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BRIEF REPORTS

Vaccination approval literacy and its effects on intention to receive future COVID-19 immunization

Elizabeth Carmosino*, Janelle F. Ruisinger, Joshua Davis Kinsey, Brittany L. Melton

ABSTRACT

Background: Before the coronavirus disease 2019 (COVID-19) vaccine release, polls showed only 50% of Americans had intention to receive the COVID-19 vaccine. The vaccine hesitancy may result from a lack of confidence in vaccine safety and efficacy. More research is needed to identify whether knowledge of vaccine approval processes relates to vaccination intentions.

Objectives: The objectives of this study were to (1) evaluate participants’ knowledge regarding COVID-19 and vaccine approval processes, (2) evaluate participants’ intentions to receive the COVID-19 vaccine, and (3) compare participants’ knowledge assessment results with COVID-19 vaccine intentions.

Methods: A prospective, cross-sectional questionnaire was administered to patients participating in a pharmacist-led chronic disease state management program. The 22-item questionnaire assessed demographic information and evaluated the participant’s knowledge and vaccine intentions. Data were analyzed with an a priori alpha value of 0.05.

Results: Nearly all participants answered correctly on questions pertaining to COVID-19 infection (n = 92, 93%), COVID-19 symptoms (n = 96, 96%), and the Food and Drug Administration’s roles in vaccine approval processes (n = 92, 92%). Participants scored lower on questions involving the differing requirements between clinical trial phases (n = 20, 21%) and vaccine safety in the United States (n = 51, 53%). Most participants (n = 54, 55.1%) did not believe the trials were taking too long to produce a vaccine, but 40.4% of the participants (n = 40) believed the vaccine was approved too quickly. More than half of the participants (n = 55, 56.1%) desired more information on how vaccines get approved in the United States. Participants who scored higher on the knowledge assessment were more likely to have a plan to receive the vaccine (P = 0.008).

Conclusions: The results of this study demonstrate the influence knowledge has on intentions to receive vaccines and may aid health care providers in their attempts to promote vaccinations.

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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.1 In 2019, the WHO reported vaccine hesitancy as a top 10 threat to global health.1 The WHO also states that vaccine hesitancy has been reported in more than 90% of countries worldwide.2

The novel coronavirus, coronavirus disease 2019 (COVID-19), led to an ongoing global pandemic after 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 3 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.3 In the United States, 40% of

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* Correspondence: Elizabeth Carmosino, PharmD, PGY1 Community-Based Pharmacy Resident, Balls Food Stores and the University of Kansas School of Pharmacy, 5300 Speaker Rd., Kansas City, KS 66106.

E-mail address: carmosinoe@gmail.com (E. Carmosino).

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Objectives

The objectives of this study were to evaluate participants’ knowledge regarding viral infections, COVID-19, and vaccine approval processes; evaluate participants’ intentions to receive the COVID-19 vaccine; and compare participants’ knowledge assessment results with 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 diabetes. The cardiovascular program includes patients with hypertension, dyslipidemia, and clinical atherosclerotic cardiovascular disease, whereas the diabetes program includes patients with both type 1 and type 2 diabetes mellitus.

The 22-item questionnaire (Appendix 1) presented statements and questions as true or false; agree, disagree or unsure; and multiple-choice. In statements 1 to 12, 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. In addition, the questionnaire assessed participants’ vaccine intentions via statement 13 and assessed participants’ beliefs on vaccines through statements 14 to 17. Using questions 18 to 22, participants’ demographic information including sex, age, race/ethnicity, and level of education were 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. In addition, they had to either be an employee or their significant other using 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. The pharmacist explained the purpose of the questionnaire and allowed time for completion, but was not involved in the participant’s completion of the questionnaire. To ensure anonymity, all participants were offered a private area for questionnaire completion and were instructed to place the completed questionnaire in an envelope, seal it, and then return 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 29 grocery store locations. Each pharmacist administering the questionnaire was trained on the purpose of the study and how to administer the questionnaire before study commencement. The questionnaire was piloted among a convenience sample of 10 volunteers to assess clarity and feasibility.

