

Vaccination Approval Literacy and Its Effects on Intention to Receive Future COVID-19 Immunization

Background

The World Health Organization (WHO) defines vaccine hesitancy as the reluctance or refusal to receive a vaccine despite availability and identifies a lack of confidence in vaccine safety and efficacy as the major contributors. ^[7] In 2019, the WHO reported vaccine hesitancy as a top 10 threat to global health. ^[7] The WHO also states that vaccine hesitancy has been reported in over 90% of countries worldwide. ^[8]

The novel coronavirus, COVID-19, led to an ongoing global pandemic following its emergence in December 2019. The resulting infections and deaths from COVID-19 increased the urgency to develop a vaccine to decrease continued disease spread. As of June 2021, the Food and Drug Administration (FDA) has issued emergency use authorization for three COVID-19 vaccines. However, individuals' willingness to accept vaccines falls along a spectrum. The available polls reported 50% of Americans are reluctant to receive the COVID-19 vaccine. ^[9] In the United States, 40% of those reluctant to vaccinate report being open to learning more information about vaccine safety. ^[2]

Even before the global pandemic, the Center for Disease Control and Prevention (CDC) and the WHO worked to promote vaccine confidence as a way to significantly combat vaccine hesitancy. Building vaccine confidence involves establishing trust between 1) patients and providers making vaccine recommendations, 2) providers administering the vaccines, and 3) processes leading to vaccine development, manufacturing and approval. ^[1] A patient must have trust in all three elements to have full confidence in their decision to receive a vaccine. The CDC encourages healthcare providers to help patients build trust in vaccines with open conversations at the community level. As one of the most trusted and accessible healthcare professionals, pharmacists are well positioned to engage in vaccine-related discussions with their patients and correct misinformation in their communities. ^[6] Currently, there is little information regarding the general public's knowledge of the vaccine approval process and whether that plays a role in vaccine hesitancy. Overall, this study seeks to identify whether vaccine approval process literacy and vaccine confidence relates to vaccination intentions.

Objectives

The objectives of this study were to evaluate participants' knowledge and perceptions regarding viral infections, COVID-19, and vaccine approval processes; evaluate participants' intentions to receive the COVID-19 vaccine and concerns for the vaccine's safety; and compare participants' knowledge assessment results with perceptions and COVID-19 vaccine intentions.

Methods

A prospective, cross-sectional questionnaire was administered to patients participating in a pharmacist-led chronic disease state management program within a self-insured, regional grocery store chain of pharmacies located in the Midwest. Both employees and their significant others on the company's benefit plan may participate in the pharmacist-led chronic disease state management program. This program includes eligible patients with cardiovascular disease and/or diabetes. The cardiovascular program includes patients with hypertension, dyslipidemia,

and/or clinical atherosclerotic cardiovascular disease, while the diabetes program includes patients with both type 1 and type 2 diabetes mellitus.

The 22-item questionnaire presented statements and questions as true/false, agree/disagree/unsure, and multiple-choice. The questionnaire included a knowledge assessment that evaluated participants' basic knowledge of COVID-19, the clinical trial phase requirements for vaccines, the FDA's role in vaccine approvals, and vaccine safety in the United States. Additionally, the questionnaire assessed participants' vaccine intentions and concerns. Participants' demographic information including sex, age, race/ethnicity, and level of education were also collected. Written patient education materials developed by the CDC regarding vaccine approval processes were provided to participants upon questionnaire completion.

Participants were eligible if they were 18 years of age or older and could read in English or Spanish. Additionally, they had to either be an employee or their significant other utilizing the company's health insurance and participating in one or both of the chronic disease state management programs. Participants were excluded from the study if they were unable or unwilling to complete the questionnaire during their visit with a pharmacist. Data collection occurred between October 1, 2020 and January 31, 2021. The paper questionnaires were distributed in person and completed on site during a chronic disease state management visit with a pharmacist. To ensure anonymity, the participant placed the completed questionnaire in an envelope, sealed it and then returned it to the pharmacist who placed it into a manila collection envelope. All completed questionnaires were then returned to the primary investigator at regular intervals during the study period. Eight clinical pharmacists administered the questionnaires to participants from twenty-nine grocery store locations. Each pharmacist administering the questionnaire was trained on the purpose of the study and how to administer the questionnaire prior to study commencement. The questionnaire was piloted among a convenience sample of ten volunteers to assess clarity and feasibility.

Statistical analyses were performed using SPSS version 27 with an a-priori alpha value of 0.05. Descriptive statistics were used to assess participant demographics, knowledge, and vaccination intentions. Participants' knowledge was reported as an overall percentage of items correct. The comparison between participants' knowledge versus perceptions and intentions were evaluated using multinomial logistic regression. The study was granted exemption from the University of Kansas Medical Center Human Research Protection Program.

Results

A total of 100 questionnaires were collected. Missing responses on the questionnaires were excluded and each section reflects the total number of participants who answered each item. The majority of respondents were Caucasian (78.7%), male (63.6%), and aged 50 years or older (73.7%). Additionally, nearly two-thirds of respondents reported completion of a high school education, GED, or higher.

In regards to the knowledge assessment, more than 90% of participants answered correctly on questions pertaining to COVID-19 infection and symptoms, and questions pertaining to the FDA's role in vaccine approval processes. Additionally, 76% of participants answered correctly in regards to the FDA's post-marketing vaccine surveillance. Participants achieved 60% correct scores on questions pertaining to animal testing prior to human use, available vaccines for COVID-19, and the number of people per clinical trial phase. Participants'

scores were lower ($\leq 55\%$) on questions involving vaccine safety in the United States, clinical trial phase requirements, and the FDA's safety regulations during a pandemic. Specifically, only 21% of participants scored correctly on the number of phases required for clinical trials.

