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Vietnamese Americans' Level of Trust in Sources of Information and Willingness to Participate in COVID-19 Clinical Trials

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Abstract

The survey investigates COVID-19 information source trust levels and Vietnamese Americans' willingness to participate in clinical trials. Analysis of 212 completed surveys revealed that trust in COVID-19 clinical trial information from university hospitals and drug companies was associated with willingness to participate in clinical trials. Trust in COVID-19 information from federal governments and state governments was also associated with willingness to participate in clinical trials. However, trust in local health facilities was linked to trial participation reluctance. The results suggest that Vietnamese Americans' participation in clinical trials can be increased by identifying and using trusted sources of information.

Introduction

According to the U.S. Census Bureau, around 24 million Asian Americans resided in the United States in 2021 [1]. Of those 24 million, 2.3 million are of Vietnamese descent, making them one of the largest Asian American populations [1]. During the COVID-19 pandemic, finding data regarding the Asian, Native Hawaiian, and Pacific Islander (AANHPI) populations was challenging, let alone disaggregated data about different ethnic populations [2]. While some states report disaggregated data on COVID-19 AANHPI healthcare disparities, availability is limited in Texas despite the large AANHPI and Vietnamese population [3].

As researchers raced to develop vaccines and treatments for this new infectious disease, historically marginalized communities were inadequately represented in COVID-19 clinical trials [4-6]. However, increased participation of racial and ethnic minorities is essential for understanding diseases, preventive factors, and treatment effectiveness across populations. Efforts to increase minority groups' enrollment among research participants, such as the Revitalization Act of 1993, require that clinical trials that the National Institutes of Health fund include women and minority participants. Unfortunately, such efforts have failed to gain substantial improvement [7].

Limited research has examined facilitators and barriers to COVID-19 clinical therapeutic trial participation among Vietnamese Americans and associations with levels of trust [8,9]. Other studies looking at AANHPI participation in clinical trials have found that Asians were less familiar with the term "clinical trials," and Vietnamese groups may have lower knowledge of clinical trials compared to other AANHPI ethnic groups [10,11]. A more recent investigation

found that Asian Americans were less willing to participate in health research than other ethnic groups, but they were as likely to trust researchers [¹²].

The National Institutes of Health (NIH) Community Engagement Alliance (CEAL) Against COVID-19 Disparities works with communities that COVID-19 disproportionately to conduct community-engaged outreach and research. Through collaborations with the Texas CEAL Consortium and community-based organizations (CBOs), we investigated the association between information source trust levels about COVID-19 and COVID-19 clinical trials and Vietnamese Americans' willingness to participate in COVID-19 clinical trials.

Methods

NIH CEAL developed the Common Survey 2 instrument, which contains 23 questions about social determinants of health, information, trust, risk perception, testing and disease control, COVID-19 vaccination, and demographics. We examined the questions about trust in sources to provide pertinent information about COVID-19, trust in sources to provide correct information about COVID-19 clinical trials, and if respondents were to get COVID-19, how willing they were to sign up for a hypothetical therapeutic trial. The survey instrument contained questions pertaining to trust in various sources of information about COVID-19 and COVID-19 clinical trials as distinct variables. While various options for COVID-19 information sources, such as news, social media, or governments, exist, fewer and potentially different information sources exist about COVID-19 clinical trials like the NIH, drug companies, and researchers.

To ensure that participants were part of the target population, they self-assessed their race from the following categories: Hispanic or Latino, American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian/Pacific Islander, and or white. They could then select all ethnicities that applied.

A translator from a partnering CBO translated this survey from English to Vietnamese. Then, the survey was back-translated from Vietnamese to English by a different CBO translator. Native Vietnamese speakers at another CBO reconciled the translations to ensure that they were understandable by the population of interest. The survey and consent form was available online in both English and Vietnamese. The average time to complete the survey was 15 minutes in English and 20 minutes in Vietnamese.

