database via DIL weekly through the extraction, transformation, and loading (ETL) process for both incremental and full data refreshes. Each week multiple REDCap project forms are extracted, unioned, and cleaned before being imported into the HIPAA secure database. The data

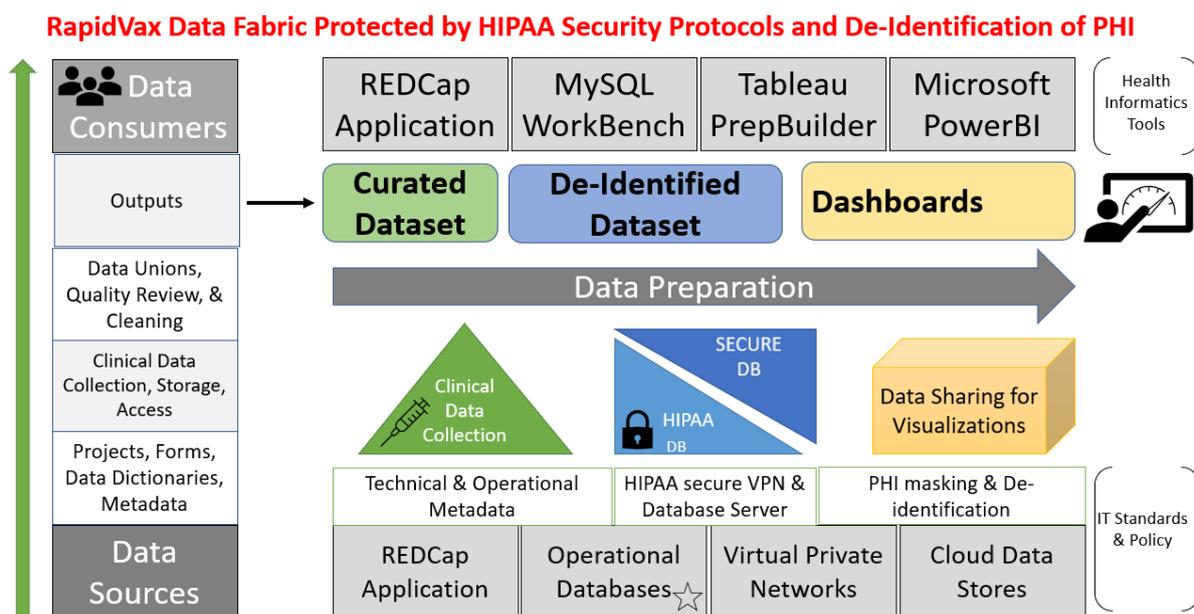


Figure 3: The comprehensive RapidVax data fabric.

model is a traditional analytic star schema in the HIPAA database and a modern Business Intelligence Platform for the de-identified database. The stand-alone data preparation tool, Tableau Prep Builder, supports data integration functions such as unions and outputs and data quality improvement with cleaning steps. The results are then de-identified by removing PII and imported to the de-identified database and Power BI visualizations and dashboards.

2.5 Data Quality Check

We developed two data quality matrices that include completeness and concordance in order to determine the quality of the data. Completeness is the most commonly assessed dimension of data quality (Nicole G. Weiskopf, 2017). Completeness refers to whether a fact about a patient is present or not in the dataset. Most studies use the term completeness to describe this dimension, in addition to data availability or missing data (N. G. Weiskopf & Weng, 2013). We considered a record complete if all findings and information described in section 2.2 are present or not in the datasets (Reimer, 2016). Concordance was measured by determining the agreement between the information recorded during the registration time; dose 1 information and dose two information are the same. For example, if a patient received the Moderna vaccine, then, vaccination type must be “Moderna” in both dose one and dose two form. However, if the vaccination type is Moderna in one form and Pfizer in the second form, then the concordance between

these two information sources will be 0 (disagreement).

We generated concordance reports using Cohen’s Kappa statistics. Cohen’s Kappa statistics are used to measure inter-rater agreement between two annotators/reviewers/data fields. Kappa value typically falls between 0 to 1. It is interpreted as follows. values ≤ 0 as indicating no agreement and 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement (McHugh, 2012).

