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Clinical Research Principal Investigators' Perspectives of Improving the Diversity of Clinical Research Participants

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Abstract

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MS, Icahn School of Medicine at Mount Sinai, 2016

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Public Health

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Abstract

Clinical trials are needed to make new medications, devices, and diagnostic tools available. Participants in these clinical trials have historically come from a homogeneous group, and there is a recognized need for increased diversity and representation in these clinical research studies. The absence of diversity in clinical trials makes it difficult for clinicians and researchers to know which medications and devices are safe and effective for specific populations. This basic qualitative phenomenological study was conducted to explore the experiences of clinical research principal investigators regarding diversity in clinical research studies and how to improve it. The theoretical framework for this study was the socio-ecological model. The participants were principal investigators from clinical trials who were recruited through social media, professional groups, forums, and word of mouth. Participant interviews were recorded, transcribed, coded, and thematically analyzed to identify the emergent themes. The seven emergent themes were: (a) passionate about working in clinical trials, (b) increased awareness over time, (c) frustration with stringent eligibility criteria, (d) the perception that increased diversity among staff is needed, (e) knowledge and awareness of multifaceted barriers to having diverse participants in clinical research, (f) concerns that no formal training exists, and (g) optimism for the future with strategies and solution. The study's implications for positive social change include the study findings being used as a guide to attract more underrepresented minorities to participate in clinical trials that could result in increased diversity in clinical research studies to help bridge the gaps in health disparities and improve health equity.

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Dedication

I dedicate this dissertation proudly and with love to the unwavering support I have received from friends and family.

Firstly, to my son, Logan. I see so much of myself in you every day. You have been with me for most of this doctoral journey and I thank you for waiting until the end of my Spring 2020 quarter to make your grand arrival! Thank you, Logan, for all your patience. I could not have asked for a baby with a better temperament. I hope this serves as an inspiration for you to achieve anything you want and to grow up to be a meaningful and purposeful member of society. I will be right there to guide you.

To my other half, Arthur, I thank you for your guidance, wisdom, your love, and your unconditional support now and always.

To my Aunt Judy, thank you for always pushing higher education. Who would have thought that from being the first in the family to go to college, that here I would be graduating with a PhD? Thank you for everything!

To my Chair, Dr. Jeanne Connors, I thank you for your patience, your expertise, and for pushing me through this.

To my dear friend, Ann, I miss you and I wish you were here to see the outcome.

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Chapter 1: Introduction to the Study

Background of the Study

A clinical research study is an investigation or research that involves one or more human subjects that is undertaken to assess or evaluate the safety or effectiveness of a medical device (U.S. Food and Drug Administration [FDA], n.d.). Clinical research studies are conducted to test the safety and efficacy of promising, novel treatments and diagnostic tests (Umscheid et al., 2011). The findings from clinical research studies fill knowledge gaps by providing new information about ways to treat, prevent, and diagnose diseases (Umscheid et al., 2011). Studies are needed to advance medicine and health care as well as optimize outcomes (Umscheid et al., 2011). Volunteers join these studies and contribute to the data. In many of these studies, the diversity of the participants is not representative of the general population (Selker et al., 2018). Some populations, such as African Americans and Hispanics, are disproportionately underrepresented in medical research studies (Occa et al., 2017). Evidence has indicated that outcomes, such as adverse reactions and efficacy, can differ by certain patient characteristics, such as gender and ethnicity (Stronks et al., 2013). Clinical research studies need to consider diversity when the goal is to improve care and outcomes for all patients.

There is a big gap in research where the volunteer patients evaluated in the clinical trials and the target patient populations differ (Selker et al., 2018). In the real world, outside of the trials, this creates an issue where there is not enough data about the general population (Selker et al., 2018). This difference in the knowledge about treatment effects in diverse patient populations is widespread in medical practice and occurs with

some of the most prescribed medications (Selker et al., 2018). According to Kennedy-Martin et al. (2015), when the external validity of randomized control trials in the fields of cardiology, mental health, and oncology were examined, it was found that more than 70% of the patient participants included in these trials were not representative of the patients encountered in routine clinical practice. The population difference between the trials and real-world practice could significantly impact the external validity of randomized clinical trial findings (Kennedy-Martin et al., 2015).

There is a need for a more diverse participant pool in clinical trials (Oh et al., 2015). Limited studies have explored the viewpoints of clinical research principal investigators on this topic. For each clinical research study, a team of individuals conducts the clinical trial at a trial site. The investigator is the responsible leader for the team and may be called the principal investigator (FDA, n.d.). The FDA reported in 2013 that diversity for clinical research participants is pivotal for approval decisions and that subgroup analyses are conducted for most applications for the highest-risk medical devices (Fox-Rawlings et al., 2018). It is unknown if the analyses included numbers that could be of statistical significance, were conducted for most of the major subgroups, or if safety, effectiveness, or accuracy were considered (Fox-Rawlings et al., 2018).

Problem Statement

Multiple research studies have been conducted to determine the reasons for the underrepresentation of people of color in clinical trials. The reasons included the mistrust of researchers; fear of receiving the placebo treatment; lack of transportation to the research center; childcare or dependent obligations; language challenges; low research

awareness; stigma; cultural values; beliefs about research; poor engagement from researchers; and general inaccessibility to research in deprived areas, including concerns of costs of time and money (Amorrortu et al., 2018; Treweek et al., 2020). Representation of the population in research studies is essential to ascertain that clinical research study results are generalizable to the population using the therapy (Clark et al., 2020). In 1993, a law required the National Institutes of Health (NIH) to include women and racial-ethnic minorities in relevant research studies, and while most federal agencies adhered to the same policy, the FDA did not (Fox-Rawlings et al., 2018). The reason for this exemption by the FDA was that the clinical trials conducted are designed and sponsored by industry or other private entities and not by government employees or U.S. taxpayers (Fox-Rawlings et al., 2018). The lack of a diverse patient participant pool and a shortage of publicly available data meant that health care providers and patients often cannot discern which medications and devices are safe and effective for specific demographics (Fox-Rawlings et al., 2018).

There are limited studies focusing on clinical research professionals and their views about how best to address the urgent need to improve diversity in clinical research studies. Some studies have explored the perceptions of the clinical research coordinators but not those of experts, such as the principal investigator (Haley et al., 2017). In this study, I explored the lived experiences of clinical research principal investigators to gain deeper insights into the importance of having diversity in clinical research participants. The results of this study can drive social change by helping to develop approaches toward increasing diversity in clinical research studies.

Purpose of the Study

The purpose of the study was to explore the perceptions of clinical research principal investigators on the absence of diversity in clinical trials. When the participants in clinical research studies are not diverse, the generalizability of the research findings is diminished and indicates a disparity in access to high-quality care (Hamel et al., 2016). Previous researchers have not captured the lived experiences of clinical research professionals and their insights into the need for increased diversity in clinical research participants. The need for increased understanding of this topic from the perspective of clinical research professionals will help to advance social change toward the inclusion of more diverse participants in clinical research. The results of this study can be used to guide clinical research awareness and recruitment strategies toward improving trial diversity. Achieving diversity in clinical trials can help improve health equity and bridge gaps in health disparities.

Research Questions

1. What are the lived experiences of clinical research principal investigators regarding diversity in clinical research?
2. What do clinical research principal investigators identify as concerns for diverse participants in clinical trials?

Conceptual Framework

I used the socio-ecological model (SEM) as the conceptual framework for understanding the experiences of clinical research principal investigators regarding underrepresentation in clinical trials. The SEM is powerful, multifaceted, and includes

intrapersonal, interpersonal, organizational, environmental, and public policy factors (Scarneo et al., 2019). The premise of SEM is that a person's behavior is integrated into a network of intrapersonal characteristics, interpersonal processes, institutional factors, community features, and public policy (Salihu et al., 2015). In the SEM, it is assumed that the interactions between individuals and their environment are reciprocal (Salihu et al., 2015). This reciprocity implies that individuals are influenced by their environment, and the environment is influenced by individuals (Salihu et al., 2015).

I used the SEM to examine principal investigators' perceptions, attitudes, beliefs, concerns, and opinions as they relate to diversity in clinical research participants. The SEM also offered a helpful framework for addressing the challenges in participant recruitment and retention in clinical trials (see Salihu et al., 2015). The principal investigators shared their perspectives on diversity in clinical trials and offered suggestions on how the situation could be improved.