We used a convenience sample of Vietnamese Americans. The inclusion criteria were people at least 18 years old, of Vietnamese heritage, living in Texas, who could read and write in

English or Vietnamese. The survey was open from September 20, 2021, to March 4, 2022. Recruitment occurred virtually in English and Vietnamese through email lists, social media, an online webinar, and an internet ad from January 6 to 23, 2022. Participants were also recruited in person at literacy classes and two health fairs organized by CBOs. Recruitment flyers in English and Vietnamese were also posted in two health clinics serving Vietnamese populations. All participants who completed the survey and provided a valid email address or phone number were entered into a raffle for one of five \$50 credit card gift cards. The University of Houston Institutional Review Board approved this research.

We analyzed those willing and unwilling to sign up for a clinical trial for COVID-19 using available case analysis. Those who responded with “prefer not to answer” or “no opinion” were excluded from the analysis. Willingness to participate in COVID-19 trials was originally scored on a 7-point Likert scale with 1=Not at all willing and 7=Very willing. Willingness was then dichotomized, with unwillingness defined as responses of 1-4 and willingness as responses of 5-7. This threshold (>4) combines all endorsements of clinical trial participation above the neutral option (4). Trust in sources of information about COVID-19 in general or COVID-19 clinical trials was measured as the proportion of participants who responded that they had “a great deal” of trust. Chi-square tests and logistic regression assessed statistical significance and the magnitude of relationships, respectively, between trusted sources of information and willingness. The data analysis was performed using STATA 17.

Results

Of the 224 surveys Vietnamese Texans submitted, the 212 surveys containing complete responses regarding participants’ willingness to sign up for a clinical trial were used. Table 1 provides the demographics of the 212 respondents.

Trust in COVID-19 Clinical Trial Sources of Information

Willingness to participate in a clinical trial was significantly associated with past participation in a trial (OR=4.32; 1.64-11.36), trust in information about trials from university hospitals (OR=4.91; 1.35-17.89), and from drug companies (OR=4.14; 1.77-9.67). Conversely, trust in information that local clinics provided was significantly associated with less willingness to participate in a trial (OR=0.30; 0.12-0.73). Table 2 provides the odds ratios and tests of

significance between willingness to participate in COVID-19 clinical trials and previous enrollment in a COVID-19 clinical trial.

Trust in COVID-19 Sources of Information

Participants who trusted information about COVID-19 from the federal government (54.55%) were significantly more willing to participate in COVID-19 clinical trials (OR=2.27; 1.16-4.47). Trust in information about COVID-19 from the local and state government (51.85%) was significantly associated with willingness to participate in COVID-19 clinical trials (OR=2.30; 1.17-4.52). Table 3 provides odds ratios and tests of significance between willingness to participate in COVID-19 clinical trials and trust in sources regarding COVID-19 information.

Discussion

Our principal finding was that a significant association existed between Vietnamese Americans' high trust levels in drug companies and university hospitals and their willingness to participate in COVID-19 clinical trials. This finding means that researchers should identify trusted sources of information. After identifying such trusted information sources, researchers can collaborate with them to provide education regarding clinical trials to the Vietnamese American population and increase awareness and recruitment. This increased awareness will help recruit participants for clinical trials from different racial and ethnic subgroups to identify harms and benefits in specific populations.

These findings correlate with other studies that have examined trust and COVID-19 clinical trial participation. For example, Abdelhafiz et al. found that a general lack of trust in pharmaceutical companies, physicians, and hospitals prevented a Middle Eastern population from participating in COVID-19 clinical trials [8]. Thompson et al. examined medical mistrust and found that most participants, including Asians, were unwilling to participate in a vaccine trial [9]. In general, distrust of pharmaceutical companies discouraged participation in clinical trials involving pregnant people and women [13,14]. A common barrier to clinical trial participation among Blacks, Latinos, Asian Americans, and Pacific Islanders is mistrust, which is rooted in fear of being mistreated, taken advantage of by the researchers, and treated as “lab rats” or “guinea pigs” [15].

Another major finding from our analysis was that participants who had greater trust in the federal, state, or local government about more general COVID-19 information showed greater

willingness to participate in COVID-19 therapeutics trials. Greater willingness is essential because government resources and investment led to the rapid undertaking of the vaccine development for the novel SARS-CoV-2 virus. A government initiative to collaborate with pharmaceutical companies and university hospitals could raise awareness of COVID-19 clinical trials in Vietnamese Americans and improve representation.

