Title: Developing Patient Communications for Pharmacist-Administered COVID-19 Vaccines

Abstract:

The Food and Drug Administration (FDA) has so far approved three COVID-19 vaccines via Emergency Use Authorization. Since April 2021, Tennessee has had COVID-19 vaccines available to all age groups. The U.S. Department of Health and Human Services (HHS) created an estimation data tool that predicted COVID-19 vaccine hesitancy in Tennessee to be ~40%. This estimator reveals that it is in fact vaccine hesitancy that currently stands as one of the major reasons why that people who have not yet been vaccinated have taken action to receive the vaccine. Due to their widespread presence in the community and trusted reputation, pharmacists are well-positioned to serve as an accessible source of reliable health information. Currently, there is a lack of data about the impact of pharmacist-provided COVID-19 vaccine education on patient vaccine hesitancy. Research in this area could help inform future efforts to achieve mass vaccination against preventable diseases. The purpose of this study is to provide pharmacies in Tennessee with patient-friendly educational materials that can be used as a supplement to patient counseling on COVID-19 vaccination, and to evaluate the impact of these materials and pharmacist-provided education on COVID-19 vaccine hesitancy.

A patient educational brochure was distributed to Tennessee pharmacies via a partnership with the Tennessee Pharmacists Association (TPA). Surveys for providers and patients were intended to accompany the educational materials to assess perception and use. Vaccination rate data was also pulled from a publicly available database from the Tennessee Department of Health.

While survey response rates were low, COVID-19 vaccination rates within the state increased by 5.48% during the one-month period following distribution of the educational materials to TPA members. This results is difficult to interpret given the number of external factors influencing vaccination rates. A longer study period and closer follow-up with participants is further needed. This study serves as a proof of concept of a collaboration with a state pharmacy association to develop and distribute materials in order to facilitate pharmacist discussions with vaccine-hesitant patients.

Introduction:

The first U.S case of COVID-19 was reported by the Centers for Disease Control and Prevention (CDC) in January of 2020[1]. As of March 14, 2021, there have been over 29 million documented cases in the U.S, resulting in over half a million deaths[1]. The transmission and mortality rate of the novel coronavirus presented a unique imperative to quickly develop effective vaccines to impart acquired and herd immunity.

The Food and Drug Administration (FDA) has so far approved three COVID-19 vaccines via Emergency Use Authorization[1]. Since April 2021, Tennessee has had COVID-19 vaccines available to all age groups. To date, the Tennessee Department of Health has reported over two million residents completely immunized[2]. This leaves over 60% of the Tennessee population not being immunized. MacDonald and the SAGE Working Group on Vaccine Hesitancy (2015) defines vaccine hesitancy as the delay in acceptance, reluctance, or refusal of vaccination despite the availability of vaccination services. With that being said, the U.S. Department of Health and Human Services (HHS) created an estimation data tool that predicted COVID-19 vaccine hesitancy in Tennessee to be ~40%[3]. This estimator reveals that it is in fact vaccine hesitancy that currently stands as one of the major reasons why that people who have not yet been

vaccinated have taken action to receive the vaccine. Soares et al. states that vaccine hesitancy factors must be grouped by contextual influences, individual and group influences, COVID-19 disease-specific and by COVID-19 vaccine-specific[4]. Knowing that there are several different approaches be made to address vaccine hesitancy, a tailored consultation must be based off of how those patients who have not been vaccinated are found. The pharmacist will take their tailored approach to build the patient's trust so that these consultations be effective.

Due to their widespread presence in the community and trusted reputation, pharmacists are well-positioned to serve as an accessible source of reliable health information[5]. Furthermore, they have been one of the driving forces behind increased vaccination rates for years. A systematic review reported that out of 22 studies examining the impact of pharmacy-based immunization services, all of them found an increase in vaccine coverage associated with pharmacist involvement. This effect was neither tied to whether the pharmacist was the educator, facilitator, or administrator, nor the specific vaccine given[6]. During the pandemic, pharmacies were called on to play a larger role in public health and vaccination initiatives. For example, the number of influenza vaccinations provided in pharmacies grew a considerable amount from the 2019-2020 to 2020-2021 flu season (33.2 million in December 2019 to 46.8 million in December 2020), whereas the number provided in physician medical offices slightly decreased (33.2 million in December 2019 to 30.3 million in December 2020)[7]. This change likely reflects the greater perceived safety and convenience of pharmacies as vaccination sites.

