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Clinical Study

Greater Awareness and Knowledge of Clinical Research Increases Willingness to Participate in Future Vaccine Trials- An Examination of the Enduring Impact of COVID-19 Pandemic

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Abstract

The devastating impact of COVID-19 pandemic, its fast-tracked vaccines and authorized treatments have led to more volunteers signing up to be part of clinical studies than any time in recent history. We sought to investigate the relationship between increased knowledge of vaccine clinical trials and willingness to participate in future vaccine trials. A convenience sample survey of the United States residents was conducted in May 2021. Over 1,100 adults completed questions about their knowledge of clinical vaccine trials and attitudes toward participation in future trials. A total of 1149 respondents completed the survey. The median age was 29. Amongst respondents, 47.9% were women. Over 85% had attended college. Most were married (60.1%). A significant proportion of respondents were of Hispanic origin (42.2%). Higher Knowledge Scores were observed for female respondents ($p < 0.001$); >30 years-old respondents ($p < 0.001$) and respondents with a bachelors' degree or higher ($p < 0.05$). Overall, the survey respondents felt that their COVID-19 pandemic experience had increased their knowledge of vaccine trials (807, 70.2%) and willingness to participate in future vaccine studies (677, 58.9%). In addition, over half of the respondents expressed willingness to sign up for a future vaccine study of any kind (51.5%) with another 38.0% willing to consider it. The findings from this survey confirms significant increased interest in clinical vaccine study participation in the midst of COVID-19 pandemic and provides actionable insights to improve outreach efforts with under-represented populations in clinical research.

Keywords: COVID-19; Clinical Trials Participation; Vaccine Research; Willingness; Knowledge

Introduction

The COVID-19 pandemic has affected current clinical research in various ways with more than 1,100 randomized clinical trials related to COVID-19 occurring by the end of 2020 [1]. The devastating impact of COVID-19 pandemic led to more volunteers signing up to be part of clinical studies than at any time in recent history. COVID-19 vaccines have been evaluated in tens of thousands of participants in clinical trials with over 351 million doses of COVID-19 vaccine given in the US alone in the first 8 months of availability [2]. Historically, clinical trials in the US have not included proportional representation of racial and ethnic minority groups and prior research indicates significantly lower awareness of clinical trials amongst Blacks and Hispanics groups [3]. However, the trials for the currently FDA-authorized vaccines were considerably more diverse than other similar trials in the past, with over 20% participation of Hispanic and approximately 10% Black participants [4].

- There has been significant attention by major news channels and social media platforms surrounding COVID-19 vaccine development with focus on clinical trials, emerging data, and volunteerism.
- Vaccine trials are clinical trials that aim to establish the safety and efficacy of vaccines before being licensed. With the increased public attention and awareness of clinical trials and the success of many of COVID-19 vaccines investigational studies, it is reasonable to hypothesize that the vaccine/clinical trial participation hesitancy amongst ethnic and racial minorities in the US may have lessened.
- In this study, we sought to investigate the relationship between increased knowledge of clinical trials and willingness to participate in future vaccine studies of any kind.

Materials and Methods

This cross-sectional nationwide survey of the United States residents was conducted during May 2021, using a convenience sampling method. Over 1100 adults aged 18 years or older responded via a self-administered survey available on an online platform. This survey was promoted by college students through social media and various institutional clubs, and religious institutions with primarily Hispanic and Black audiences. The survey captured demographic information, knowledge of clinical trial/vaccine studies, and attitudes/behaviors toward future vaccine studies.

The survey was developed using Primary Data (<https://primarydata.us/>) by Illumina Consulting Group (<https://icgsolutions.com/>). Primary Data uses Google Sheets as the interface for creating and modifying surveys, controlling access, and capturing data. Primary Data enabled the team to collaborate effectively on the survey design, question phrasing and types, and testing various iterations of the survey with formal reviewers. The survey was released on May 8, 2021. Excel and Python were used to check for data quality control measures. The final analysis dataset included responses from 1149 respondents. Both R and Tableau were used to create graphs and charts to help visually analyze the data and to perform statistical tests such as Chi-square test, and



ANOVA (Analysis of Variance).

Foundational understanding of clinical trials was assessed utilizing a 10-question scale (Table 1). For each respondent, a Knowledge Score was calculated, representing the sum of correct answers. The top quartile (8-10) was considered good knowledge, the second quartile (5-7) was considered moderate knowledge and third and fourth quartiles were considered inadequate knowledge (0-4).