2.6 Automated Report Generation

After receiving the raw data from the REDCap server, we pre-process the data. During the pre-processing, we converted raw data into an understandable format. For example, we unionid the same patients’ registration information, dose one, and dose two information in one text file. Next, we determine the data quality as demonstrated in section 2.5 (completeness and concordance). Next, if the data is accurate, then we generate reports. Every week, we generate two reports, one for internal use (short report) and one for the PDPH (elaborated report). These reports are generated automatically using computer algorithms. If the data quality is poor, we go back to the REDCap database and ensure the data consistency and accuracy (see Figure 4).

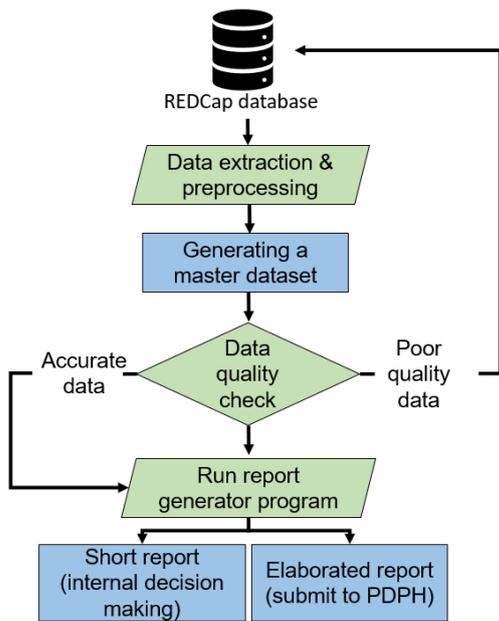


Figure 4: Data processing, data quality, and report generation process.

2.7 Power BI Dashboard

Last, Integrated data analysis and interactive visualization of the RapidVax information have been performed using PowerBI Dashboard and statistical software to evaluate the program outcomes, understand patient social determinants of health, recognize the evolving patterns, identify vaccine hesitancy, and discover geographic areas and population groups of focuses. The dashboard is interactive to explore multiple understand patient social determinants of health, recognize the evolving patterns, identify vaccine hesitancy, and discover geographic areas and population groups of focuses. The dashboard is interactive to explore multiple variables with illustrations. We also performed trend analysis and outcome assessment of the programs. The trend analysis helps the RapidVax leaders make evidence-based decision making, such as strategically adjusting the vaccine types, quantities, and outreaching approaches to lower vaccine hesitancy and reduce vaccine wastes.

3 RESULTS

3.1 Total Vaccination and Sites

We vaccinated a total of 3,942 people (including our CPH staff, students, and faculty) in the Philadelphia,

PA area. As demonstrated in the Figure 5, we visited a total of 23 sites for vaccination. Detailed information on the sites is present in Figure 5. As demonstrated in Figure 6, 45% of our population were females, 41% males, and the remaining transgender, third gender, or missing information. Similarly, the majority of our population consisted of Black or African American race (44%), followed by White (18%).

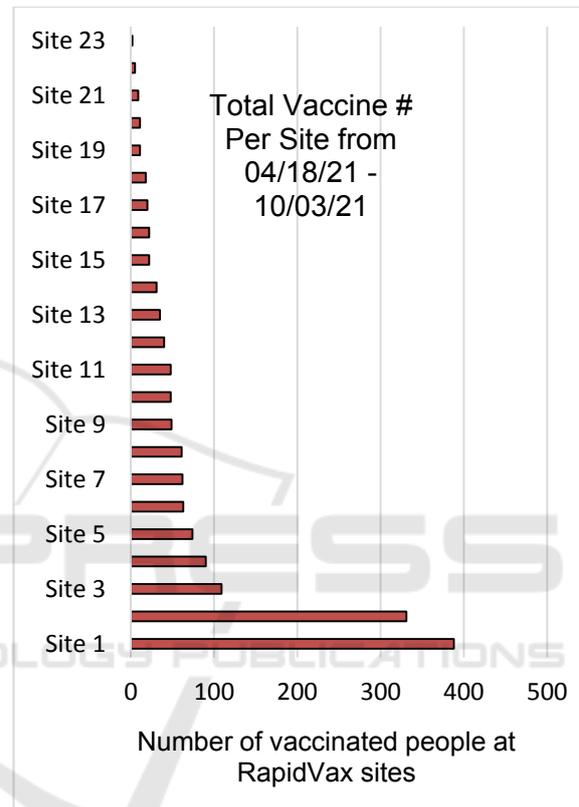


Figure 5: RapidVax vaccination sites.