Nature of the Study

In this study, I used a qualitative, hermeneutic phenomenological approach to explore the perceptions of principal investigators regarding diversity in clinical trials. Hermeneutic phenomenology seeks "to understand the deeper layers of human experience that lay obscured beneath surface awareness and how the individual's lifeworld, or the world as he or she pre-reflectively experiences it, influences that influence this experience" (Neubauer et al., 2019, p. 94). My education and knowledge base as the researcher were considered in this qualitative phenomenological study. The expectation that the researcher takes an unbiased approach is not consistent with

hermeneutic phenomenology; instead, researchers should recognize their preconceptions and consider how their subjectivity is a part of the analysis process (Neubauer et al., 2019). In this study, I sought key informant, one-on-one interviews with eight to 20 principal investigators for data collection. All the interviews were conducted remotely, recorded, transcribed, and analyzed for themes with NVivo software. Interviews continued until data saturation was achieved.

Assumptions

There were a few assumptions associated with this study. I assumed that principal investigators would have participated in this study and have been familiar with the need for diverse participants in clinical research. Another assumption was that the participants would share their honest and unbiased views during the interviews. I also assumed that important and helpful information would be obtained by conducting and recording these interviews with principal investigators on the need for more diverse participants in clinical trials.

Scope and Delimitations

This study had participants delimited to the inclusion criteria of being English-speaking principal investigators with at least 2 years of experience in clinical trials and experience in the United States. Having a minimum of 2 years of experience helped to ensure that the principal investigators had enough experience in the field with the phenomenon of interest to share comfortably on this topic. The scope of this study was limited to remote interviews conducted via Zoom of clinical research principal investigators in the United States. My descriptions of the procedures and findings were

crucial to address any issues with transferability. The interview transcripts will continue to remain secure and will be destroyed 5 years after the study is completed.

Limitations

I identified some limitations of this study. One of the challenges in qualitative research is that the researcher is also the research instrument; therefore, the researcher's subjectivity, identity, and positionality can influence the research process and methods, ultimately impacting the data and findings (Ravitch & Carl, 2016). Another limitation was that there were a small number of participants.

Significance

Clinical research recruitment efforts should be customized for underrepresented populations (Treweek et al., 2020). Underrepresentation exists due to a limited familiarity with and understanding of clinical research opportunities and processes (Hughson et al., 2016). There are limited published qualitative studies that have considered the viewpoints of clinical research professionals, such as principal investigators, and the importance of having a diverse clinical research participant pool. Clark et al. (2020) investigated the barriers affecting underrepresented patients' willingness to participate in trials and sought input from key stakeholders, including underrepresented populations, referring physicians, investigators, and trial coordinators. They identified several themes from solutions that resonated with stakeholders and used a transtheoretical model of behavior change to create a communications message map to support approaches for overcoming critical participant barriers. To date, there are no extant studies exploring the viewpoints of principal investigators on this phenomenon. This study's findings will help develop

recommendations for recruiting underrepresented participants. Achieving representation in clinical research can improve health outcomes, health equity, and health disparities.

Summary

Clinical research studies are needed to make improvements in care, and the absence of diversity in clinical research can be detrimental to underrepresented populations. There is a gap in the literature on the lived experiences of clinical research principal investigators and their perspectives on this problem. In this study, I conducted remote interviews with principal investigators to fill this gap in knowledge. There is the potential for the study's findings to lead to positive social change by being used to ultimately address health disparities and equity concerns and improving care for all. Chapter 2 includes the literature review on this topic. Chapter 3 presents the details of the study's methodology and design. Chapters 4 and 5 will present the results and a discussion of the findings.

Chapter 2: Literature Review

In this study, I explored the perceptions of clinical research principal investigators on the lack of diversity in clinical trials. When the participants in clinical research studies are not diverse, the lower enrollment of underrepresented populations reduces the generalizability of the research findings and signifies a disparity in access to high-quality care (Hamel et al., 2016). This creates a problem where it becomes difficult to know if certain therapies are safe and effective for certain subsets of the population. Principal investigators lead clinical trials at their research sites, and their perceptions of and experiences on this topic have not been explored. As leaders in clinical trials, the perceptions and experiences of principal investigators are valuable to explore. The findings of this study exploring the perceptions of the principal investigators and the need to improve trial representation can be used to guide clinical research awareness and recruitment strategies toward improving trial diversity, which will help advance positive social change. In Chapter 2, I synthesize and discuss the peer-reviewed literature related to diversity in clinical research.

Previous Research on Diversity in Clinical Research

Several studies have emphasized the absence of diversity in clinical research participants and how this affects the generalizability of the results from clinical trials (Lesko et al., 2017). Not having representation in clinical trials means there is not enough data on the safety and efficacy of many medications, which can lead to adverse outcomes for many members of the population. How effective or safe medication is can differ among population subgroups, depending on factors, such as gender, age, race, ethnicity,

lifestyle, and genetic background (Clark et al., 2020). As racial and ethnic minorities remain underrepresented in clinical trials, barriers have been identified, but viable solutions have not been realized (Clark et al., 2020). Numerous barriers and challenges can impede the successful recruitment and retention of clinical research studies that target underrepresented populations (Salihu et al., 2015). Hamel et al. (2016) recognized the complexity of the barriers to enrolling racial and ethnic minorities and concluded that multilevel interventions likely have the best potential to be successful. Common barriers to participation in clinical trials include fear and a mistrust of medical research due to misinformation and knowledge of numerous historical injustices (Hughes et al., 2017).

Common Barriers to Participation

The barriers to clinical trial enrollment that patients face is well documented but not much has been done to learn about the barriers the clinical research coordinators face (Haley et al., 2017). Much of the literature has focused on barriers to participation, and some have interviewed clinical research coordinators, but there is no research on the principal investigators (Clark et al., 2020; Haley et al., 2017; Hamel et al., 2016; Hughes et al., 2017; Salihu et al., 2015). In this literature review, I focused on the importance of diversity in clinical research participants, concepts relevant to qualitative research, and the SEM. The literature review comprised relevant research from numerous scholarly sources, including peer-reviewed articles.

Clinical trials are needed to provide evidence for advancing medicine. The findings from these trials support the FDA with the approval of new therapies and inform physicians and patients as they make decisions about using these medications or medical

devices (Downing et al., 2016). These clinical trials gather and provide the data to evaluate the safety and efficacy of new medications and diagnostic tools (Clark et al., 2020). Due to many contributing factors, such as age, gender, race, ethnicity, lifestyle, and genetic influences, the efficacy and safety of new medical products could differ among population subgroups (Clark et al., 2020). Genetics can influence how a person metabolizes and responds to medications.

When a new medication is approved, it is approved for everyone (Ciociola et al., 2014). If the study participants were mostly a homogenous group and lacked diversity, there is no way to discern if the newly approved medication will be safe and effective for all. To understand if a medication or medical device is safe and effective for all, it is crucial that the participants in the clinical trials represent those who will use these products in the real world; therefore, the clinical trial participants must be representative of the general population. Unfortunately, representation in many clinical trials is often not achieved because participants in clinical research studies tend to be homogeneous, and racial and ethnic minorities remain underrepresented (Clark et al., 2020). This underrepresentation restricts the researchers' ability to test a new intervention's safety and efficacy across different population subgroups (Amorrortu et al., 2018).

Previous studies have identified the barriers to participating faced by the patients and the perceptions of the clinical research coordinators. Clark et al. (2020) identified mistrust, discomfort with the research process, fear, stigma, time constraints, and lack of awareness as barriers to participating in clinical trials. Other barriers to enrolling racial and ethnic minority patients include failure to meet the eligibility criteria and associated

costs (Hamel et al., 2016). Haley et al. (2017) explored the perspectives of neurological clinical research coordinators and discovered barriers to participating in clinical trials related to translation, literacy, family composition, and the severity of the medical diagnosis. Principal investigators lead the clinical research studies at their respective research sites and are important in the recruitment process; however, to date, no studies have addressed the perceptions, viewpoints, and lived experiences regarding the diversity of clinical research participants of clinical research principal investigators.

Health Disparities and The Need for Representation

Racial and ethnic minority groups are routinely disproportionately affected by health conditions such as Type II diabetes mellitus, cardiovascular disease, stroke, HIV/AIDS, and many types of cancer (Noonan et al., 2016). Many studies of diseases, such as different forms of cancers, neurologic diseases, and cardiovascular disease, have revealed that the study populations are not representative of the racial and ethnic make-up of those who are most affected by these diseases (Amorrortu et al., 2018). When clinical trials do not have diverse participants, the results may not be generalizable or applicable to the general population, including those from the ethnic backgrounds most likely to be affected by the disease (Lesko et al., 2017).