Results

The demographic of the respondents is captured in (Table 2). The median age of the respondents was 29 (mean= 30.6 7.3 SD). Amongst respondents, 47.8% were women (n=550). Most had college education or were still in college (33.2% a bachelor's degree and 7.8% with advanced degrees). Among those with a college education, 42.7% had medical or clinical degrees. Most respondents were married (60.5%). A significant proportion of respondents were of Hispanic origin (42.2%). The racial make-up consisted of 69.6% White, 13.2% Black/African American, 13.0% Asian and 12.7% other/not specified. Geographic distribution of survey respondents is depicted in (Figure 1).

The overall Knowledge Score was 6.9 1.84 SD (n=1,149). Higher Knowledge Scores were observed amongst female respondents (p <0.001); >30 years-old respondents (p <0.001) and respondents with a bachelors' degree or higher (p <0.05) (Figure 2).

(Table 1) lists the questions used to assess the knowledge of clinical trials, along with the percentage of correct answers. Most respondents provided correct answers to the following questions: why vaccine studies are needed (93.5%), the need for participation of healthy volunteers in vaccine studies (91.5%) and inclusion of individuals with chronic conditions and disabilities (66.6%). Additionally, a significant portion of respondents selected the correct answer for the following: the requirement to obtain consent from all participants (88.4%), freedom to withdraw consent (70.8%), and compensation transparency (88.9%). Four vaccine research knowledge areas received the lowest correct answers (Table 2).

Generally, younger respondents (18-30 years old) with lower levels of education (up to high school) and of Hispanic background scored lower on these topics.

Across all knowledge score categories, most respondents reported increased knowledge of vaccine research and, not surprisingly, with the highest percent increase in respondents in the good knowledge category (317, 76%) (Figure 3).

Increased willingness to participate in future vaccine trials was associated with

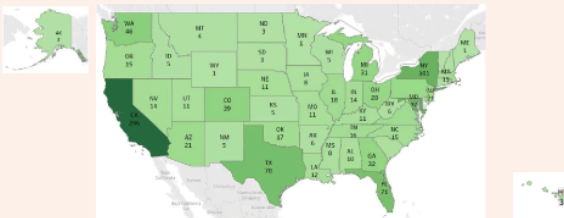


Figure 1: Geographic Representation: Respondents in the United States.

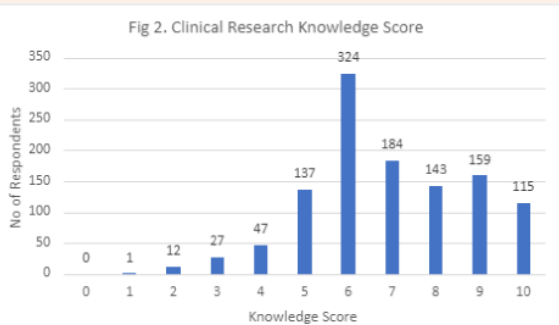


Figure 2: Clinical Research Knowledge Score.

the Moderate (63.4%) and Good Knowledge scores (54.9%). Interestingly, 42.5% of respondents with Inadequate Knowledge score reported decreased willingness to participate in future vaccine studies (Figure 4).

Over half of respondents in the Moderate Knowledge group were willing to sign up for a future vaccine study, with slightly lower levels of Good Knowledge respondents (45.3%) and significantly lower respondents in the Inadequate Knowledge group (Figure 5).

Discussion

The key finding from our analyses was that the COVID-19 pandemic experience has increased the foundational knowledge of vaccine research (Knowledge Score) and increased willingness to participate in future clinical trials amongst all Knowledge Score categories. Higher Knowledge Scores were observed amongst female respondents (p <0.001); >30 years-old respondents (p <0.001); Non-Hispanic White respondents (P<0.05) and respondents with a bachelors' degree or higher (p <0.05) (Figure 2). This highlights the need for ongoing educational campaigns targeted to men, younger individuals (<30 years old), Hispanics, and those without a college education. Among the vaccine knowledge questions, two had over 50% incorrect answers (Table 3).