The majority of participants ($n=52$, 52.5%) had plans to receive the COVID-19 vaccine when it became available to them. Additionally, 27.3% of participants ($n=27$) were unsure of their plans to receive the COVID-19 vaccine, and 20.2% of participants ($n=20$) had no plans to receive the COVID-19 vaccine even when available to them. In regards to participants' perceptions, 40.4% ($n=40$) of the participants were worried the vaccine was approved too quickly. Alternatively, the majority of participants ($n=54$, 55.1%) did not believe the trials were taking too long to produce a vaccine, and 56.1% of participants ($n=55$) desired more information on how vaccines get approved in the United States.

When comparing participants' knowledge assessment results to vaccine intentions, participants who scored higher on the knowledge assessment were more likely to have an intention to receive the COVID-19 vaccine ($p=0.007$). The pseudo R-square showed 11.7% of vaccine intentions were explained by the participants' knowledge assessment results.

Four of the eighteen items evaluating participants' perceptions compared to their knowledge assessment results reached statistical significance. Specifically, participants who did not believe the vaccine was approved too quickly also scored correctly on questions pertaining to the United States history of vaccine safety ($p=0.001$), FDA's safety regulations during a pandemic ($p=0.010$), FDA's post-approval monitoring ($p=0.013$), and number of people per phase ($p=0.003$).

Discussion

The CDC defines vaccine confidence as the trust patients have in the recommended vaccines, the providers who administer the vaccines, and the processes and policies that lead to vaccine development, licensure, authorization, manufacturing and approval. ^[1] The results of this study support the emphasis on knowledge of the vaccine development and approval process to promote vaccine confidence. The study also highlights specific opportunities regarding vaccine approval processes that healthcare providers can capitalize upon to help build trust in vaccines. To the authors' knowledge, this is the first study to compare knowledge of vaccine approval processes with vaccine perceptions and intentions. It is prudent to identify ways to promote vaccine confidence among the general public in order to increase vaccine uptake, especially in times of a global pandemic.

In our study, the majority of those who did not believe the COVID-19 vaccine was approved too quickly answered correctly on questions pertaining to post-approval monitoring, the United States vaccine safety history, the FDA's inability to cut corners on safety, and number of people per clinical trial phase requirements. These results suggest that knowledge of the process correlates to trust in the system. Conversely, Kestenbaum et al. reported that those without sufficient knowledge about vaccines are more likely to have negative attitudes towards immunizations and lack trust in the individuals and institutions responsible for immunizations. ^[5] The significant relationship between COVID-19 vaccine approval perceptions and the specific correct scores on the knowledge assessment in our study supports the correlation between increased knowledge and positive vaccine perceptions. Additionally, this study identified the specific perceptions that significantly correlated to participants' intentions to receive the vaccine.

The history of vaccine safety in the United States, the safety regulations required by the FDA during a pandemic, the FDA's post-approval monitoring, and the number of people per phase can all be used as conversation guides for healthcare providers attempting to build trust in vaccines.

The results of this study also showed a significant relationship between a higher score on the knowledge assessment and likelihood to intend to receive the COVID-19 vaccine. This demonstrates that understanding of the vaccine development and approval process plays a role in vaccine intentions. In accordance with these claims, Jarrett et al. explored strategies for addressing vaccine hesitancy. They reported that interventions with the largest observed increases (>25%) in vaccine uptake were those that aimed to increase vaccine knowledge and awareness, along with those that targeted the under-vaccinated populations, and improved convenience and access to vaccines. ^[4] Overall, this suggests that providing patient education to promote vaccine knowledge and awareness may contribute to increased vaccination rates. In contrast, Dubé et al. suggests that public health interventions based on providing information alone to promote vaccines have not been successful in enhancing vaccine uptake. They proposed vaccine promotions should move beyond addressing a lack of knowledge to an individualized communication method. ^[3] Based on our study and data from Jarrett et.al., increasing knowledge is one element to reducing hesitancy, and as Dubé and colleagues recommend, individualizing the provision and content of the information must be considered.

Our study showed that 11.7% of vaccine intentions were explained by the participants' knowledge assessment results which demonstrates that knowledge remains a key element in promoting vaccines. Less than 50% of participants answered correctly on most questions pertaining to vaccine clinical trial phase requirements and vaccine safety facts, which identifies knowledge gaps regarding the United States vaccine approval processes. These identified gaps further highlight specific areas to develop targeted communication to utilize in an effort to build trust in vaccines. Providers should emphasize the history of vaccine safety in the United States, detail the FDA's required safety regulations and post-approval monitoring, and report the quantity of people per clinical trial while individualizing their conversations to promote vaccines. The inclusion of this information may strengthen patient's confidence in the recommended vaccines, the providers who administer the vaccines, and the processes and policies that lead to vaccine development, licensure, authorization, manufacturing and approval.

There were limitations to this study. Not all participants completed the entire questionnaire, but the responses from incomplete questionnaires were included in the data analysis. Additionally, using patients enrolled in a chronic disease state management program may have potentiated a bias as these patients have individualized, more frequent and direct access to healthcare providers, particularly pharmacists. However, the program includes individuals from all positions in the company, and their significant others, to allow results to be more generalizable.

Conclusion

Participants who scored higher on the knowledge assessment were more likely to have intent to receive the COVID-19 vaccine. Additionally, those who scored higher on the knowledge assessment were more likely to not perceive the vaccine as approved too quickly. Overall, these results demonstrate the influence knowledge has on both perceptions of vaccines and intentions

to receive vaccines. These results identify specific areas for pharmacists to guide vaccine discussions and provide future opportunities to promote vaccines with their vaccine hesitant patients.

References

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