Interestingly, high trust in clinical trial information that local clinics and hospitals provided was linked to a reluctance to join a COVID-19 clinical trial. This linkage might be because community facilities, which focus on healthcare rather than research, might offer less detailed trial information, creating perceptions of inadequate knowledge. This limited exposure could affect participation decisions due to doubts about the clinics' information depth and relevance to the trials.

Although limited data exists regarding the association between AANHPI, trust in government, and participation in COVID-19 clinical trials, research on the key role the government plays in a pandemic and the influence it has on vaccine adherence and clinical trials does. For example, Riersen et al. found that trust in government was associated with fewer COVID-related deaths in a global analysis of the government's role and COVID-19 outcomes [16]. Furthermore, the government has a critical role to play in establishing trust and confidence in the public about clinical trials through monitoring research guidelines and ethics, establishing policies that protect those participating in clinical trials, and communicating about the safety and importance of clinical research [17].

Building trust in government is vital to improving the diversity of clinical trial participants. However, it is understandable that historically marginalized populations are hesitant to volunteer. Black bodies have been exploited for centuries by American researchers, including on behalf of the U.S. government [18,19]. Native Hawaiians have reported mistrust related to a researcher's agenda not serving the community [15]. Future research could examine if a broader population of Vietnamese Americans have high trust levels in university hospitals, pharmaceutical companies, and the government and if that trust is associated with participation in clinical trials for other conditions.

This survey study had challenges and limitations. One challenge was that participants were required to complete a captcha verification before responding to the survey questions to prevent the influence of bots and ensure a representative sample. However, one CBO reported

that older adults encountered difficulties with this verification process. Thus, future research should explore alternative verification methods and include paper surveys to promote sample representation and address accessibility concerns in this population.

Regarding limitations, the survey instrument was specific to COVID-19 clinical trials and COVID-19 information and may not be generalizable to other conditions. Also, the results of this cross-sectional study do not demonstrate causality. Moreover, the sample was restricted to self-identified Vietnamese Americans in Texas who could complete an online survey. The online survey format introduces biases favoring technologically adept, younger, and more English-acclimated Vietnamese Americans. These format biases skew participation, potentially excluding older or less tech-savvy individuals. Consequently, data might not represent diverse opinions or those lacking digital access. Furthermore, the overrepresentation of highly educated respondents introduces bias, reflecting specific socioeconomic and cultural subsets, possibly misrepresenting those with lower education or diverse backgrounds among Vietnamese Americans.

Additionally, participants who responded as “prefer not to answer” or “no opinion” were removed from the analysis. Excluding participants who chose not to provide an answer or expressed no opinion can lead to a biased sample that does not accurately reflect the diversity of opinions within the target population. Therefore, these findings may not be generalizable to those with neutral, ambivalent, or other more nuanced opinions about clinical trial participation.

Nonetheless, this study provides insights into the beliefs and attitudes of Vietnamese Americans to increase the diversity of clinical trials. Vietnamese Americans’ high trust in pharmaceutical companies and university hospitals to provide correct information about COVID-19 clinical trials and governments to provide correct information about COVID-19 is associated with willingness to participate in SARS-CoV-2 therapeutics trials. By striving to identify these trusted sources of information, we can increase the participation of Vietnamese Americans in clinical trials and help to ensure that these treatments are safe and effective for use in this population.