Having populations that are representative in the clinical research studies that are ultimately used to transform standards of care is essential to reduce disparities in outcomes and encourage equity in health care (Loree et al., 2019). Durant et al. (2014) indicated that a multilevel approach is needed to address the challenges and obstacles to improving recruitment of underrepresented populations in cancer clinical trials. Though

their study focused specifically on cancer trials, the results can be applied to other disease areas because there are many strategies suggested to be utilized to raise awareness and address the absence of representative populations in clinical research studies.

Several studies have addressed the need for more representation in clinical trial participants (e.g., Clark et al., 2019; Durant et al., 2014; Fox-Rawlings et al., 2018; Loree et al., 2019; Occa et al., 2017). Previous studies have also addressed the barriers to participating and the facilitators to participating in these clinical trials (Clark et al., 2020; Hughes et al., 2017; Salihu, 2015). Much of this information was collected from a review of the data and members of underrepresented populations; however, very little of this information came from the principal investigators who recruit, enroll, and follow the participants through their journey in the clinical trials. Having representative participants in clinical research studies is important for advancing new medical therapies and moving health care forward, and the advancement of health care, clinical care, and science depends on having more diversity in clinical research studies. When a new therapy shows promise in clinical trials, it can be hard to discern if the conclusions are relevant for populations not represented in the studies. Suppose certain groups of the population did not participate in the clinical trial. In that case, there is no safety and efficacy data on the new therapy for these population groups; however, if the medication is approved, it is approved for all.

Many prevailing health conditions are disproportionately seen in the African American community, a group often underrepresented in clinical research studies (Amorrortu et al., 2018). Increased participation from this group is needed to develop

safe and effective therapies and diagnostic tests to help to lessen or eliminate these disparities. The obstacles and barriers leading to a lack of representation in clinical research need to be addressed because clinical trials are vital to eliminating health disparities and improving health equity. New therapies only become available after extensive clinical research (Ciociola et al., 2014). Despite the benefits of clinical research, many potential participants who are approached and offered the opportunity to participate ultimately decline due to myths about the research process, historical injustices, and mistrust (Salihu et al., 2015).

The results of the current study can add new knowledge to the field that could inform the recruitment practices of underrepresented minorities to participate in clinical research studies. Outcomes from this study could also influence policymaking decisions about strategic targeting, partnerships, and collaborations in underrepresented communities to advance care by participating in clinical trials. Ultimately, the knowledge gained from this study could assist in empowering and encouraging members of underrepresented populations to become more aware of clinical trials as an option for their care.

In Chapter 2, I present the literature search strategy and the study's relevant concepts. The review commenced by expanding on the search criteria, conceptual framework, and methodology used to support this qualitative research study. In this chapter, I also discuss the current literature (i.e., articles published in the last 5 years) on diversity in clinical research.

Literature Search Strategy

Search Criteria

I included peer-reviewed journal articles, books, internet sources, and other publications in this study. Peer-reviewed research articles published between the years of 2015 to 2021 were the core of the literature covered in this review. I used Walden University's online library to access the following research databases and search engines: Google Scholar, ProQuest, EBSCO, PubMed, and NCBI.

Keywords and Phrases

I used the following keywords and phrases to search the literature: *representation in clinical research, minority participation in clinical research, principal investigators and underrepresentation in clinical research studies, diversity in clinical trials, perceptions of clinical research professionals in clinical research studies, clinical research and health equity, clinical research and health disparities, qualitative research and underrepresentation in clinical research studies, social-ecological model, socioecological model and clinical trials,* and *generalization of clinical research studies.* The search yielded articles and resources that provided evidence for the literature review.

Literature Search Process

I used peer-reviewed journal articles and books, mostly published between 2015 and 2021, to evaluate and investigate several aspects of this study, including (a) barriers and obstacles for clinical trial participation for underrepresented populations, (b) perceptions of clinical research professionals about diversity in clinical trials, (c) health disparities and health equity, (d) the SEM and how it can be used for clinical trials, and

(e) the relevance or generalization of clinical research data when the participant pool was not representative of the people afflicted by the condition. I also searched for information on the SEM and its applicability to principal investigators and diversity in clinical research.

Theoretical Framework

The theoretical framework for this study, the SEM, provided a basis for me to understand the perceptions of clinical research principal investigators towards the overall absence of diversity in clinical research studies and how strategies could be potentially developed and implemented to improve participation and raise awareness. The SEM was first proposed as a conceptual model for understanding human development by Bronfenbrenner (2009) in the late 1970s and was later formalized as a theory in the late 1980s (Kilanowski, 2017). The SEM provided a sound foundation for me to identify the factors that affect an individual's decision to participate in a clinical research study.

In the SEM, the ecological environment is considered as a set of nested structures, each inside the next, like a set of Russian Dolls (Bronfenbrenner, 1979). The innermost level is an immediate setting containing the developing person, which can be a home; classroom; or for research purposes, a laboratory or testing room. In the next level, the single settings and their relationship are considered. The third level of the ecological environment comprises a consideration of a hypothesis that an individual's development is affected by events in settings where the person is not present. By understanding the reasons that guide an individual's behavior, there is context, combining both naturalistic and experimental means of observation (Bronfenbrenner, 1979). There are four levels for

interpreting the interrelationships: the micro-, meso-, exo-, and macrosystems (Bronfenbrenner, 1979).

According to the SEM, the microsystems surrounding people and those closest to an individual yield the strongest influences and influence the interactions and relationships of the immediate surroundings (Kilanowski, 2017). In the model, it is further posited that health is "affected by the interaction between the characteristics of the individual, the community, and the environment that includes the physical, social, and political components" (Kilanowski, 2017 p.295). In the SEM, behavior is connected via a network of intrapersonal characteristics, interpersonal processes, institutional factors, community features, and public policy (Salihu et al., 2015). The model contains an assumption that the interactions between individuals and their environment are reciprocal (Salihu et al., 2015).

The SEM focuses on important social and ecological influences on health behavior by defining the different levels of influence, including public policy, organizational, community, interpersonal, and intrapersonal (Williams & Swierad, 2019). When considered during the implementation of health promotion campaigns, the levels that focus on health education help to strengthen the influence of that campaign on targeted behaviors (Williams & Swierad, 2019). In this study, I explored the perceptions of clinical research principal investigators and how constructs of the SEM could be applied to address areas of concern with underrepresented populations.

Literature Related to Key Variables and Concepts

Benefits of Diverse Clinical Research Participants

The medications available, whether prescribed or purchased over the counter, go through a rigorous evaluation process via the clinical trials process to determine how safe and effective they are. One of the challenges faced in clinical trials is recruiting and enrolling participants of diverse racial and ethnic backgrounds whose primary language is not English (Gabler et al., 2021). The absence of diversity in the participant pool for these clinical trials can affect how much is known about the safety and effectiveness of medications for different groups of people. This issue of diversity in clinical trials has scientific and global health implications (Rubio & Schliebner, 2020). As of 2020, of the 330 million people in the United States, 13% identified as Black, yet only 5% of the clinical trial population was Black (Gabler et al., 2021; Watson, 2020). The unbalanced representation in clinical trials means that when a medication is approved for all, it may not be as safe and effective for all populations, and this can lead to further divides in health outcomes, health equity, and health disparities (Rubio & Schliebner, 2020).

Times are changing. A one-size-fits-all approach is not applicable in clinical trials. Medications are becoming more modern, precision medication is getting closer to reality, gene therapy use is increasing, and the absence of diversity in clinical trials creates obstacles to creating a comprehensive profile of a medication's safety and efficacy across different population subgroups (Kantor, n.d.). Health disparities and equity are important and commonly used terms in public health. According to the Office of Disease Prevention and Health Promotion (2021), a health disparity is

> a particular type of health difference that is closely linked with economic, social, or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater social or economic obstacles to health based on their racial or ethnic group, religion, socioeconomic status, gender, age, or mental health; cognitive, sensory, or physical disability; sexual orientation, gender identity, geographic location, or other characteristics historically linked or discrimination or exclusion.

Health equity is "the principle underlying a commitment to reduce and ultimately, eliminate disparities in health and its determinants, including social determinants" (Braveman, 2014, p. 2). To pursue health equity means that the goal is to attain the highest possible health outcomes for everyone but with paying attention to the needs of those at an increased risk of adverse health outcomes based on social conditions (Braveman, 2014). One of the keys to advancing health equity is ensuring that people from diverse backgrounds participate in clinical trials (U.S. [FDA], 2021). The benefits that could result from increased diversity in clinical trials are enormous. Ensuring diversity in clinical trials is a matter of equity and has the potential to reduce health disparities.