Currently, there is a lack of data about the impact of pharmacist-provided COVID-19 vaccine education on patient vaccine hesitancy. Research in this area could help inform future efforts to achieve mass vaccination against preventable diseases. The purpose of this study is to provide pharmacies in Tennessee with patient-friendly educational materials that can be used as a supplement to patient counseling on COVID-19 vaccination, and to evaluate the impact of these materials and pharmacist-provided education on COVID-19 vaccine hesitancy.

This program was done in collaboration with the Tennessee Pharmacists Association (TPA). TPA's mission statement is: "The Tennessee Pharmacists Association advances, protects and promotes high-quality pharmacist-provided patient care in Tennessee"[8]. TPA is a membership organization that has over 4,000 pharmacist members across the state. With representation of pharmacists in communities all across the state, TPA has the ability to extend reach to Tennessee residents who have yet to receive a COVID-19 vaccine.

The primary objective of this study is to evaluate the impact of pharmacist-provided education combined with textual materials on patient COVID-19 vaccine hesitancy within Tennessee. The secondary objectives of this study include increasing patient awareness about availability of COVID-19 vaccines in pharmacies and increasing the capacity for COVID-19 vaccine education by pharmacists in Tennessee. The study also evaluated change in vaccination rates within the state during the study period.

Methods:

Study design and materials:

Done in collaboration with the Tennessee Pharmacists Association (TPA), this descriptive study utilized two separate cross-sectional surveys that were distributed to pharmacies and patients across the state of Tennessee. The survey for pharmacists consisted of 5 items including a statement of consent. Questions focused on assessing the usefulness of provided educational materials, and were primarily in the form of Likert scales with one free-response question to illicit general feedback. The patient survey consisted of 9 items including a

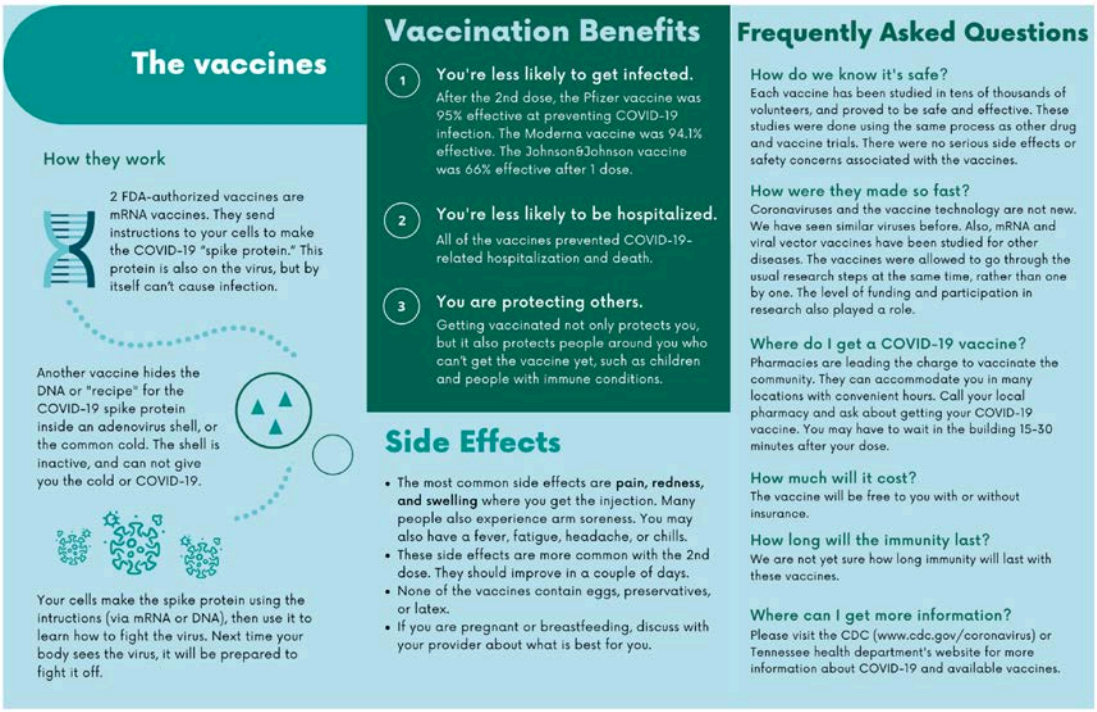
statement of consent. Again, questions were formatted as Likert scales and focused on measuring the pharmacist's effect on the patient's level of knowledge, comfort level, and vaccine hesitancy about COVID-19 vaccination. Two free-response questions asked the reason behind the patient's refusal to be vaccinated (if they had refused), and for general feedback. In order to keep the surveys short, demographic data was not collected in either questionnaire. Both surveys were hosted on Google Forms, and results were only accessible to the researchers.

