ORIGINAL RESEARCH

Gaining Insights into Clinical Trial Recruitment Engaging Underserved Communities. Perspectives from Investigators, Research Coordinators, and a Community Advisory Panel

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Abstract

The underrepresentation of minority populations in clinical research has long been a concern, with implications for health equity and the generalizability of research findings. Legislative and regulatory efforts have aimed to address this issue, emphasizing the importance of inclusivity in clinical trials. In the Los Angeles Area, the COVID-19 Vaccine and Prevention Network (CoVPN) conducted three phase three COVID vaccine trials. One trial was the Phase 3 Covid-19 AZD1222 (ChAdOx1 nCoV-19) Vaccine trial by The Lundquist Institute at Harbor-UCLA Medical Center (Lundquist Institute). This was done in collaboration with a community consultant panel (CCP) which led to adjustments in recruitment strategies, and outreach initiatives to increase minority participation.[1]

After completion of COVID vaccine trials we further investigated factors affecting minority participation in clinical research. We surveyed three involved stakeholder groups at The Lundquist Institute: infectious disease investigators, clinical research staff, and an HIV community advisory board (CAB) made up of 20 individual representatives of the local community, predominantly those of color. Our survey gathered perspectives on key factors influencing minority participation to provide actionable priority based recommendations This study highlights the multifaceted nature of barriers to enrollment of diverse participants in clinical research and provides unique insights offered by stakeholder groups and the CAB. These emphasized logistical, transportation, and knowledge-related factors. The CAB's unique prioritization of these factors also underscores the significance of involving community representatives in the clinical trial recruitment process.

Keywords: Community Advisory Board, Diversity, Equity, Inclusion, Clinical Trials, COVID-19

Introduction

The underrepresentation of minority populations in clinical research has been a growing concern. It was not until 1993 that the NIH Revitalization legislation was signed. This law ensured inclusion of women and minorities in clinical research.[2] In 2022, the FDA expanded guidelines for sponsors to include more ethnic and racial diversity within the trial design process.[3] Investigators are increasingly aware of the crucial mandate to conduct studies applicable to the entire population while also providing therapeutics to the most needy.

Background

Three UCLA-affiliated sites in Los Angeles conducted phase 3 COVID-19 vaccine trials through the COVID-19 Vaccine and Prevention Network. The Covid-19 AZD1222 (ChAdOx1 nCoV-19) Covid-19 Vaccine trial was conducted by The Lundquist Institute. The three sites proactively made efforts to enhance enrollment of underrepresented populations by collaborating with a community consultant panel. These included recruitment strategies, adjustments, outreach initiatives, and trial protocols. The trials recruited relatively high minority participants across the sites (Figure 1), ranging from 55% to 78%.[1] The methods of community engagement employed resulted in strong diversity.

Methodology

To enhance minority participation in future research, we developed a structured 20-question survey to assess what different minority groups thought would enhance enrollment. The survey was designed based on review and insights from expert stakeholders, including infectious disease investigators, CAB, and clinical research staff. The questions were framed to cover the themes identified in the literature, including logistical (9 questions), information and engagement (5 questions), and cultural and community factors (6 questions). Each question could be ranked using a Likert scale of 1 through 5, 1 being not important at all and 5 being very important regarding minority recruitment in clinical research.

Survey Distribution:

The Google Form survey was distributed electronically via email and in a Zoom chat to Lundquist Institute infectious diseases investigators, clinical research staff who participated in the COVID-19 vaccine clinical trial, and the local CAB meeting. All participants received a brief explanation of the study's purpose and were informed about the voluntary and confidential nature of their participation.

Data Collection:

Data collection was carried out over 2 weeks, with reminders sent to non-respondents to maximize the response rate. Respondents completed the survey anonymously and each submission was timestamped.

Data Analysis:

Quantitative data was analyzed using descriptive statistics, including mean (with standard deviation) and median (interquartile range) calculated for each survey question. Additionally, means and medians of the factors were rank ordered 1-20 and show the most significant factors for each group.