Barriers to Participating in Clinical Trials

Clinical trials and research studies are needed to develop new treatments to improve health. Randomized clinical trials are often considered the gold standard in clinical research and are the key to advancing medical knowledge and improving patient care and outcomes (Djurisic et al., 2017). In cancer clinical trials, a major limitation for

developing new therapies is the challenges of recruiting patients, not the trials (Cartmell et al., 2020). Less than 5% of cancer patients participate in a cancer clinical trial; disparities are evident by age, race, and gender (Cartmell et al., 2020). Common barriers to cancer trials include fear, concerns about communicating with medical professionals, health insurance concerns, transportation challenges, and perceptions about the medical providers and treatment (Cartmell et al., 2020). Other barriers to participating in clinical trials are financial concerns and the restrictive inclusion criteria (Nipp et al., 2019). The eligibility criteria can result in the exclusion of certain patient populations, which helps to increase the disparities often seen between those who enroll in the clinical trials and those treated in routine medical practice or standard of care (Nipp et al., 2019). These barriers to recruitment and their hindrance to improving health disparities and health equity are recognized. The limitations these barriers put on advancing medicine are known. Efforts to address these barriers are being investigated and explored (Nipp et al., 2019).

Clinical Research Coordinators

Clinical Research Coordinators (CRCs) are on the front lines for clinical research recruitment, retention, data collection, and reporting adverse events (Haley et al., 2017). The principal investigator often has limited time and delegates some responsibilities to the CRC. The influence of the CRC on patient composition and the potential for selection bias has been recognized; however, most research on barriers and potential strategies has focused on the organizational, medical provider, and patient levels (Haley et al., 2017). CRCs are a valuable resource in working towards increasing diversity in clinical trials. The barriers CRCs identified include translation, literacy, family composition, patient

demographics, symptom severity, and the historical context of racial treatment in medical research studies (Haley et al., 2017). The CRCs also suggested ways to improve recruitment and retention in clinical research. These suggestions included improved preparation, tools for patient education and awareness, community education, informing hospital staff about clinical trials, relationship building with patients and hospital staff, and improved CRC hiring using competency assessments and training (Haley et al., 2017).

Principal Investigators and Clinical Research

Principal investigators are an important part of the clinical trials which bring the findings from basic science lab research into therapeutics for humans (Feehan & Garcia-Diaz, 2020). They must produce high-quality, meaningful, scientific research and be responsible for preserving public trust (Feehan & Garcia-Diaz, 2020). A clinical trial principal investigator is expected to act with integrity and provide training and oversight to staff (Feehan & Garcia-Diaz, 2020). Their roles are of such importance that the success or failure of multicenter clinical research studies depends mostly on how involved the principal site investigator is (Mentz & Peterson, 2017). An example of the workload of the principal investigator can include the screening and eligibility process, informing potential participants and their families about the trial, conducting study-specific patient visits, and participating in the monitoring and regulatory visits (Mentz & Peterson, 2017). Principal investigators are often held responsible for a study's recruitment challenges and failure to meet enrollment requirements even though they may not have had a role in developing the trial's protocol (Mentz & Peterson, 2017). Given their important role in

the clinical trial process, including recruitment, it is important to learn principal investigators' perspectives and lived experiences as it relates to diversity in clinical trials.

Summary

In this chapter, I reviewed the literature that highlighted the need for studies on the perceptions and experiences of clinical research principal investigators and diversity in clinical research studies. The review revealed gaps and identified a need for extended research to examine the perceptions and experiences of principal investigators on diversity in clinical research participants. Literature is scarce from the clinical research professional's perspective on the importance of having representation in clinical research participants. This study attempts to fill the gap in principal investigators' knowledge, perceptions, and experiences and how this knowledge can impact policy and programs to increase diversity in clinical trials.

The SEM is the theoretical framework that was used to guide this study. This model served as the data collection and study's theoretical foundation. The premise of the model provided the basis for understanding the perceptions and experiences of principal investigators and how they can be applied towards increasing diversity in clinical trials. Chapter 3 presents the research design and methodology used to guide this study.

Chapter 3: Research Method

I conducted this study to understand principal investigators' experiences with clinical trials and develop potential strategies to enroll diverse participants. In this chapter, I describe the design and methods used in the study. The qualitative approach and phenomenological design that I chose are also explained. The core of this study depended on collecting the experiences and perceptions of the participants, and in this chapter, I discuss the steps taken to ensure that the participants were treated ethically, their identities were protected, and that participants were engaged without bias. This chapter also includes a description of the plan for data collection, data analysis, and maintaining the study's integrity. I end the chapter by explaining how I maintained the ethical standards related to participant privacy, data analysis, and the forming the themes and conclusions of this study.

Research Design Rationale

This study addressed the following research questions:

1. What are the lived experiences of clinical research principal investigators regarding diversity in clinical research?
2. What do clinical research principal investigators identify as concerns for diverse participants in clinical trials?

The factors of interest in this qualitative phenomenological study were how principal investigators' lived experiences influenced their response to the absence of diversity in clinical research. The views of other clinical research professionals had already been explored in previous research. I used a basic qualitative approach to explore

the lived experiences of principal clinical research investigators. Qualitative research involves asking participants about their experiences and allows researchers to gather insights and understand the world as another person experienced it (Austin & Sutton, 2014). Qualitative researchers usually begin their work by recognizing that the researcher's position can shape how the research questions are formulated, methods are selected, data are collected and analyzed, and results are reported (Austin & Sutton, 2014).

Before selecting a basic qualitative inquiry as the approach for this study, I considered other types of research methods. While quantitative methodology could have been used in this study, it was not considered because it was not in alignment with the purpose of this study. Use of a quantitative approach for this study would not have allowed for the collection of principal investigators' lived experiences. However, conducting a quantitative study on this topic after this study's results are published could provide additional knowledge and further address the gap in the literature. I could have conducted a quantitative cross-sectional study using a survey for data collection to learn more about the perceptions of clinical research principal investigators regarding diversity in clinical trials; however, this approach would not have allowed me to gather themes related to the lived experiences of principal investigators.

The phenomenological design is used when attempting to understand problems, ideas, and situations from common understanding and experience rather than differences (Austin & Sutton, 2014). Furthermore, phenomenology helps to understand how human beings explore their world (Austin & Sutton, 2014). This design gives researchers some

powerful tools to understand what would otherwise be subjective experiences (Austin & Sutton, 2014). Phenomenology helps researchers to explore lived experiences, thoughts, and feelings and helps to understand the meaning of how people behave (Austin & Sutton, 2014).

Role of Researcher

The role of the researcher in this study was to serve as the interviewer, collect the data, conduct the data analysis, and report the findings. I recognized my role and importance as a researcher and interviewer by remaining objective and unbiased throughout my interviews, not interjecting my viewpoints, and allowing the participants to speak freely.

My experience with the absence of diversity in clinical trials created a potential bias in how I formed questions and interpreted the participants' responses. I have over 15 years of experience in clinical research. Throughout my career, I have noticed that those participating in the clinical trials tend to be a very homogenous group. Even for conditions, such as systemic lupus erythematosus (SLE), which disproportionately affects women of color, those participating in the clinical trials do not represent those who live daily with the condition. I was a CRC for the Belimumab study when it was approved by the FDA to treat SLE. After Belimumab was approved, a new clinical research study specifically sought participants who self-identified as Black or African American (Ginzler et al., 2020). This is because the enrollment of participants of African ancestry with SLE in the original clinical trial was not reflective of the racial distribution observed in the SLE population (Ginzler et al., 2020). I have seen many people who live with

conditions where there are no cures benefit from participating in clinical trials. Their quality of life improved possibly from receiving the investigational therapy. As a result, I often wished there was more awareness about clinical trials as an option to care. My experience is that many people simply are not aware that participating in a clinical trial could be a viable option to their treatment plan and care. I have noticed that many potential participants are not even provided an opportunity to participate in a trial as an option for their care. Many people are unaware that a clinical trial may offer hope for their condition. With this background and what I have experienced, it has been a passion of mine to increase awareness of clinical trials and see more representation in clinical trials.

Maintaining objectivity in qualitative research can be challenging, and some researchers believe that objectivity is a "myth and that attempts at impartiality will fail because human beings who happen to be researchers cannot isolate their backgrounds and interests from the conduct of a study" (Austin & Sutton, 2014, p. 437). It is necessary to be transparent about possible subjectivity, allowing readers to arrive at their own conclusions about the interpretations presented through the research itself (Austin & Sutton, 2014). The researcher must identify any underlying biases and assumptions (Austin & Sutton, 2014).