In addition to receiving a patient handout to use during counseling on COVID-19 vaccination (Figure 1), promotional materials were also provided to participating pharmacies. These included a printable flyer to advertise the availability of COVID-19 vaccines at pharmacies generally, and a set of matching images formatted for use on various social media platforms (Facebook, Twitter, Instagram). These supplemental materials were intended to emphasize the importance of COVID-19 immunization, as well as increase awareness of their availability in local pharmacies.

Figure 1. COVID-19 vaccination patient education brochure provided to pharmacies

Front:

Back:



Data regarding total number of COVID-19 vaccines administered within the state before and after the project was also collected from the Tennessee Department of Health[9]. Vaccination rates were also broken down by demographic, including sex, race, and age range.

Study population and respondent recruitment:

The study population consisted of Tennessee pharmacists at facilities registered as COVID-19 vaccine providers with the state health department. Patients who received the brochure as part of their counseling on COVID-19 vaccination were also included in the study regardless of demographic. Respondents who completed less than half of the survey were excluded from data analysis.

Distribution:

Educational and promotional materials were made available through the TPA website under a page dedicated to COVID-19 resources for pharmacies. The program was announced through the organization's email newsletters that are sent out to member pharmacists weekly. These newsletters provided a link to the materials for easy access. Additionally, pharmacies registered with the state health department ad COVID-19 vaccination providers were directly emailed about the project and provided with the materials.

Pharmacists were provided with a QR code to take the survey through emails and the TPA website. The patient survey was also linked to a QR code attached to the patient education brochure.

Data analysis:

Data analysis was performed using Microsoft Excel. Likert scale questions were summarized with the frequency of each answer choice. Descriptive statistics were used to report

the mean and mode of responses to the survey, as well as the change in vaccine administration throughout the state during the study period. Free text answers were paraphrased. Descriptive statistics were used for all demographic information.

Results:

Participants

The materials and surveys were sent out to TPA's over 4,000 member pharmacists across the state of Tennessee. However, due to low survey response rates, the impact and usage of the educational materials generated by this project were not able to be reported at this time.

Vaccination Data

At the start of the study period, on June 25, 2021, a total of 2,498,036 people in Tennessee had received at least one dose of a COVID-19 vaccine (Figure 2). Educational materials were distributed and advertised starting on this date. After approximately one month, on July 22, 2021, an additional 144,745 people received at least one dose (Figure 3). This was an increase of 5.48%. The number of patients who are fully or partially vaccinated is broken down into demographic groups in Figure 4.