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References

1. Asian American, Native Hawaiian and Pacific Islander Heritage Month: May 2023. United States Census Bureau. Published March 3, 2023. Accessed July 29, 2023. <https://www.census.gov/newsroom/facts-for-features/2023/asian-american-pacific-islander.html>
2. Yan BW, Hwang AL, Ng F, Chu JN, Tsoh JY, Nguyen TT. Death Toll of COVID-19 on Asian Americans: Disparities Revealed. *J Gen Intern Med.* 2021;36(11):3545-3549. doi:10.1007/s11606-021-07003-0
3. Tai DBG, Sia IG, Doubeni CA, Wieland ML. Disproportionate Impact of COVID-19 on Racial and Ethnic Minority Groups in the United States: a 2021 Update. *J Racial Ethn Health Disparities.* Published online October 13, 2021:1-6. doi:10.1007/s40615-021-01170-w
4. Craft JF, Travassos MA, Palacios CF, Openshaw JJ. Inadequate Minority Representation within SARS-CoV-2 Vaccine Trials. *Am J Trop Med Hyg.* 2021;104(1):32-34. doi:10.4269/ajtmh.20-1294
5. Pepperrell T, Rodgers F, Tandon P, et al. Making a COVID-19 vaccine that works for everyone: ensuring equity and inclusivity in clinical trials. *Glob Health Action.* 2021;14(1):1892309. doi:10.1080/16549716.2021.1892309
6. Murali M, Gumber L, Jethwa H, et al. Ethnic minority representation in UK COVID-19 trials: systematic review and meta-analysis. *BMC Med.* 2023;21(1):111. doi:10.1186/s12916-023-02809-7
7. Clark LT, Watkins L, Piña IL, et al. Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. *Curr Probl Cardiol.* 2019;44(5):148-172. doi:10.1016/j.cpcardiol.2018.11.002
8. Abdelhafiz AS, Abd ElHafeez S, Khalil MA, et al. Factors Influencing Participation in COVID-19 Clinical Trials: A Multi-National Study. *Front Med.* 2021;8:608959. doi:10.3389/fmed.2021.608959

9. Thompson HS, Manning M, Mitchell J, et al. Factors Associated With Racial/Ethnic Group–Based Medical Mistrust and Perspectives on COVID-19 Vaccine Trial Participation and Vaccine Uptake in the US. *JAMA Netw Open*. 2021;4(5):e2111629. doi:10.1001/jamanetworkopen.2021.11629
10. Paterniti DA, Chen MS, Chiechi C, et al. Asian Americans and cancer clinical trials: A mixed-methods approach to understanding awareness and experience. *Cancer*. 2005;104(12 Suppl):3015-3024. doi:10.1002/cncr.21522
11. Ma GX, Seals B, Tan Y, Wang SY, Lee R, Fang CY. Increasing Asian American participation in clinical trials by addressing community concerns. *Clin Trials*. 2014;11(3):328-335. doi:10.1177/1740774514522561
12. Liu Y, Elliott A, Strelnick H, Aguilar-Gaxiola S, Cottler LB. Asian Americans are less willing than other racial groups to participate in health research. *J Clin Transl Sci*. 2019;3(2-3):90-96. doi:10.1017/cts.2019.372
13. Pahus L, Suehs CM, Halimi L, et al. Patient distrust in pharmaceutical companies: an explanation for women under-representation in respiratory clinical trials? *BMC Med Ethics*. 2020;21(1):72. doi:10.1186/s12910-020-00509-y
14. Palmer S, Pudwell J, Smith GN, Reid RL. Optimizing Participation of Pregnant Women in Clinical Trials: Factors Influencing Decisions About Participation in Medication and Vaccine Trials. *J Obstet Gynaecol Can*. 2016;38(10):945-954. doi:10.1016/j.jogc.2016.04.100
15. George S, Duran N, Norris K. A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health*. 2014;104(2):e16-e31. doi:10.2105/AJPH.2013.301706
16. Reiersen J, Romero-Hernández M, Adán-González R. Government Reactions, Citizens' Responses, and COVID-19 around the World. *Int J Environ Res Public Health*. 2022;19(9):5667. doi:10.3390/ijerph19095667

17. Bhatt A. Government's role in shaping public perceptions about clinical research. *Perspect Clin Res*. 2012;3(3):87-89. doi:10.4103/2229-3485.100643
18. Wailoo K. Historical Aspects of Race and Medicine: The Case of J. Marion Sims. *JAMA*. 2018;320(15):1529-1530. doi:10.1001/jama.2018.11944
19. Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, Edwards D. More than Tuskegee: Understanding Mistrust about Research Participation. *J Health Care Poor Underserved*. 2010;21(3):879-897. doi:10.1353/hpu.0.0323