Methodology

In this section, I discuss the methodological approach taken to investigate the research questions, including participant selection, instrumentation, data collection, and data analysis. This basic qualitative inquiry involved semistructured interviews with

principal investigators in clinical research. I screened the participants for this study for eligibility before selected them for inclusion in the study. The recruitment flyers were posted on social media, including Facebook, Facebook groups, Twitter, What's App groups, and LinkedIn pages and groups. Participant interviews were guided by an interview protocol that was developed to focus on answering the research questions. The purpose of an interview protocol is to standardize the interview process across participants (Rubin & Rubin, 2012).

Participant Selection Logic

The participant selection logic provides a framework for recruiting participants for this study. In this subsection, I describe the population of clinical research principal investigators, the sampling strategy, and the eligibility criteria for their selection. The determining factors for data saturation are also discussed.

The population for this study included principal investigators with at least 2 years of experience conducting clinical trials in the United States. These principal investigators had experience in academia, industry, or government agencies with medicines and devices. Experience in any of the four phases of clinical trials was considered. I sought eight to 20 principal investigators conducting clinical trials in various settings (e.g., academic medical centers, hospitals, and private practice). In total, 15 participants ended up taking part in the study.

After receiving approval from Walden University's Institutional Review Board (IRB), I used purposeful sampling to identify participants for this study. Participants were recruited via groups on Facebook and LinkedIn. In addition to the social media platforms,

the flyers were shared with national forums and groups on Facebook, LinkedIn, and Twitter. I contacted relevant group leaders or administrators on these social media platforms to request that they post a flyer announcing that this study was seeking participants. Potential participants reached out to me via the contact information provided on the flyer. Participants were encouraged to share the invitation to participate with their colleagues who met the inclusion criteria. Participants provided informed consent and had any questions they had regarding the study answered and addressed before the qualitative interview process commenced. After each interview, I sent the participant a $25 Amazon gift card via email.

Unlike quantitative studies, qualitative research studies do not need large sample sizes that mimic the general population to be valid (Ranney et al., 2015). Large sample sizes are unnecessary and could harm the quality of qualitative data; however, obtaining an adequate and diverse sample is important for data credibility (Ranney et al., 2015). I continued conducting interviews until data saturation was reached. Data saturation is the "point during data collection where additional data do not provide new information to researchers" (Ranney et al., 2015, p. 5). Data saturation depends on the research project and the qualitative discipline, but the concept implies that the research team has been analyzing data in real time to determine when no new data is arising from the interviews or saturation has been achieved (Ranney et al., 2015). I conducted interim data analysis and debriefing after each interview. Saturation was achieved when the interviews revealed no new data, themes, or codes.

Instrumentation

In this study, I employed a basic qualitative inquiry approach. The instrumentation included a demographic questionnaire to collect baseline data and demographics and a semistructured interview guide. The instruments were developed to align with the study's conceptual framework and research questions. I used the instruments to gather principal investigators' lived experiences on the absence of diversity in clinical research. After an extensive review of the literature, I identified a gap reflecting that no prior published study had explored the lived experiences and perceptions of clinical research principal investigators regarding the absence of diversity in clinical research. Thus, the instrumentation for this study was designed to address the gap in the literature.

Questionnaire for Principal Investigators

The purpose of the questionnaire in this study was to gather basic information about the principal investigators to better inform me in preparation for the semistructured interviews. The questionnaire provided baseline information regarding the principal investigators' demographics, length of time as principal investigators in clinical research, and their disease areas of expertise. The questionnaire can be found the Appendix.

Principal Investigator Interview Guide

I developed the interview guide for interviewing participating principal investigators. The research questions and theoretical framework were considered when developing the interview guide. The interview guide can also be found in the Appedix.

Other Data Sources

I took field notes during and after each interview. In qualitative research, field notes can provide critical context to the interpretation of audio-recorded data and can help to remind the researcher of situational considerations that could be important in the data analysis (Sutton & Austin, 2015). My field notes included observations about participant behaviors, sighs, any hesitations, facial expressions, laughter, stumbles, and gestures. I combined the field notes with the data from the interview transcripts and questionnaires to address the research questions and help ensure validity.

Pilot Study

I designed a pilot study to determine if the interview questions would elicit reflections about diversity in clinical trials by the principal investigators. This allowed me to practice and pilot the semistructured interviews before interviewing real participants. I drafted the pilot study interview questions for the principal investigators and recruited two participants to test and pilot the interview guide. The participants were selected based on their experience in clinical trials as a principal investigator. After the interviews, I asked these first two participants about the clarity of the questions and for their recommendations . Based on their feedback, no revisions to the questionnaire were needed. Since no changes to the interview guide were needed, the responses from the first two participants were used in the data analysis. I would not have included their data in the analysis if changes to the questionnaire were needed.

Data Analysis Plan

There are many approaches to qualitative data analysis. It roughly takes an experienced researcher 8 hours to transcribe one 45-minute, audio-recorded interview, and this process can generate 20–30 pages of written dialogue (Sutton & Austin, 2015). I began the data analysis process by reviewing the recorded interviews and the field notes taken during those interviews.

Ethical Procedures

All researchers need to consider ethical procedures when conducting a study. This study was reviewed and approved by Walden University's IRB before data collection commenced. The IRB approval number is # 05-11-22-0231848. Participation in this study was completely voluntary. I made all efforts to protect data integrity and participant confidentiality. All participants were properly informed about the purpose of the study, and informed consent for each participant was obtained prior to the interview and data collection process.

The nature of qualitative research itself can make it difficult and create challenges towards protecting participants' privacy, minimizing harm, and respecting the shared experiences of others. Qualitative researchers often develop strong relationships and rapport with their study participants, especially in studies where the topic is sensitive (Rubin & Rubin, 2012). One of the ethical challenges in qualitative research is that the researcher is the research instrument; therefore, the researcher's subjectivity, identity, and positionality can influence the research process and methods, ultimately impacting the data and findings (Ravitch & Carl, 2016). I needed to consider my role throughout all

phases of the research process in an effort to not introduce bias into the study and its findings.

Data management is key to protecting the privacy of study participants. In publications, participants' identifying factors should not be included, and pseudonyms can be substituted instead (Ravitch & Carl, 2016). If a researcher promised confidentiality, they should do their part to maintain that trust, barring no laws being broken. However, in this era of the internet and social media age, there are concerns with privacy rights, which can make promises of confidentiality difficult to maintain (Ravitch & Carl, 2016). Lastly, the researcher ought to respect the experiences of others even when in disagreement. As the facilitator or moderator of a focus group, it will be their responsibility to ensure that participants in the group are respectful of the perspectives of others. People should be treated fairly, justly, and equally (Ravitch & Carl, 2016). Certainly, these challenges are present in qualitative research, and researchers need to learn and understand the techniques to ensure sound data.

Trustworthiness

Trustworthiness is vital in any research study, and I ensured that trustworthiness was established throughout all aspects of this study. Trustworthiness in qualitative research refers to how researchers can affirm that their findings reflect the participants' experiences (Ravitch & Carl, 2016). To be trustworthy, qualitative research needs to be based on a strong understanding of the local context and the researchers' personalities, and it needs to be developed through multiple sessions of joint discussion (Nyirenda et

al., 2020). Four components encompass trustworthiness in qualitative research: credibility, dependability, confirmability, and transferability (Nyirenda et al., 2020).

Credibility

Credibility refers to the internal validity of the study and is concerned with how much the study's findings align with reality (Nyirenda et al., 2020). There are some qualitative approaches to ensure credibility, and they include "prolonged engagement, triangulation, saturation, rapport building, iterative questioning, member checking, and an inclusive coding approach where all themes are coded iteratively rather than reduced to fit predetermined criteria and reflexivity" (Nyirenda et al., 2020, p. 2). By having participants with varying years of experience and from different specialties in clinical research, I ensured that the study's findings aligned with reality and were credible.

Dependability

A study's dependability refers to its reliability and the degree to which it can be replicated (Nyirenda et al., 2020). Dependability is also concerned with the number of observers, and when there are multiple observers, dependability concerns agreement among them (Nyirenda et al., 2020). The methods, interview guide, and questionnaires have been provided to replicate this study if needed.