Statistical analyses were performed using the 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 (independent variable) and intentions (dependent variable) was evaluated using multinomial logistic regression. Stepwise variable selection was used in the regression, and therefore, variables that were not statistically significant were not included in the model to be reported. 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. Most respondents were Caucasian (78.7%), male (63.6%), and aged 50 years or older (73.7%). In addition, nearly two-thirds of respondents reported completion of a high school education, General Educational Development, or higher (63.6%), and aged 50 years or older (73.7%). In addition, nearly two-thirds of respondents reported completion of a high school education, General Educational Development, or higher (63.6%), and aged 50 years or older (73.7%). In addition, nearly two-thirds of respondents reported completion of a high school education, General Educational Development, or higher (63.6%), and aged 50 years or older (73.7%). In addition, nearly two-thirds of respondents reported completion of a high school education, General Educational Development, or higher (63.6%), and aged 50 years or older (73.7%). In addition, nearly two-thirds of respondents reported completion of a high school education, General Educational Development, or higher (63.6%), and aged 50 years or older (73.7%). In addition, nearly two-thirds of respondents reported completion of a high school education, General Educational Development, or higher (63.6%), and aged 50 years or older (73.7%).

Regarding the knowledge assessment (Supplemental Material), more than 90% of participants answered correctly on questions pertaining to COVID-19 infection and symptoms and postmarketing vaccine surveillance. Participants achieved 60% correct scores on questions pertaining to animal testing before human use, available vaccines for COVID-19, and the number of people per clinical trial phase.

Table 1

| Characteristic                              | Participants |
|---------------------------------------------|--------------|
| Gender                                      | n = 99       |
| Male                                        | 63 (63.6)    |
| Female                                      | 36 (36.4)    |
| Age (y)                                     | n = 99       |
| 18–29                                       | 3 (3.0)      |
| 30–39                                       | 7 (7.1)      |
| 40–49                                       | 16 (16.2)    |
| 60–69                                       | 32 (32.3)    |
| > 70                                        | 4 (4.0)      |
| Race/Ethnicity                              | n = 94       |
| White                                       | 74 (78.7)    |
| Black or African American                   | 2 (2.1)      |
| Asian                                       | 2 (2.1)      |
| Native Hawaiian or Pacific Islander         | 1 (1.1)      |
| American Indian or Alaska Native            | 1 (1.1)      |
| More than one race                          | 8 (8.5)      |
| Prefer not to answer                        | 6 (6.4)      |
| Ethnicity                                   | n = 99       |
| Not Spanish, Hispanic, or Latino            | 82 (82)      |
| Spanish, Hispanic, or Latino                | 16 (16)      |
| Prefer not to answer                        | 1 (1)        |
| Education                                   | n = 99       |
| Some high school                            | 9 (9.1)      |
| High school/GED                             | 35 (35.4)    |
| Some college                                | 32 (32.3)    |
| Undergraduate degree                        | 17 (17.2)    |
| Master’s degree or higher                   | 1 (1.0)      |
| Prefer not to answer                        | 5 (5.0)      |

Abbreviation used: GED, General Educational Development.

Note: Values are n (%).

Participants’ scores were lower (≤ 55%) on questions involving vaccine safety in the United States, clinical trial phase requirements, and the FDA’s safety regulations during a pandemic. In particular, only 21% of participants scored correctly on the number of phases required for clinical trials. Most participants (n = 52, 52.5%) had plans to receive the COVID-19 vaccine when it became available to them. In addition, 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. Regarding participants’ beliefs, 40.4% of the participants (n = 40) were worried the vaccine was approved too quickly. Alternatively, most 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 with vaccine intentions, participants who scored higher overall on the knowledge assessment were more likely to have an intention to receive the COVID-19 vaccine (P = 0.008) (Table 2). The pseudo R-square showed 11.7% of vaccine intentions were explained by the participants’ overall knowledge assessment results. Demographic variables were found to have no statistically significant impact on the results. There were 4 specific questions on the knowledge assessment that affected participants’ intention to receive the vaccine, and these questions pertained to the COVID-19 vaccine, the clinical trial phase requirements, the U.S. history of vaccine safety, and the FDA’s postapproval monitoring. When comparing participants’ knowledge assessment results with participants’ beliefs on the timing of the vaccine release, 4 of the 18 items reached statistical significance. In particular, participants who did not believe the vaccine was approved too quickly also scored correctly on questions pertaining to the U.S. history of vaccine safety (P = 0.001), FDA’s safety regulations during a pandemic (P = 0.010), FDA’s postapproval 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.3 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 health care 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 intentions. It is prudent to identify ways to promote vaccine confidence among the general public to increase vaccine uptake, especially in times of a global pandemic.