Figure 2: Number of patients in Tennessee with at least one dose of a COVID-19 vaccine as of June 25, 2021

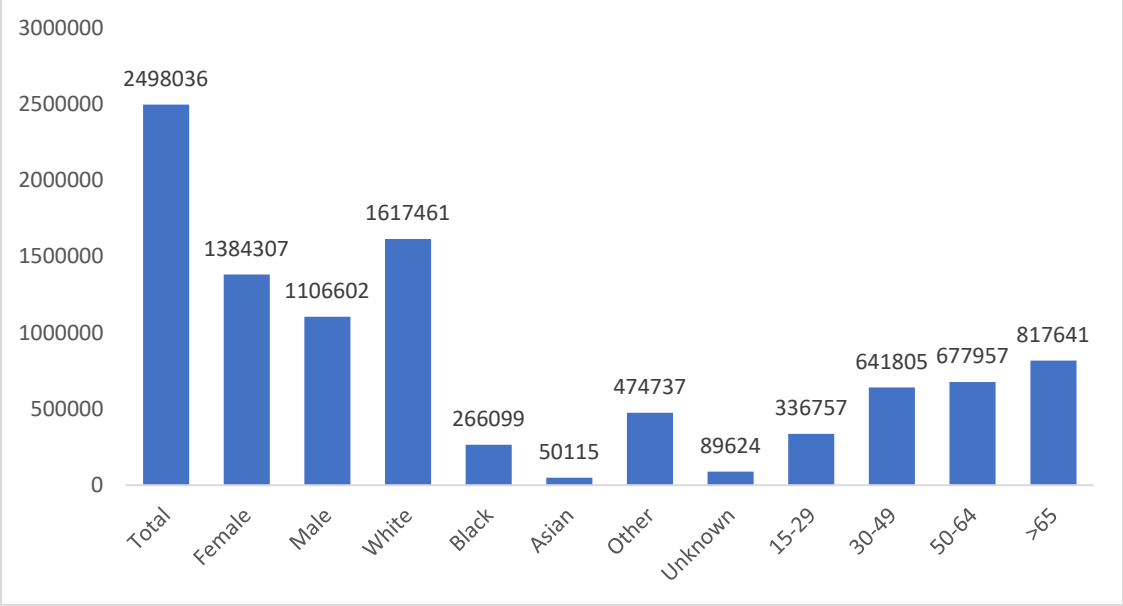


Figure 3: Number of patients in Tennessee with at least one dose of a COVID-19 vaccine as of July 22, 2021