Confirmability

Confirmability refers to objectivity or the neutrality the researcher needs towards interpreting the research findings (Nyirenda et al., 2020). The findings should be free from bias, including social-desirability bias (Nyirenda et al., 2020). One of the terms in qualitative research that aligns with confirmability is reflexivity. Reflexivity considers

and recognizes how the researchers' beliefs and experiences can influence the research process, including responses, data collection, interpretation, analysis, and presentation (Nyirenda et al., 2020). I was sure to focus on the participant's contributions to the conversation and not on my own.

Transferability

Transferability refers to the generalizability of the study's findings. Like the external validity in quantitative research, transferability concerns the degree to which the qualitative results apply to other settings, populations, or contexts (Renjith et al., 2021). The key informants in this study provided data that allowed for the transferability of this study's findings. The description I provided above accurately reflects the conduct of this study and is sufficient to enable transferability.

Summary

Chapter 3 included the research design, rationale for this study, the role of the researcher, study instrumentation, data analysis, trustworthiness, data collection, and ethical consideration. A basic qualitative inquiry approach was used to learn more about the lived experiences of principal investigators in clinical research. Study participants were principal investigators in the United States who spoke English and have at least 2 years of experience in clinical trials. They were recruited via various social media platforms and groups through purposeful sampling. The data were gathered from completing the baseline demographic questionnaires, through the semistructured qualitative interviews which were conducted remotely, and via field notes taken during the participant interviews. The interviews were audio recorded and transcribed for

analysis. I adhered fully to confidentiality and ethical practices to protect the rights of the participants throughout the process. Chapter 4 presents the results and findings of the study.

Chapter 4: Results

This study's purpose was the exploration of the perspectives and lived experiences of clinical research principal investigators on improving diversity in clinical research participants. Using an interview guide enabled me to explore study participants' experiences, including how they navigate diversity in clinical research studies. Additionally, I explored the barriers, historical context, how the situation has changed over time, and potential strategies and solutions to improve diversity in clinical research studies.

In this chapter, I provide an overview of this qualitative study's results, including the settings and the participant demographics. The chapter commences with a discussion of the pilot study and participants. I also describe the data collection and analysis processes, including providing evidence of trustworthiness, and conclude with a comprehensive report of the study's findings.

I conducted semistructured interviews with the principal investigators via Zoom. The interviews were audio recorded using Easy Voice Recorder software. Following each interview, each audio recording was transcribed via a transcription service provided by Time Etc. I emailed an attachment of each audio recording to the Time Etc. assistant who transcribed the interviews. The same assistant transcribed all the transcripts. None of the audio recordings contained identifying information, and I titled each recording after the participant's study identification number. I received each transcript approximately 2 days after emailing the audio recordings. After receiving each transcript, I listened to the recording while reading the transcripts to ensure each transcript's accuracy. Data cleanup

was also conducted to remove any identifiers, if any were found. I re-read the transcripts to become familiar with the data and identify similarities in ideas or concepts. The data were then coded, the codes placed into categories, and the themes were identified.

I used NVivo Qualitative Research Software, Version 12 in the analysis process. Each transcript was uploaded to NVivo and saved in a file called "Diversity in Clinical Research Perspectives of Principal Investigators." Next, I coded each transcript into nodes in NVivo. I reviewed each sentence and, sometimes, entire paragraphs to identify and group the emerging nodes. The preliminary coding of the 15 transcripts yielded 86 nodes. My next step was categorizing these nodes into 12 major categories and subcategories by grouping. I completed the sorting based on concepts that emerged that were the same or similar. Some nodes were merged or deleted because they were repetitive. The last phase of the data analysis process involved reviewing the categories in NVivo and manually producing themes based on recurrences in the data from the transcripts of the 15 participants. The result was seven primary themes and several subthemes that revealed the lived experiences of the principal investigators when addressing diversity in clinical research studies.

Research Questions

The following two research questions guided this study:

RQ1: What are the lived experiences of clinical research principal investigators regarding diversity in clinical research?

RQ2: What do clinical research principal investigators identify as concerns for diverse participants in clinical trials?

Pilot Study

I started with a pilot study to determine whether my interview guide and questions needed revisions. A pilot study was necessary as indicated in this study's proposal and in compliance with the IRB approval. The pilot study was needed to determine whether the interview guide was clear and to gauge whether the questions were appropriate to provoke meaningful responses from the principal investigators as they relate to their experiences with diversity in clinical research. To recruit pilot study participants, I posted my IRB-approved flyer on LinkedIn, Twitter, Whats App, and Facebook to relevant clinical research professional groups as well as on my personal pages. The first two respondents to my flyer met the eligibility criteria for the study, and I proceeded to have them complete the informed consent form. I asked if they had any questions, and if any were posed, I answered them. Once informed consent was obtained, I sent them the link via email to fill out the demographic questionnaires and proceeded to schedule the interviews based on their availability.

Of the two participants in the pilot phase of the study, one worked in ophthalmology in a private medical practice and the other worked in an academic medical center in pulmonology. When the interviews concluded, Participants 001 and 002 provided positive feedback on the interview guide (see Appendix). According to their feedback, the questions were clear and well-understood and allowed the participants to share their lived experiences freely. The participants in the pilot study indicated that no edits were needed for the interview questions, so these questions were used in the final

data collection and analysis. Because the participants in the pilot study did not recommend changes to the interview guide, their data were used in the final analysis.

Participant 001 self-identified as an Asian, female optometrist with 2 years of experience as a principal investigator. Most of her research was conducted on a Native American reservation. At the time of the interview, she worked at a private medical practice. Participant 002 self-identified as an Asian woman with 8 years of experience who worked at an academic medical center at the time of the interview. Both participants engaged in the Zoom interviews at their scheduled dates and times. Both indicated that they were in a private and safe location for the interview.

The participants mentioned appreciation of the research on this topic and wished me well in my studies. The principal investigators shared openly, and the depths of their responses helped me to explore the challenges faced by principal investigators and the potential strategies employed relating to diversity in clinical research. I also learned about how they strategized and what they would need to help them in their clinical research practices.

Research Setting

I recruited and interviewed 15 principal investigators who met the eligibility criteria for this study. The participants selected the setting location for their remote interview, and during the screening process, I emphasized that they would need privacy and the ability to speak freely about the topic. During the Zoom interviews, I noticed the participants were in an office-like setting. During the interviews, I did not ask the

participants to disclose their setting and proceeded with the interview questions upon confirming their privacy, comfort, and convenience.

Demographics

A total of 23 potential participants contacted me, but the study ended up involving a total of 15 participants (see Table 1). One potential participant did not respond to emails to determine their eligibility. While conducting the screening for eligibility, I determined that seven prospective participants were ineligible: Three had experience as principal investigators but not in the United States, three were CRCs and not principal investigators, and one had experience in lab-based bench research but not in clinical trials. I realized their ineligibility during the interview of the three who did not have U.S.-based experience. One of the CRCs also made it to the interview stage. In these instances, I apologized for the inconvenience but explained that the study's eligibility criteria were not met, so they could not be included in the analysis portion of the study.

Table 1

Demographic Information for Participants

Participant number	Gender	Race	Ethnicity	Experience (years)	Specialty	Type of practice
001	Female	Asian	Non-Hispanic	2	Optometry	Private medical practice
002	Female	Asian	Non-Hispanic	8	Pulmonology	Academic medical center
003	Female	Other	Hispanic	10	Rheumatology	Academic medical center
004	Female	White	Non-Hispanic	2	Endocrinology	Academic medical center
005	Female	Other	Unknown	11	Family medicine	Clinical research center
006	Male	White	Non-Hispanic	25	Internal medicine	Clinical research center
007	Female	Asian	Non-Hispanic	2	Internal medicine	Clinical research center
008	Female	Asian	Non-Hispanic	15	Emergency medicine	Industry
009	Female	White	Non-Hispanic	36	Internal medicine	Clinical research center
010	Female	Black or African American	Non-Hispanic	3	Rheumatology	Academic medical center
011	Female	Other	Hispanic	4	Rheumatology	Academic medical center
012	Male	Asian	Non-Hispanic	2	Neurology	Academic medical center
013	Female	Other	Non-Hispanic	5	Rheumatology	Academic medical center
014	Female	Black or African American	Non-Hispanic	12	Rheumatology	Academic medical center
015	Female	Asian	Non-Hispanic	2	Rheumatology	Academic medical center

Data Collection

I achieved saturation at 12 participants; however, I oversampled to ensure that I could explore the lived experiences of the principal investigators. One day prior to the interviews, I contacted each participant via email to remind and reconfirm the scheduled interview and asked if they had any questions about the study. At the beginning of each interview, I briefly introduced myself, described the purpose of the study, and reminded that participants that the interview was being audio recorded. They were also informed that they could stop the interview at any moment and withdraw from the study at any time. I arrived to the Zoom meeting 5 minutes prior to the start of each interview. If a participant was late, I waited 10 minutes before contacting them to reschedule. Principal investigators can be busy, and there were times interviews had to be rescheduled multiple times. The interviews occurred between June 2022 and October 2022.

