USC Race and Equity Center

June 2025

CLINICAL TRIALS AS A VEHICLE FOR HEALTHCARE ACCESS

Affordable healthcare is a hot button issue for many Americans in general, and merely accessing any healthcare at all is a struggle for countless people within this population. Barriers to access include but are not limited to: financial cost and burden, geographical regions, discrimination and medical bias, and language difference. While such obstacles increase the likelihood that individuals in need of healthcare will not be able to access such services, some individuals use clinical trials to bridge medical insurance gaps to receive quality healthcare. And although this practice can be controversial and has its own set of issues, it is worth understanding more about this phenomenon given that such opportunities can be used to influence medical and pharmaceutical innovation, as well as provide information regarding preventative medicine for society at large. Given this, we have written this brief to help readers understand how clinical trials provide access to healthcare for vulnerable and minoritized populations. In this work we provide an overview of what this access looks like, identifying problems and challenges so that clinical trials can be improved and medical innovations advanced. Since this topic has received inadequate attention, we also provide recommendations on new directions for research to increase awareness and improve knowledge in this area.

CLINICAL TRIALS AS HEALTHCARE ACCESS

For individuals without health insurance, clinical trials may serve as a portal to the healthcare system, as such persons may use them as an onramp for other medical interventions. While clinical trials that prioritize ethical considerations and inclusion can deliver positive outcomes for patients and advances for the medical and scientific community, this needs to be coupled with the notion that there are also

individuals interested in gaining entrance into these trials to help treat their personal medical conditions, and improve their prognoses and quality of life. Considering benefits to risks should also be part of this important discussion of inclusion within clinical trials. All individuals enrolled and participating in clinical trials will not have positive patient experiences and may not actually have positive medical outcomes. Given this, equal opportunity for inclusion, whenever scientifically appropriate, should be the overall goal for all clinical trials.

Though this aspiration is a worthy goal, more meaningful and intentional work needs to occur around including more diverse populations. Doing so will produce the kind of medical innovations and advances that more directly result from clinical trials research that benefits all racial and ethnic groups. Before this goal can be achieved, however, research and medical communities should be mindful about putting said populations in harm's way under the guise of inclusion. There is a long, controversial, and unethical history that has been captured by scholars that illustrates the nefarious actions of medical professionals disguised as inclusionary practices (Smith, 2008). Unfortunately, some of the medical findings and outcomes from those trials and experiments provide the foundations of many current surgical practices and therapeutic innovations (Noah, 2002).

It is highly debated if utilizing clinical trials as a portal to healthcare is useful and sustainable based on the foundational concept that individuals have clear and attainable access to participate in clinical trials. It is often the case that there are financial barriers to enrolling and participating in trials (Nipp, Hong, and Paskett, 2019). The term "financial toxicity" refers to the modern-day phenomenon of rising health insurance costs, which leads to economic and social burdens (Chino and Zafar, 2019). Also important to the concept of financial toxicity are indirect costs, specifically those associated with enrollment and participation in clinical trials. Indirect costs include travel to trial sites, lodging if needed, and potentially lost wages from work absences. Other barriers to clinical trials as healthcare access for vulnerable populations should be considered as well.

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Barriers to Clinical Access Participation

The gap between what clinical trials should be and what they are is quite apparent as researchers try to understand the multiple barriers to access that undoubtedly affect trial outcomes and overall benefits to larger society. It is known that participation in clinical trials by a varied and diverse demographic of individuals has the potential to yield more robust outcomes that provide data that can directly translate to medical and pharmaceutical innovations.

However, many of the same issues that obstructed entry into participation in clinical trials twenty years ago still exist today. In fact, they may be even more prevalent now. It would be unfair to only highlight the most prevalent barriers to clinical trial participation, which include: geographical location, (in)direct costs, and lack of insurance. Some of the other issues that influence access and ability to participate in clinical trials are mistrust in the medical community, healthcare provider bias, and language difference. Some of these barriers disproportionately affect specific populations, including racially marginalized groups, but research consistently demonstrates that even when groups that are disproportionately affected by certain medical conditions, they are still not adequately represented in clinical trials.

The demographic groups at highest risk for financial toxicity are the exact groups that currently have the lowest participation in clinical trials. These are potentially also the same individuals that may be attempting to use clinical trials as a vehicle for access to quality healthcare. This practice may also prove to be unsustainable because of barriers that already exist in gaining access to participation in clinical trials. Due to resources, both clinic and hospital locations are clustered in urban areas leaving more rural populations without the same access to enrollment and participation in trials. Geographic locations with higher socioeconomic levels tend to have higher clinical trial accrual of patients (Chino and Zafar, 2019). Scholars argue that this disparity may explain the underrepresentation that we see in clinical trial patients and even outcomes. The practical component of utilizing trial sites in these areas cannot be ignored, as these areas provide resources that are not often replicated in geographical areas where these medical resources are scarcer. Densely populated urban areas provide more access to racially and ethnic diverse populations, but they can also indicate fewer travel restrictions to trial sites due to location and possibilities of public transportation. That withstanding, the “practicality should not be the main determinant of clinical trial site location” (Seidler et al., 2014).

UNDERSTANDING DISPARITIES IN CLINICAL TRIALS ACCESS

Disparities in clinical trials access exists for a number of reasons, one of which is the financially prohibitive cost to participation. In order to remedy this particular barrier, a number of measures have been developed to increase diversity in the participant pool. One example is that nonprofit organizations and philanthropic foundations often provide limited funds to help offset direct and indirect costs associated with enrollment and participation in a clinical trial. This limited funding should be viewed as a stopgap until a more sustainable and long-term solution is presented and offered widely.