Ethical Considerations and IRB Exemption:

This research was conducted in compliance with ethical standards for human subject research. Before initiating the study, a thorough review was undertaken to determine Institutional Review Board (IRB) oversight applicability. Given the study's nature, which involved analyzing perspectives on clinical trial recruitment strategies without direct patient interaction or access to sensitive personal data, it was deemed exempt from IRB review. Exemption was based on category 2: Research that only includes interactions involving educational tests, surveys, interviews or observations of public behavior. Informed consent was obtained from all participants.

Results

The 39 participants were stakeholders in the Covid-19 Vaccine trial at the Lundquist Institute, with high response rates: investigators (100%, 7); research staff (100%, 12); and CAB members (95%, 20). The survey questions are presented in the Table 1. The mean responses of the different groups for logistical factors, information and engagement and culture and community are summarized in Table 2 and Table 3. Mean logistical factors scores for all three groups ranged between 4.0 and 4.3. There was greater disparity for Information and Engagement with Investigators seeing this as somewhat lower importance compared to the CAB and research staff. For cultural and community assessment, the CAB felt this was less important than the research staff and investigators. When considering three most important and least important by group, there was similar discordance by group surveyed.

Discussion

This study provided perspectives of research staff and investigators regarding the barriers to diversity enrollment in clinical research. Logistical factors were the primary concern among research staff, while information and engagement were ranked as lower priorities among investigators. Interestingly, cultural and community factors were rated most highly among investigators/research staff, with lower ratings by the CAB. Additionally, all groups ranked childcare as one of the least important factors affecting clinical trial recruitment.

Logistical Factors:

Research staff's emphasis on logistical factors as the highest-ranked barrier suggests that operational challenges may significantly hinder clinical research diversity. Logistical challenges include issues related to patient transportation, scheduling, and access to trial sites. Addressing these concerns may streamline the recruitment process and reduce burdens on potential minority participants. The research staff's day-to-day duties include navigating the logistics of the clinical trials which may influence their prioritization.

Information and Engagement:

The lower ranking of information and engagement factors among investigators raises questions about the communication and outreach efforts within clinical research teams. It suggests a potential gap in strategies to inform and engage potential participants, which may be particularly relevant for minority communities. This underscores need for improved communication strategies, tailored information dissemination, and enhanced patient engagement initiatives to bridge this gap.

Cultural and Community Factors:

The high ranking of cultural and community factors among investigators suggests recognition of the importance of cultural competence and community engagement in clinical research. This aligns with growing recognition that understanding the cultural context and building trust within communities are essential for effective recruitment of diverse populations. Investigators should understand the significance of cultural sensitivity and community involvement factors that may impact diversity.

The CAB:

Notably, CAB members identified different priorities compared to other groups that placed a higher priority on cultural factors. The CAB perspectives illustrate the importance of community representatives in clinical trial recruitment strategies. Their perspective suggests potential community participants may be more discerning in the availability and effectiveness of existing treatments when contemplating clinical trial participation. Acknowledging this concern is useful when designing trials that resonate with participants' needs and preferences.

The CAB's emphasis on access to reliable transportation, such as ride sharing apps or public transit, is consistent with understanding of logistical challenges facing potential participants. Awareness of the barriers to participation extend beyond the trial itself and highlights the importance of addressing transportation-related concerns to improve inclusivity.

The CAB's recognition of the importance of knowledge about the condition or investigational drug suggests a commitment to informed decision-making within their communities. This underscores need for robust patient education and information dissemination to empower potential participants with the required knowledge to make informed choices about trial participation.

The CAB's unique prioritization of these factors underscores the significance of involving community representatives in the clinical trial recruitment process. Their insights provide a vital bridge between research teams and local communities, ensuring recruitment strategies resonate with the specific needs and concerns of minority populations. Tailoring recruitment efforts to address these concerns can enhance the inclusivity and effecttive clinical trial participation among underrepresented groups.