All interviews were conducted in English. When needed, I asked participants for clarification and used prompts and probes to allow the participants to provide more details to their responses. This process helped them to expand on and share their lived experiences. All 15 participants completed the Zoom interviews without any problems. I took field notes during each interview to record my observations. At the conclusion of each interview, I emailed the participant a $25 Amazon gift card. One participant declined the $25 Amazon gift card.

Data Analysis

I reviewed every transcript following each interview to ensure data saturation. I followed the second cycle coding method, which indicates that recoding is needed from

the original codes and some ideas could be merged (see Saldana, 2016). My initial review of the data yielded 86 codes. From there, I continued to review the data and sorted codes into 12 major categories by combining codes that identified similar concepts. For example, I placed time constraints, stringent eligibility criteria, and language barriers under the category of principal investigators' barriers/challenges/obstacles to clinical research recruitment. I merged categories that were similar and deleted the ones that were duplicates. This was an iterative process in which I reviewed the interview transcripts and my field notes to ensure that I was thorough in the quest for emerging themes.

Seven primary themes were identified that addressed the research questions. I considered the relevance of the themes to the research questions and specifically to the field of public health and how they could promote social change. There was a lot of data, so I used data reduction. In qualitative research, "researchers reduce data by eliminating repetitive statements and data irrelevant to the phenomenon being examined" (Roulston, 2014, p. 304). While conducting data analysis, I would routinely give myself breaks and then return to the process later. I found this practice helped to prevent burnout and allowed me to look at the data when refreshed and refocused to ensure the representations of the principal investigators were accurate and factors were not being missed or overlooked.

Evidence of Trustworthiness

Credibility

Credibility refers to the ability of the researcher to consider all the complexities that can emerge in the study to address patterns that are not easily explained (Ravitch &

Carl, 2016). Throughout the research process, I ensured credibility through various means. First, I triangulated the data from the demographic questionnaires, interview transcripts, and field notes and observations for each participant. I addressed any discrepancy by relistening to the recording to ensure the transcript was correct. At the conclusion of each interview, each participant also had the opportunity to add additional comments that were not addressed during the interview. I wanted to confirm that they shared a comprehensive view of their thoughts and lived experiences which helped to build credibility. My analysis also included direct quotations from the interview transcripts. There is no paraphrasing or editing from me as the researcher. The words and experiences in the findings are included as described by the participants.

Transferability

Transferability is also known as external validity. Transferability represents how a qualitative research study is applicable, or transferable, in a broader context (Ravitch & Carl, 2016). The participants in the current study were from different clinical research settings. Having participants from different research settings helped to inform the external validity of the study. After all, in the real world, principal investigators work in many different research settings.

Dependability

Dependability focuses on the stability of the data (Ravitch & Carl, 2016). I included a full description of the research procedures from the start to conclusion of this study, which makes replication of the study possible. I also included the participant recruitment flyer, interview guide, and demographic questionnaire to ensure that another

researcher can replicate the participant recruitment and data collection processes. The data analysis process of assigning nodes and using themes were explained so that other researchers can confirm them or use them in a future study. If another researcher wanted to replicate this study, all the study procedures have been provided to ensure dependability.

Confirmability

Confirmability often compares to the quantitative concept of objectivity (Ravitch & Carl, 2016). To address the issue of confirmability, I ensured that study findings were the result of what was shared by the participants and the findings were not influenced by my own ideas. I asked participants for clarity during the interview if I was uncertain or repeated the question if needed. Confirmability was also ensured by rephrasing or summarizing the participants' responses without interjecting my own experiences. I took field notes and observation notes during and immediately following each interview. I also listened to the recordings and compared my notes to the transcripts to further solidify the data. One of the goals in confirmability is for the researcher to acknowledge and explore how biases and prejudices can influence interpretations of the data and to resolve these as best as possible (Ravitch & Carl, 2016). The topic of this study is one that I am passionate about, and I put my biases aside during the interviews and data analysis process to ensure that there were no preconceived assumptions on my part influencing the analyses.

Findings

From June 2022 until October 2022, I conducted 15 semistructured interviews using the interview guide (see Appendix C). I took notes of my observations during each interview and wrote a brief summery at the conclusion. These summaries and notes were helpful once I received the transcripts because they allowed me to reflect on the content and substance of each interview and anticipate prospective codes and themes. Once the interview was transcribed, the NVivo import feature was used to import the interview transcript into the software for data analysis. I assigned nodes for each interview transcript and moved excerpts from the transcripts into NVivo nodes. The nodes were further reviewed and allowed for codes to be assigned, which were then grouped into categories and, ultimately, assigned themes. I repeated this process for each interview. Codes were examined for repetition and merged as needed. When I realized there were no new codes emerging, I determined data saturation had been achieved. In the following subsections, I identify the themes and subthemes that emerged during the data analysis process.

I used the SEM as the framework for understanding the experiences of clinical research principal investigators regarding underrepresentation in clinical trials. The SEM is a powerful model because it is multifaceted and includes the intrapersonal, interpersonal, organizational, environmental, and public policy factors (Scarneo et al., 2019). The demographic questionnaire and interview guide (see Appendix) were based on the concepts of the SEM and were used to guide the study analysis. Tables 2 and 3

includes the themes and subthemes identified from the data and their aligned research questions.

Research Question 1

Five themes emerged in the data to address RQ1. Table 2 includes information about the number of participants who contributed to each of the five themes and the number of mentions for each theme.

Table 2

Themes for RQ1

Theme	Number of participants	Percent (%)
Theme 1: Passionate about working in clinical trials	9	60
Theme 2: Increased awareness over time	10	67
Theme 3: Frustration with stringent eligibility criteria	9	60
Subtheme: Perceived belief that sponsors can do more		
Subtheme: Link diversity goals to funding		
Subtheme: Partner with patients		
Theme 4: Perception that increased diversity among staff is needed	7	47

Theme 1: Passionate About Working in Clinical Trials

The participants were prompted to share what attracted them to serve as a principal investigator on clinical research studies. Serving as a principal investigator can be a challenging role. The principal investigators shared that they enjoyed the innovative components and the medical aspects of being involved in clinical research studies. They enjoyed being a part of the process to help their patients and to being new therapies to the

market. Participants were asked about what attracted them to the field. Study Participant 002 stated “there's something in the intervention which benefits the patient, and which benefits the society.” Study Participant 001 stated “it was really exciting to kind of be in the know of what was going on” and “And to also be involved with trials that were had an unmet need in eye care.” Study Participant 012 indicated he “wanted to be able to answer clinical questions, like, for example, if the drug is of a particular interest in this population, or if one therapy is superior to the other in this patient population, and so and so.” Overall, principal investigators were drawn to this field to become the best physicians and researchers they can be so that they can better serve their patients.

Theme 2: Increased Awareness Over Time

The principal investigators who participated in this study have an average of 9 years of experience and over the course of their career they have seen some changes as it relates to diversity in clinical research. There is more awareness about the need to have representation in the clinical trials. There are mandates and recommendations from government entities urging pharmaceutical companies to address this. Participant 010 indicated that the COVID-19 pandemic has helped to shape some of the conversations around this. She stated, “since the pandemic has started and since, you know, people's eyes have been open to social justice issues in this country.” Participant 010 also stated:

> but also the FDA who are saying, hey, to form a, you need to make sure that diversity is a priority, you need to make sure that the patient voice is a priority. And so, the FDA is finally standing up to pharma, and all the clinical trials and making it a priority in order to get drugs approved. So that's the biggest thing.

> There has been policies, procedures and regulations put in place to make sure that populations who are participating in clinical trials are representative of the actual population living with the disease.

Study Participant 003 indicated that now there are plans in the research development to reach underrepresented groups. During the interview Participant 003 stated:

> I think that now people talk about, you know, they discuss their analysis plan, even for secondary data analysis, or for checking, or registry analysis and analysis about recruitment of patients have been recruited or being that is already existing, and you switch perspective and then they say, oh, what are we gonna do about race and ethnicity? So now they're trying to make an effort to talk about that.