As demonstrated in Figure 6, 45% of our population were females, 41% males, and the remaining transgender, third gender, or missing information. Similarly, the majority of our population consisted of Black or African American race (44%), followed by White (18%). The remaining sample consisted of Asians, Native Hawaiian, American Indian, Other, and missing data. Most of our population (68%) spoke English, followed by Spanish as demonstrated in Figure 7.

3.2 Data Completeness

Figure 9 demonstrates the completeness of our data. We discovered that date of birth, manufacturer, and vaccination series were reported for all patients

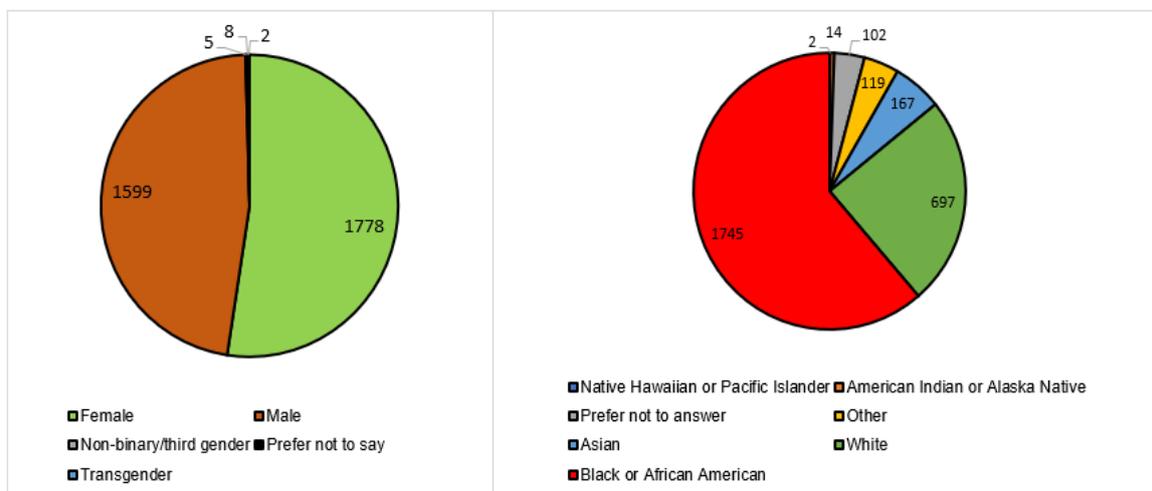


Figure 6: Demographics of RapidVax population.

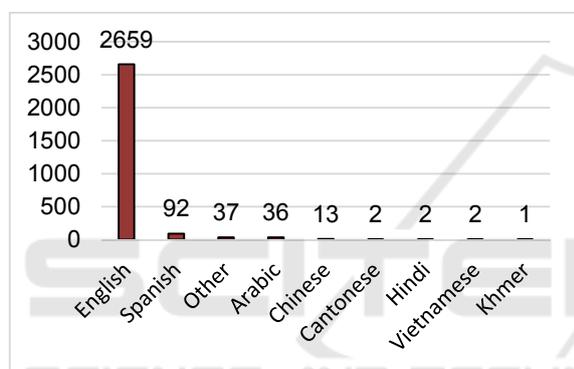


Figure 7: Spoken language by RapidVax population.

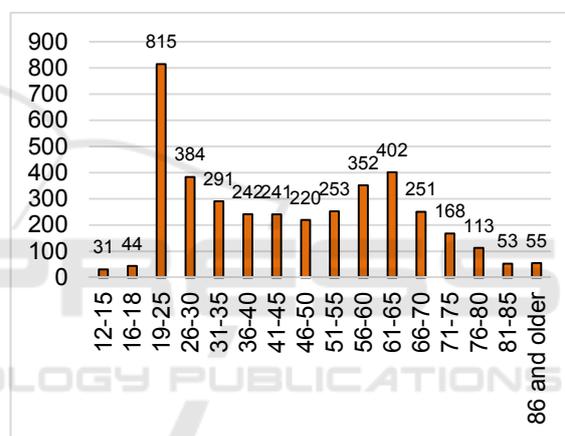


Figure 8: Age distribution of RapidVax population.