Recommendations

Based on this study, addressing barriers to diversity enrollment in clinical research requires a multifaceted approach that considers the unique perspectives of different stakeholder groups. In particular, the low ranking of childcare across all groups and the differing priorities of the CAB compared to research staff and investigators provides valuable insights for improving recruitment strategies. Specific recommendations are listed below:

Childcare Support:

While childcare was consistently ranked as a low priority among all stakeholder groups, it is important not to entirely disregard this concern. To make clinical trials more accessible, consider offering childcare services during trial visits or providing financial assistance for participants' childcare expenses outside of school hours. The inclusion criteria of the study may also be a factor if the target patient demographic includes many parents or guardians. This could help alleviate a potential barrier for some individuals. However, if funding is not available, clinical trial visits could be expanded to include weekends or during times that do not conflict with parents' work hours.

Transportation Solutions:

Recognizing the importance of transportation access, as highlighted by the CAB, research sites should collaborate with local transportation providers, such as share ride apps or public transit, to ensure that participants have convenient and reliable transportation options to and from trial sites. This can remove a significant logistical barrier to participation.

Cultural Sensitivity and Translation Services:

Acknowledge the emphasis placed on cultural sensitivity and translation by research staff and investigators. Invest in training programs to enhance the cultural competency of research teams and provide language translation services to accommodate participants from diverse linguistic backgrounds. This can improve communication and trust between participants and research staff.

Tailored Information Dissemination:

Given the CAB's focus on information, developing tailored information dissemination strategies that consider the informational needs of potential participants. Study teams should create clear, culturally relevant materials that explain the trial, its benefits, and the research process. It is important to engage the CAB in the development and review of these materials to ensure their effectiveness.

Community Engagement:

Clark and colleagues have stated that “mistrust: lack of understanding the value, fear, stigma of participating, and communication style of investigator/staff” are major barriers to study participation.[4] Thus, continuing to involve the CAB or similar community groups in protocol development and study participation may be beneficial. Their unique insights into community needs and concerns can inform the design of trials and recruitment strategies. This collaborative approach can help build trust within minority communities and enhance trial participation. While the Castellon-Lopez study observed good, if not great, diversity enrollment, it cannot be assumed that community involvement was directly responsible.[1]

Regular Stakeholder Collaboration:

By establishing regular communication and collaboration channels between stakeholders, Lundquist’s monthly CAB meetings can disseminate information about ongoing trials and foster an ongoing dialogue. Research teams and CAB members can continually assess and adapt recruitment strategies based on evolving priorities and feedback.

Data Collection and Analysis:

Many studies collect and analyze data on participant demographics, including their experiences. This type of ongoing assessment can provide insights into the effectiveness of implemented strategies and guide further improvements.

Education and Training:

Continually providing education and training opportunities for research staff and investigators on the importance of diversity enrollment in clinical research may address the unique needs of underrepresented populations. Cultural competence is an essential aspect of conducting ethical and effective research.

Incorporating these recommendations into clinical trial recruitment strategies can help address diversity barriers, enhance inclusivity, and ultimately contribute to producing more generalizable and equitable research findings.

Conclusion

Addressing barriers to diversity enrollment into clinical research is a multifaceted endeavor that requires ongoing collaboration, tailored strategies, and a commitment to inclusivity. The successes achieved in increasing minority participation in the Phase 3 Covid-19 AZD1222 Vaccine trials at The Lundquist Institute through collaboration with the CCP serve as a promising model for enhancing inclusivity in clinical research. By considering the recommendations derived from this study and continuing to engage with diverse stakeholder groups, we can work toward more equitable and representative clinical research.