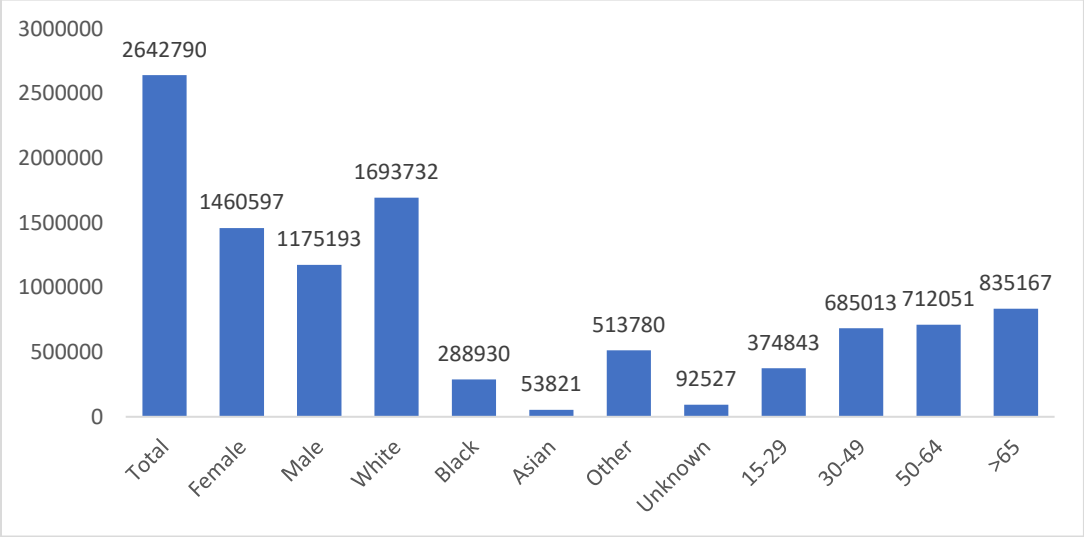
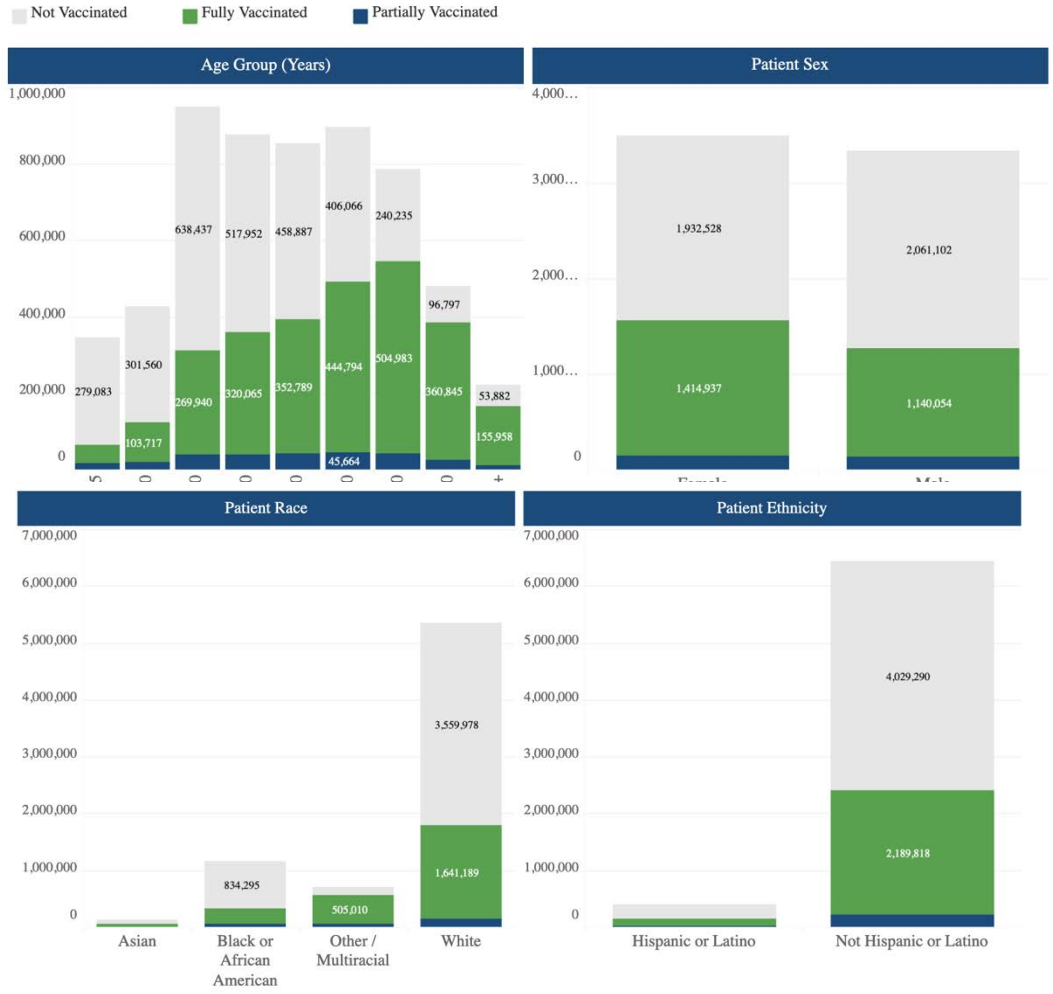


Figure 4: Vaccination status in Tennessee by demographic as of July 22, 2021



Discussion:

While the number of Tennesseans with at least one dose of a COVID-19 vaccine increased during the study period, it is difficult to pinpoint the impact of our project given the low survey response rate. Many other external factors, such as the political climate and changes in access to the vaccines, contribute to the increase. Additionally, the short follow up period of one month remains a limitation of this study. A longer study period and closer follow-up with local pharmacies to encourage survey use would improve this study in the future. Strengths of this study include pioneering a partnership with a state pharmacy organization to distribute patient educational materials that pharmacists can use to facilitate a discussion with patients about COVID-19 vaccines. A priority should be made to continue to train and educate pharmacists to have difficult and honest conversations about COVID-19 vaccinations with their patients at the point of care. In particular, there is significant room to improve the proportion of vaccinated individuals within the 21-40 year old age group, and amongst the black and white population of Tennessee.

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