(100%), followed by zip code (99%), prior vaccination information (98%), vaccination refusal (97%), and complications (96%).

Completeness of variables such as gender, vaccine admin site, lot number were between 80 to 90%. Race, language, and ethnicity were recorded for approximately 70% RapidVax population. ** Lot numbers must be reported to the Philadelphia Department of Health 100% of the time, thus missing lot numbers were corrected in real-time to ensure completeness of the vaccine record for the department of health.

3.3 Data Concordance

We determined concordance between the information recorded in the registration form, dose one, and dose two forms. The concordance measure between the person's name was 0.91 Cohen's Kappa value. Similarly, the concordance value for the date of birth variable, race, gender, and vaccination type was 0.90.

In 22 records, we found the vaccination names were different. Hence, we created an automatic program that investigates the manufacturer information and automatically updates the vaccination type information in the dataset.

3.4 Dashboard

Using the PowerBI statistical software, we visualized RapidVax population characteristics, demographics, and vaccination doses (see Figure 10). As demonstrated in Figure 9, we also determined geographic areas of vaccinations to make clinical decisions. This dashboard also helps us with the program outcomes, understand patient social determinants of health, recognize the evolving patterns, identify vaccine hesitancy, and discover geographic areas and population groups of focuses.

RapidVax Community Dashboard by Sep 29, 2021

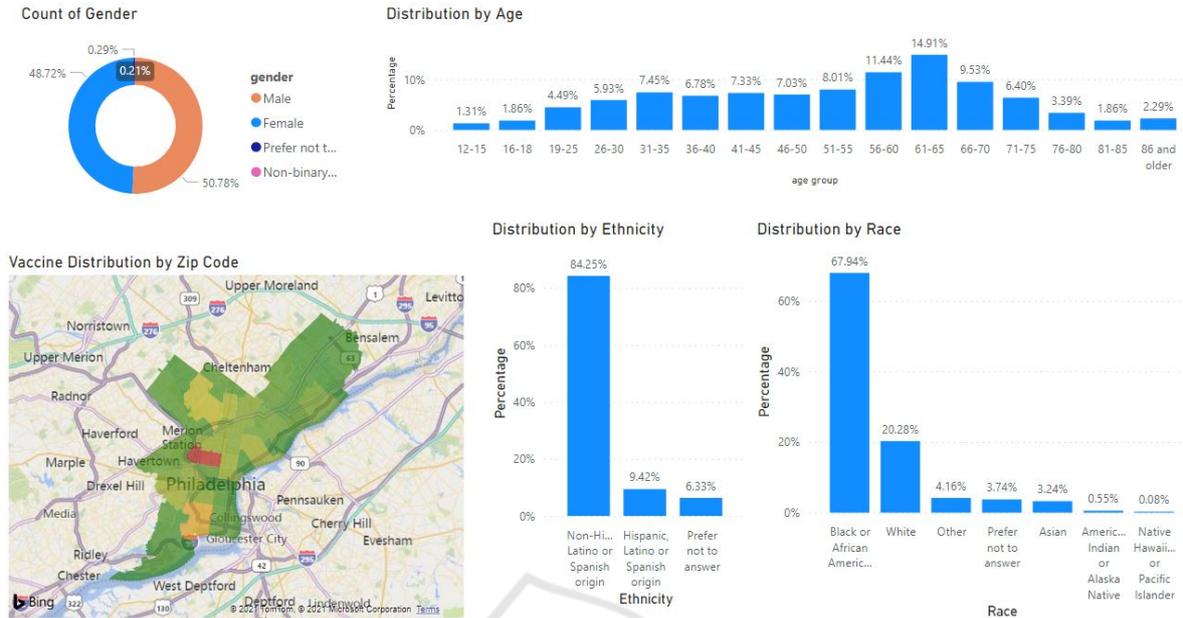


Figure 9: RapidVax Dashboard.

We update this information every week for our staff, faculty, authorities, and the public for their knowledge and decision-making.

3.5 Performance of the Automated Algorithms



Figure 10: RapidVax data completeness.