Another barrier linked to disparities in access is the lack of awareness about clinical trials. This can be addressed through increased communication and relationship building with community partners. In developing better enrollment strategies that target racially marginalized and geographically diverse populations, site directors and trial coordinators need to design thorough and strategic communication plans that provide not only medical information about the trial, but also about the (in)direct costs of the trial to ensure that individuals have this information and can make informed decisions prior to enrolling. Clinical trial coordinators can also create campaigns and informationals to educate potential participants and other key community stakeholders.

> "Addressing disparities in clinical trials among ethnic, racial, and socioeconomic groups has the possibility of delivering more thorough and wide-ranging applicability of medical outcomes (Heneghan et al. 2017)."

Another reason for such disparities is oversight. An example is the 1993 National Institutes for Health (NIH) guidelines for inclusion. This directive, which required women and racial/ethnic minorities to be included in clinical trials, did not include geographic minorities and more specifically, rural populations (Seidler et al., 2014). The takeaway being that developers of policy and practice should be mindful that such omissions, among others, likely contribute to problems with inclusion disparities in clinical trials. Addressing disparities in clinical trials among ethnic, racial, and socioeconomic groups has the possibility of delivering more thorough and wide-ranging applicability of medical outcomes (Heneghan et al. 2017). Conversely, limited patient participation may skew the outcomes and provide data that cannot be extrapolated and applied to a larger population.

This can be a problem even with more clinical trials being produced. While there are a multitude of clinical trials occurring around the globe with voluntary patients, some of the most popular trials are for cancer therapeutics, HIV/AIDS, and even more recently COVID-19. Women and racially marginalized individuals represent some of the most advanced cases of the aforementioned diseases and medical conditions, but they are still underrepresented in clinical trials for a variety of reasons that still present conundrums to researchers (Castillo - Mancilla et al., 2014).

While there are no official statistics to confirm the number of individuals utilizing clinical trials as a method of healthcare access, there is enough scattered information to conclude that the number is small and the individuals able to do this may actually not be the presumed population. In most cases, clinical trials require participants to have some form of medical insurance even if the individual has to pay out of pocket for indirect costs associated with trial enrollment and participation. The requirement of medical insurance, even if it is not quality or full coverage insurance, can be used as a high value predictor for clinical trial coordinators and doctors to determine if individuals will successfully enroll and finish the trial. Clinical trial coordinators and medical professionals also utilize certain information and measures for participant predictors for longevity and success in the

trial. Gaining entry into trials may not be as easy as once assumed. Individuals may or may not be enrolled based on factors, such as: socioeconomic status, insurance status, ability to travel to sites regularly, education level, medical comorbidities, and awareness of the trials.

Improving Gaps in Clinical Trials Access

For individuals to consider clinical trials as a viable method for healthcare or even increase their odds of being selected for a trial, the recruitment and selection process for clinical trials has to be updated and the current state of medical insurance coverage needs to be redesigned. In the short term, expanded coverage to include costs associated with clinical trials would allow more individuals to stay eligible during the entire clinical trial process. Increasing financial incentives as a way to increase recruitment pool and participation could also be a promising strategy. It would not only decrease financial burden, but it would also create more opportunities across demographics to participate in appropriate clinical trials. The process of reducing financial barriers has the potential to attract and retain historically underrepresented groups in clinical trials (Schmotzer, 2012).

"Expanded coverage to include costs associated with clinical trials would allow more individuals to stay eligible during the entire clinical trial process."

Indeed, clinical trials hold tremendous potential for advancing society-benefitting medical and scientific research. However, there remain considerable gaps that need to be addressed to more fully actualize this goal. One of these is the underrepresentation of certain populations in clinical trials. Scholars interested in this area should look at similarly situated programs excelling at this to learn from them about what is working. And though many people use clinical trials as a means of assisting them with medical care, little is known about their motivations for doing so. Given this, more research is needed to obtain updated insights about this phenomenon. Such an opportunity is ripe for acquiring useful data on the number of people approaching clinical trials as a form of healthcare; their reasons and motivations for doing this; and how they go about it. And although one may assume there is a direct correlation between financial toxicity, access to quality healthcare, and participation rates in clinical trials, more should be done to understand relationships between these three areas. Population-specific insights that consider intersections (e.g., gender, race, SES, rural/urban, education-level) would be especially useful in further understanding how certain barriers to clinical trial access might be amplified based on aspects of one's identity.

Such insights can be useful in more targeted remediation of said barriers, leading to more inclusive clinical trials across a range of human experiences.

Through this brief we have shown how clinical trials are used to access healthcare. By painting a picture of the problems and challenges associated with this phenomenon, we invite those concerned with advancing medical and scientific innovations to seriously consider how these issues could be remedied, especially since clinical trials hold much promise and are avenues to medical interventions for some. Informative briefs such as this are one of many correctives that will increase awareness of and improve knowledge about this important topic.

About the USC Race and Equity Center

The University of Southern California is home to a dynamic research, professional learning, and organizational improvement center that serves educational institutions, corporations, government agencies, and other organizations that span a multitude of industries across the United States and in other countries. We actualize our mission through rigorous interdisciplinary research, high-quality professional learning experiences, the production and wide dissemination of useful tools, trustworthy consultations and strategy advising, and substantive partnerships. While race and ethnicity are at the epicenter of our work, we also value their intersectionality with other identities, and therefore aim to advance equity for all persons experiencing marginalization. Our rigorous approach is built on research, scalable and adaptable models of success, and continuous feedback from partners and clients.

We acknowledge that our center is on the traditional land of the Gabrielino-Tongva peoples. We also recognize the Chumash, Tataviam, Serrano, Cahuilla, Juaneño, and Luiseño People for the land that USC occupies around Southern California. We honor their past and present.

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Our mission is to **ILLUMINATE**, **DISRUPT**, and **DISMANTLE** racism in all its forms.

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