In our study, most of those who did not believe the COVID-19 vaccine was approved too quickly answered correctly on questions pertaining to postapproval monitoring, the U.S. 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...
Aim to build trust in vaccines. As the CDC recommends, can all be used as conversation guides for health care providers postapproval monitoring, and the number of people per phase study identified create positive attitudes toward vaccines. In addition, an understanding and trust in vaccine approval processes can create confidence in vaccines as not approved too quickly. This suggests that both mechanisms and clinical trial details perceived the COVID-19 vaccine as not approved too quickly. This supports the correlation between increased knowledge and positive impressions of vaccines. The participants who had higher knowledge about the safety mechanisms and clinical trial details perceived the COVID-19 vaccine as not approved too quickly. This suggests that both an understanding and trust in vaccine approval processes can create positive attitudes toward vaccines. In addition, this study identified the specific factors 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 postapproval monitoring, and the number of people per phase can all be used as conversation guides for health care providers attempting to build trust in vaccines. As the CDC recommends, building confidence in vaccines involves a foundation of trust. Increasing confidence in vaccines is a critical factor in combating vaccine hesitancy. If vaccine providers correct the knowledge deficits on vaccine approval processes by emphasizing the safety practices and the monitoring mechanisms already in place, they may be able to establish a foundation of trust, grow their patients’ vaccine confidence, and increase vaccine uptake.

The results of this study also showed a statistically significant relationship between a higher total score on the knowledge assessment and likelihood to intend to receive the COVID-19 vaccine. Our study showed that vaccine intentions were affected by the participants’ knowledge assessment results, which demonstrates that knowledge remains a key element in promoting vaccines. 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 undervaccinated populations, and improved convenience and access to vaccines. In their review, they explained these interventions performed higher at increasing vaccine uptake when they were multifactorial and used a dialog-based approach. This suggests that providing patient education to promote vaccine knowledge and awareness using an open patient-provider dialog may contribute to increased vaccination rates. Our study identified 4 specific areas that had an impact on participants’ intention to receive the vaccine and highlighted specific themes to discuss in vaccine promotion. Future studies are needed to determine whether interventions focused on these themes were effective in increasing vaccine uptake.

| Plans to receive | Value | SE  | P value | OR   | 95% CI |
|------------------|-------|-----|---------|------|--------|
| Intercept        | −1.118| 0.828| 0.177   |      |        |
| Knowledge score  | 0.451 | 0.169| 0.008   | 1.569| 1.127  |
|                  |       |      |         |      | 2.184  |

Abbreviation used: COVID-19, coronavirus disease 2019.

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 U.S. vaccine approval processes. These identified gaps further highlight specific areas to develop targeted communication to use 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 postapproval monitoring, and report the quantity of people per clinical trial while individualizing their conversations to promote vaccines. These key education points can be used to promote vaccine knowledge. Based on the results of this study, increased knowledge influences vaccine intentions. Therefore, 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. If providers can strengthen patients’ vaccine confidence, they may be able to increase vaccine uptake.

There were limitations to this study. Not all participants completed the entire questionnaire, but the responses from incomplete questionnaires were included in data analysis. Using the patients enrolled in a chronic disease state management program may have potentiated a bias given that this population is considered high risk of COVID-19 infection and these patients have individualized, more frequent, and direct access to health care providers, particularly pharmacists. Participants may have had conversations with pharmacists about vaccines during the study window, but this information was not collected. In addition, the study is limited by its lack in diversity. However, the program includes individuals from all positions in the company and their significant others in an effort to mitigate this limitation.

Conclusion

Participants who scored higher on the knowledge assessment were more likely to have intent to receive the COVID-19 vaccine. In addition, 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 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

1. Geneva: World Health Organization. Ten health issues who will tackle this year. Available at: https://www.who.int/news-room/feature-stories/ten-threats-to-global-health-in-2019. Accessed July 1, 2020.
2. The Lancet Child & Adolescent Health. Vaccine hesitancy: a generation at risk. Lancet Child Adolesc Health. 2019;3(5):281.
3. Science. Just CW. 50% of Americans plan to get a COVID-19 vaccine. Available at: https://www.sciencemag.org/news/2020/06/just-50-americans-plan-get-covid-19-vaccine-here-s-how-win-over-rest. Accessed July 1, 2020.

4. COVID-19 vaccine education initiative. Adcouncil.org. Available at: https://www.adcouncil.org/covid-vaccine. Accessed April 1, 2020.

5. CDC.gov. Building confidence in COVID-19 vaccines. Available at: https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html. Accessed July 1, 2020.

6. Pharmacists once again among the most trusted professions - PBA. Health Communications. Pbahealth.com. Available at: https://www.pbahealth.com/news/pharmacists-once-again-among-the-most-trusted-professions/. Accessed September 1, 2020.