As demonstrated in the methods section, we developed an automated algorithm to generate a report for the city. We evaluated the performance of

the algorithm by conducting a manual review before implementing it. We manually reviewed a total of 630 patient records (randomly selected). Out of the 630 records, we found 448 true positives, 156 true negatives, 14 false positives, and 12 false negatives. Hence, we achieved excellent performances of the automated algorithms, as demonstrated in Table 2. Upon conducting an error analysis, we found that most of the false positive and false negative were into zip codes and vaccination names. For example, accurate zip codes are supposed to be five digits, and they cannot be more or less than five digits. However, due to the data entry errors, the program missed identified falsely entered zip codes (e.g., < 5 or > 5 digits of Zip code). Similarly, in some cases, patients were given the first dose of vaccination; however, their second dose of vaccination was missing.

Table 2: Performances of the automated programs.

Measures	Performance
Sensitivity	97%
Specificity	92%
Precision	96%
Negative pred. value	93%
False-positive rate	7%
False discovery rate	3%
False negative rate	2%
Accuracy	96%
F1 score	97%

4 DISCUSSIONS

This study demonstrated the significance of health IT tools to help control a public health problem such as the COVID-19 pandemic. The health IT tools developed in this study helped our clinicians run the vaccination task smoothly. The data provided real-time feedback for quality assurance and process improvements, such as documentation of the vaccine Lot number. Moreover, the automated tools developed in this study helped us to generate reports in a timely manner to inform authorities, PDPH, and clinicians to make decisions at the right time. As per our best knowledge, this is the first study that attempted to publish detailed report on the health-IT tools to response to COVID pandemic.

Using the dashboard and reports, in our weekly RapidVax meetings, we were able to evaluate the performance of our efforts in recruiting people for vaccinations. Moreover, the geocoding also helped us to determine where do we need to stress more efforts and develop new strategies to provide vaccination access to more people. For example, in a few areas, the response from people was low for vaccinations which we were able to determine from our analytical model. In these regions, we administrated new strategies such as giving incentives (\$25 per person) to reward people for vaccinations. In partnership with the community group, we also gave \$5 to \$10 McDonald's gift cards to recruit more people for vaccinations.

One significant component of this study is that the RapidVax project is developed by an interprofessional and interdisciplinary team consisting of computer scientists, clinicians, informaticians, and public health experts. As demonstrated in many studies that while developing health IT tools, involvement of multi-disciplinary team is extremely important for its success and this study is a proof of concept of that. Our contextual inquiry model developed by our clinicians and informaticians helped us tremendously towards success of our model (Boote , 2002; Gagnon , 2015; Lehoux , 2013).

Next, our automated algorithm performed excellent in generating reports which eliminated manual review process. Manual review process is time-consuming, expensive, and most importantly error prone. Moreover, we went through several changes in our survey forms to collect patient data as the FDA (EUA) guidelines changed multiple times as new knowledge evolved over time about Covid 19. We will make our survey forms and algorithms publicly available so other researchers can use this information for their vaccination tasks. We have also

developed a report on our HIPAA server where clinicians can query patients by their names, date of birth, and other demographic variables. This feature will be useful when we start giving booster doses to query the patient in our database and make decisions based on their previous history.

Finally, like any other studies, our study consisted of some limitations. First, not all information entered was accurate. As demonstrated in the data completeness and data concordance sections, we faced some data quality issue. However, fortunately we were able to retrieve correct information of most of the patients (> 90% of patients). Second, many times patients do not provide their correct names when they come for the second dose. As a result, our clinicians were not able to query some patients in the database. Last, we do not update our dashboard on a day-to-day basis, but we update once in a week. Hence, we may miss an opportunity to interpret day to day vaccination progress. We will address this limitation in our future work.

5 CONCLUSIONS

This study demonstrated the significance of health IT tools to help control a public health problem such as the COVID-19 pandemic. The health IT tools developed in this study helped our clinicians run the vaccination task smoothly and efficiently. Moreover, the automated tools developed in this study helped us to generate reports in a timely manner to inform authorities, PDPH, and clinicians to make decisions at the right time. This approach can be easily implemented and used by other researchers for their missions. Moreover, the dashboard developed in this project help authorities, PDPH, and our college of public health with decision making and future planning.

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