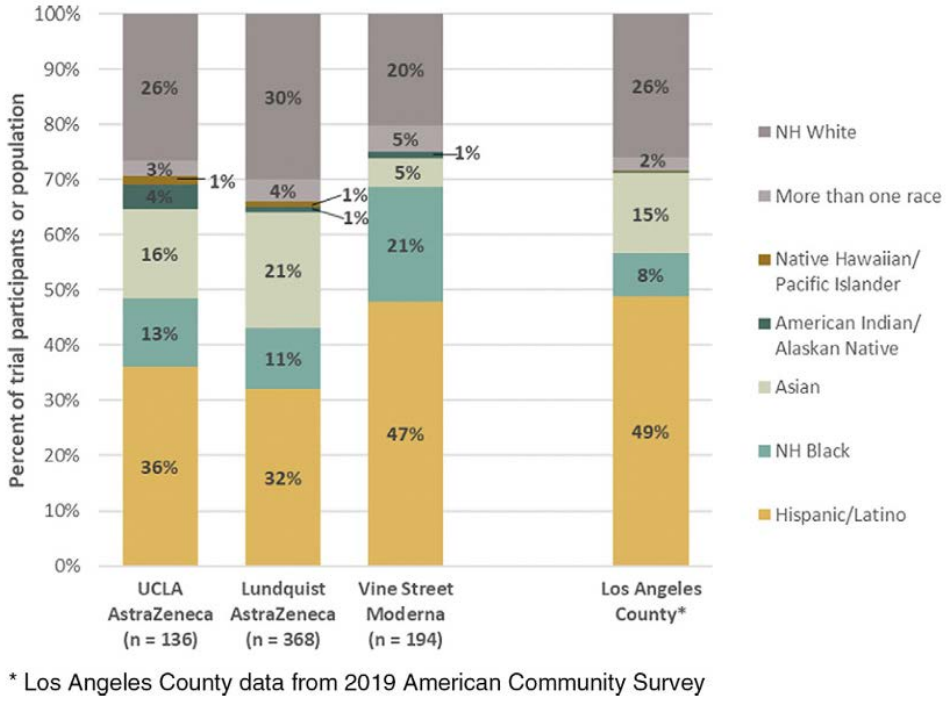

Figure 1. Racial and ethnic composition of participants enrolled in partnered clinical trials compared to Los Angeles County population. *Los Angeles County data from 2019 American Community Survey. “A community-partnered approach for diversity in COVID-19 vaccine clinical trials” by Y. Castellon-Lopez , 2022, Journal of Clinical and Translational Science, Volume 7, page number. Copyright 2022 by the Authors. Reprinted with permission.

Questions
1. Access to clinical site (ie. distance to home)
2. Access to reliable transportation (eg. uber or public transit)
3. Access to healthcare infrastructure (ie. having a primary provider or site proximity to hospital)
4. Research site directing to additional resources (eg. mental health service or food banks)
5. Financial Incentives/reimbursement for participation
6. Food and beverage availability on site
7. Child care services on site
8. Trial Duration (ie. how many weeks it is conducted)
9. Difficulty of protocol (ie. length of visits/number of tests)
10. Knowledge of condition or investigational drug
11. Quality/availability of existing treatments
12. Marketing and advertising of trials
13. Reputation of clinical site in the community
14. Clear communication and positive patient interactions
15. Family Support (eg. approval or reminder to adhere to study)
16. CAB/community engagement in protocol development and/or study participation
17. Language/translation services
18. Diversity of staff
19. Cultural sensitivity of staff
20. LGBTQ+ inclusive

Table 1. Questions distributed within the survey. Purple, logistical factors; green, information and engagement; and blue, culture and community.

Mean data of categorized responses						
Group	Logistical Factors	SD	Information and Engagement	SD	Cultural and Community	SD
CAB	4.0	1.0	4.5	0.6	3.9	1.3
Research Staff	4.3	0.9	4.5	0.8	4.5	0.8
Investigators	4.1	1.0	3.9	1.1	4.6	0.7
Total	4.1	1.0	4.4	0.8	4.2	1.1

Table 2. The mean (+SD) of responses of each group on a categorized set of questions.

Top and Bottom 3 Factors by Mean		
Group	Top 3 Factors	Bottom 3 Factors
CAB	10, 2, 11	8, 15, 7
Staff	17, 14, 19	12, 4, 7
Investigators	19, 17, 20	7, 3, 12

Table 3. Each group had all their mean responses from each question ranked in order.

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