The majority of participants were misinformed about the importance of diversity in vaccine studies, as well as the requirement to disclose possible risks and side effects of vaccine studies. In both instances, the groups that demonstrated the lowest level of knowledge were women, participants without college education, Hispanics, and individuals aged between 18-30. It was also found that Hispanics scored the lowest compared to other ethnic groups for questions with the highest percentage of incorrect answers. Although recent COVID-19 vaccine trials have been more inclusive, lower awareness and knowledge of vaccine trials is at least a partial explanation for lower minority participation in the past biomedical research. This observation indicates the need for evaluation of tailored awareness campaigns targeting Hispanic groups. Perhaps the greatest limitation of this study is with the disproportionately high representation of adults under 30. Strengths of this study include a large sample of US adults, significant number of Hispanic respondents and its time-sensitive insights in an evolving global

Table 1: Willingness to participate in a future vaccine study by knowledge score

Table with 2 columns: Questions and Correct answer, n (%). It lists 10 questions related to vaccine research and the number of correct answers and percentage.



Table 2: Respondent Demographics.

Age (Median; Range)	29; 18 - 85
	n (%)
Gender	
· Male	· 599(52.1%)
· Female	· 550(47.9%)
Education Level	
· Up to High School/GED	· 157(13.7%)
· Post-secondary	· 520(45.3%)
· Bachelor	· 382(33.2%)
· Advanced degree	· 90(7.8%)
Degree in Medical/Clinical Research	
· Yes	· 490(42.6%)
· No	· 502(43.7%)
Marital Status	
· Married	· 690(60.1%)
· Single	· 395(34.4%)
· Widowed	· 24(2.1%)
· Divorced/Separated	· 40(3.5%)
Ethnicity	
· Hispanic	· 485(42.2%)
· Non-Hispanic	· 522(45.4%)
· Not provided	· 142(12.4%)
Race	
· White	· 800(69.6%)
· Black/African American	· 152(13.2%)
· Asian	· 41(3.6%)
· American Indian/Alaska Native	· 85(7.4%)
· Not provided	· 18(1.6%)
· Native Hawaiian/Pacific Islander	· 21(1.8%)
· Other	· 32(2.8%)

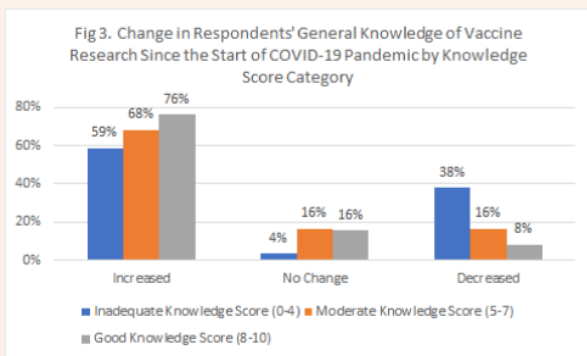


Figure 3: Change in Respondent's general knowledge of vaccine research since the start of Covid-19 pandemic by knowledge score category.

health crisis. The findings strongly suggest that awareness and knowledge of clinical trials increases the public's interest in supporting biomedical research and intent to volunteer as study participants. However, it is unclear how well this positive intent translates to actual clinical trial enrollment. Future investigations are needed to assess the relationship between willingness to enroll and actual enrollment in clinical trials.

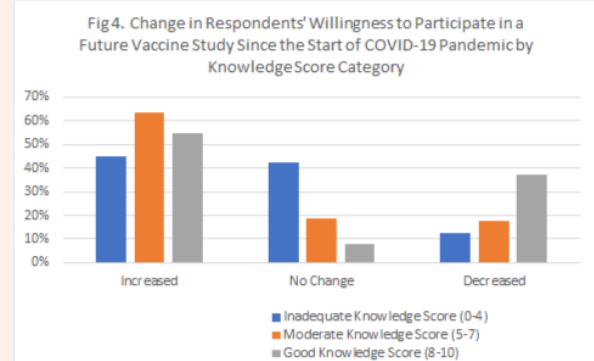


Figure 4: Change in Respondent's willingness to participate in a future vaccine study since the start of Covid-19 pandemic by knowledge score category.

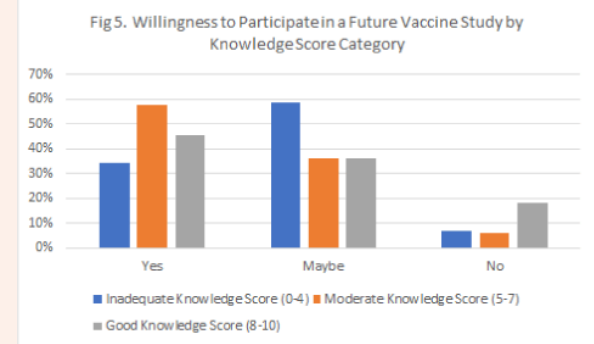


Figure 5: Willingness to participate in a future vaccine study by knowledge score category.

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