Table 1 Sociodemographic Characteristics

Characteristic	Participants (N=212)	
	<i>n</i>	%
Gender		
Female	123	58.0
Male	83	39.2
Other	6	2.8
Sexual Orientation		
Homosexual	39	18.4
Heterosexual	142	67.0
Other	31	14.6
Age		
18 to 24 years	23	10.8
25 to 34 years	40	18.9
35 to 44 years	36	17.0
45 to 54 years	36	17.0
55 to 64 years	35	16.5
65 to 74 years	34	16.0
75 years or older	8	3.8
Preferred language to use during the survey		
English	160	75.5
Vietnamese	52	24.5
Insurance Status		
Insured	185	87.3
Uninsured	27	12.7
Education		
College Degree or higher	104	49.1
Less than a college degree	108	50.9

Notes. This table highlights the sociodemographic characteristics, including gender, sexual orientation, age, preferred language to use during a survey, insurance status, and education from the online survey for Vietnamese adults living in Texas that collected data from September 2021 to March 2022.

Table 2. Association between Willingness to Participate in COVID-19 Clinical Trials and Trust in Information Sources Regarding COVID-19 Clinical Trials, (Odds Ratios, 95% Confidence Intervals, and associated p-values)

	Less Willing N=148	Willing N=64				
Trust in Sources of Information	N (%)	N (%)	Odds Ratio	Confidence Interval	p-values	Total Respondents
Past participation in a clinical trial	8 (5.67%)	13 (20.63%)	4.323	1.64-11.36	0.001	204
National Institutes of Health (NIH)	64 (74.42%)	49 (87.50%)	2.406	0.94-6.18	0.059	142
Doctor or healthcare provider	97 (88.18%)	53 (88.33%)	1.015	0.38-2.71	0.977	170
Local healthcare clinic or hospital	103 (91.15%)	46 (75.41%)	0.298	0.12-0.73	0.005	174
University hospitals	77 (78.57%)	54 (94.74%)	4.909	1.35-17.89	0.007	155
Companies that make drugs for medical use	58 (56.31%)	48 (84.21%)	4.138	1.77-9.67	0.001	160
People who do research	80 (76.19%)	48 (82.76%)	1.500	0.66-3.41	0.328	163
Friends, family, and community leaders	80 (63.38%)	41 (68.33%)	0.998	0.51-1.95	0.995	177

Notes. N=212. This table highlights trust in sources of information regarding COVID-19 clinical trials associated with willingness to participate in COVID-19 clinical trials. Participants who chose “no opinion” or “prefer not to answer” were not included in the analysis.

Table 3. Odds Ratios (OR) from Bivariate Chi-squared tests of Willingness to Participate in COVID-19 Clinical Trials and Trust in Sources Regarding COVID-19

	Less Willing N=148	Willing N=64				
Variables	N (%)	N (%)	Odds Ratio	Confidence Interval	p values	Total Respondents
Doctor or healthcare provider	113 (82.48%)	43 (71.67%)	0.537	0.26-1.10	0.085	197
Faith leader (e.g., priest, minister, monk)	36 (36.73%)	11 (23.40%)	0.526	0.24-1.17	0.108	145
People you go to work or class with or other people you know	26 (24.07%)	21 (35.59%)	1.743	0.87-3.51	0.114	167
News on the radio, TV, online, or in newspapers	65 (49.24%)	29 (49.15%)	0.996	0.54-1.84	0.991	191
Contacts on social media	31 (25.83%)	13 (23.21%)	0.868	0.41-1.83	0.709	176
Federal government	38 (34.55%)	30 (54.55%)	2.274	1.16-4.47	0.014	165
State and/or local government	37 (31.90%)	28 (51.85%)	2.299	1.17-4.52	0.013	170
Tribal leadership	5 (9.62%)	7 (16.67%)	1.880	0.54-6.51	0.308	94
The Centers for Disease Control and Prevention (CDC)	96 (72.18%)	45 (78.95%)	1.445	0.69-3.04	0.329	190
Community organization that provides services and assistance where you live	43 (38.74%)	25 (45.45%)	1.318	0.68-2.54	0.408	166

Notes. N=212. This table highlights the trust in sources for COVID-19 information associated with the willingness to participate in COVID-19 Clinical trials. Participants who chose “prefer not to answer,” “don’t know,” or “does not apply” were not included in the analysis.