7. Kestenbaum LA, Feemster KA. Identifying and addressing vaccine hesitancy. Pediatr Ann. 2015;44(4):e71—e75.

8. Jarrett C, Wilson R, O’Leary M, Eckersberger E, Larson Hj. SAGE Working Group on Vaccine Hesitancy. Strategies for addressing vaccine hesitancy – A systematic review. Vaccine. 2015;33(34):4180—4190.

Elizabeth Carmosino, PharmD, PGY1 Community-Based Pharmacy Resident, Balls Food Stores and University of Kansas School of Pharmacy, Kansas City, KS

Janelle F. Ruisinger, PharmD, FAPhA, Clinical Professor, Associate Dean for Academic Affairs, PGY1 Community-Based Residency Director, University of Kansas School of Pharmacy, Kansas City, KS

Joshua Davis Kinsey, PharmD, Clinical Pharmacist, Balls Food Stores, Kansas City, KS

Brittany L. Melton, PharmD, PhD, Associate Professor, Department of Pharmacy Practice, University of Kansas School of Pharmacy, Kansas City, KS
Appendix 1

[Part 1] — For questions 1 through 12, please indicate if the statement is true or false.

| Statement                                                                 | True | False |
|---------------------------------------------------------------------------|------|-------|
| 1. COVID-19 is an infection caused by a virus                            |      |       |
| 2. COVID-19 can cause many symptoms including fever, cough, and trouble  |      |       |
|  breathing, or no symptoms at all                                       |      |       |
| 3. At this time, there is no vaccine available to protect against        |      |       |
| COVID-19 in the United States                                            |      |       |
| 4. There is a proven and effective treatment for COVID-19 in the United  |      |       |
| States                                                                   |      |       |
| 5. Drug companies must show the vaccine is safe and effective on        |      |       |
| animals before it can be studied in humans                              |      |       |
| 6. Vaccine research on humans takes time and involves 2 phases          |      |       |
| 7. Vaccine research helps drug companies find more ways to make money   |      |       |
| 8. The different phases of vaccine research included less than 100      |      |       |
| people in each phase                                                    |      |       |
| 9. The drug company performing the vaccine research must show the Food  |      |       |
| and Drug Administration (FDA) that the vaccine works before it can be   |      |       |
| available to the public                                                 |      |       |
| 10. After approving a vaccine, the FDA stops collecting information    |      |       |
| about the safety of the vaccine                                         |      |       |
| 11. In times of a pandemic, the FDA may fast track a vaccine’s release,  |      |       |
| meaning the FDA may lower standards on safety regulations to make the    |      |       |
| vaccine available faster                                                 |      |       |
| 12. The United States currently has the safest vaccine supply in        |      |       |
| history                                                                  |      |       |

[Part 2] — For questions 13 through 17, please indicate if you agree disagree or are unsure about the statement.

| Statement                                                                 | Agree | Disagree | Unsure |
|---------------------------------------------------------------------------|-------|----------|--------|
| 13. I plan to receive a COVID-19 vaccination after it’s approved for use |      |          |        |
| in humans                                                                 |       |          |        |
| 14. I am worried that the COVID-19 vaccine release is taking too long and |      |          |        |
| I want to receive it now                                                  |       |          |        |
| 15. I am worried that the COVID-19 vaccine will be approved too quickly   |      |          |        |
| before it is properly proven to be safe and effective                    |       |          |        |
| 16. Within the last ten (10) years, I have received other vaccinations   |      |          |        |
| 17. I would like more information about how vaccines get approved in      |      |          |        |
| the United States                                                        |       |          |        |
[Part 3] – For questions 18 through 22, please indicate the option which best describes you. Your responses will remain anonymous. Please choose only one option per question.

| Question:                                                                 | Option 1 | Option 2 | Option 3 |
|--------------------------------------------------------------------------|----------|----------|----------|
| 18. What is your sex?                                                   | Male     | Female   | Prefer not to answer |
| 19. How old are you?                                                    | 18-29 years old | 30-39 years old | 40-49 years old | 50-59 years old | 60-69 years old | 70+ years old | Prefer not to answer |
| 20. Are you Spanish, Hispanic or Latino?                                | Yes      | No       | Prefer not to answer |
| 21. Which of the following best describe(s) you?                        | White    | Black or African American | Asian | Native Hawaiian or other Pacific Islander | American Indian or Alaska Native | More than one race | Prefer not to answer |
| 22. What is the highest level of education you have completed?           | Some high school | High school diploma or GED | Some college | Undergraduate degree | Master’s degrees or higher | Prefer not to answer |

Thank you! Your responses are greatly appreciated. When completed, please place this questionnaire in the envelope provided, seal the envelope and return it to the pharmacist.