Participant 011 indicated she has seen the topic mentioned more at conferences and trainings:

> I would say that it, I think that there is more awareness around the need for representation, I think it's really helped in terms of just our shift as a society around a lot of the things that are happening related to diversity, equity, inclusion, and I think that's bought an eye, especially in health care around the importance of this. I do think that there still, I have seen an increase in maybe the topics at some of our national conferences, as well as patient-specific trainings, but I would say that there's still a lot of work to be done in this area.

Some participants indicated there has been a shift in the professional field of clinical research where increases in diversity among principal investigators are being noticed. Participant 001 stated:

> when we went to some of the, like, principal investigator meetings and things like that, I was kind of looking around the room and you definitely see that there was like an old guard and kind of like a new guard. Right? A lot of your older PI's were definitely White male and start to see like in the younger set of doctors or just a few more women, maybe a couple more like Asian people, that kind of thing. So, I think it's like a slow kind of change that's happening. And honestly, it'll probably take a lot longer.

Change is happening in the industry, but it could be a while before this goal is achieved.

Theme 3: Frustration with Stringent Eligibility Criteria

The participants seemed frustrated that the study criteria often didn't match that of the average patient in their practice with the condition. The eligibility criteria for some clinical trials can be so strict that it is difficult to get the average patient with the condition into the study. Study Participant 003 stated "and although I see primarily Hispanics and African Americans, sometimes these patients do not meet criteria for some of my studies.". Study Participant 012 that he considered which of his patients would be a good candidate and then referred the patient to the clinical research coordinator for follow up. Participant 012 stated:

> Or in case of we see any patients who are on the floors, or have a specific disease pathology, then if we think that the patient is of a suitable candidate for that trial,

> then we do recommend that patient to the research coordinator who will go on asking more further questions. Everything goes based on the inclusion criteria and the exclusion criteria, which is a predefined and a preset rules and regulations for the study and once I know that the patient is meeting the criteria then I recommend this to the team as well as the other attendings who are also a principal investigators to the trial and then the research coordinator goes forward and us and sees in case the patient is fully compliant and that's how we go.

Study Participant 005 shared concerns that the laboratory diagnostic criteria was developed using Whites as the standard and has resulted in the ineligibility of many of her African American patients in clinical trials that may help them. Participant 005 stated:

> One of the biggest issues that I see is I'm very familiar with my study population. And I know what trends I see in labs. And we all know that there's research out there that shows, especially for African American communities that they're, you know, white blood cells, for example, tend to run lower than Caucasians. Our labs are standardized for Caucasians, our eligibility criteria is standardized for Caucasians, unless it's a specific ethnic trial. And just by that alone, they'll be excluded for no other reason other than they don't fit the parameters, but it's normal for that community.

Oftentimes, certain medical conditions and use of certain medications will exclude potential participants. These criteria make clinical trials inaccessible to real world patients. Participant 010 stated:

> Based on that inclusion and exclusion criteria, we either included people in this study or excluded them. And so, for our particular study, since it was focused on stroke prevention actually, and also, I'm looking at the relationship between cognitive impairment and arterial stiffness, we had to make sure that people didn't have conditions that would preclude them from developing cognitive impairment or cognitive dysfunction, or even dementia. So, anyone who had, you know, a pre-existing condition related to cognition, we had to exclude from the study. And then we also excluded people who, you know, had a higher than, I think, a higher than 35, or something like that, BMI, we also didn't include people who had strokes, et cetera, et cetera. So, we had kind of a laundry list.

When it comes to eligibility the principal investigators also consider if their patients will be reliable. A study participant can withdraw from a clinical trial at any time, and principal investigators are concerned about study dropouts. Participant 004 shared that good reliable clinical research volunteers are needed. Participant 004 stated "initially, we were looking for participants who are what we call a good study participant basically just, they're following the rules. Participant 009 shared

> Because the worst patient for a pharmaceutical company is the one that drops out at visit 15 and visit 16 is the last data point. They're worthless, you can't count that in A1C, because you have to complete the study to finish the last data point. So that is the worst patient it is to have high dropout rates.

Subtheme: Perceived Belief That Sponsors Can Do More

Many of the principal investigators mentioned that the pharmaceutical companies need to do more to address representation. If they choose clinical trial sites in neighborhoods that are not diverse, it will be difficult to ensure representation. The participants expressed that the pharmaceutical companies need to consider where and how they are selecting the research sites. Participant 009 shared "better site selection by the sponsor is the only answer." Participant 001 stated "honestly, sometimes I think that part of it is going to be responsibility of the pharmaceutical companies and like the CROs, because when they're picking the sites, you know, some sites are going to be predominantly like White neighborhoods." The principal investigators want the pharmaceutical industry to be mindful of how they select the research sites where the clinical trials are conducted.

Theme 4: Perception That Increased Diversity Among Staff is Needed

The principal investigators indicated that the field of clinical research itself isn't diverse or representative of the population served. Participant 001 suggested a potential solution would be to have more diversity amongst principal investigators "And also, just having more doctors of diversity, like as your principal investigator would be, I think a huge thing. Because as we know, like when you see someone who looks like you, it does make an impact." Participant 003 stated "Change the makeup of the workforce. I think we need to diversify the workforce that ask questions that are relevant to the population that are underrepresented minorities. Because, you know, sometimes the health care system does not see patients that are underrepresented the same way. And that is because

the workforce is not, you know, inclusive of members of the society that are underrepresented minority." Participant 014 stated:

> I would like there to be more support of PI of color and that to be strategic goals of the institution. Moreover, for that to be very intentional, in terms of how we recruit people, they should represent the population of, especially the illnesses that we see that there are disparities in various communities, and we should be able to recruit, retain, coach, mentor, sponsor PIs of color in those areas to help at the very beginning to think about study design, and how we engage people, and to have those experiences and diverse opinions at the table from the start. Moreover, when people show up to these studies, they should be able to; they should be able to see people who look like them. You know, and I think that will help as a long-term strategy.

Research Question 2

I asked Questions 6, 9, and 10 of the interview guide (see Appendix) to answer RQ2. Two themes emerged to address RQ2. Table 3 includes information about the number of participants who contributed to the two themes and the number of mentions for each theme.

Table 3

Themes for RQ2

Theme	Number of participants	Percent (%)
Theme 5: Knowledge and awareness that there are multifaceted barriers to having diverse participants in clinical research	14	93
Subtheme: Meet the needs of underrepresented populations	14	93
Subtheme: The role that race and mistrust plays		
Theme 6: Concerns that no formal training exists		
Theme 7: Optimism for the future with strategies and solutions	15	100

Theme 5: Knowledge and awareness that there are multi-faceted barriers to having diverse participants in clinical research

In their answers to the prompt "In your experience, tell me about challenges towards recruiting diverse populations into clinical research studies," the participants reported there are countless barriers faced and experienced by principal investigators as it relates to increasing diversity in clinical research studies. These barriers include difficulty in reaching these patients due to difficulty in accessing diverse patient populations. There are concerns with care responsibilities for dependents of the study participants, barriers with the time commitment, concerns with improper consent, language barriers, cultural differences, an absence of diversity among the research staff, mistrust of the medical research process, and a fear of being used as a "guinea pig." Participant 003 indicated that her practice does not routinely see members of underrepresented groups. Participant 003 stated "we don't have enough of those patients in some of our practices." Participant

001 stated “So, there's just that perception that they don't want to be a guinea pig.” Participant 004 expressed cultural differences faced when the research staff isn’t culturally congruent with the patients being recruited into the clinical trials. This participant stated:

> we need really diverse researchers, it's not just about the language, it's just a culture also. And patients do not feel like they don't have really the connection that they want someone who knows what they've been through when they're there.

Childcare or dependent care is another barrier towards the principal investigators struggles with increasing diversity in clinical research study. Study Participant 003 stated

> some of these studies require people to come in person and I noticed that underrepresented minorities have more challenges making it to in person studies, in person-based studies. Even if we're compensating them, if they are either taking care of a grandchild or a sick son or sick daughter that’s impaired, you know, limit them to go to the doctor but to their doctors, and to a study with children that they're not, you know, getting treated immediately is a deal breaker.

Participant 013 commented on the language barriers faced. She stated

> I think, honestly, because of the language barrier. A lot of them don't speak English. And a majority of the trial requires you to have a speaking English patient. So, I, sometimes it's kind of like, oh, you have this great patient, but Spanish speaking only, you know, and the trial, it wants English speaking patients.

Participant 007 expressed similar sentiments. Participant 007 stated “I think the biggest one problem we have is a language barrier. So, that is the one thing, or a lot of people do not speak English. So, that is one of our drawbacks.”

Subtheme: Challenges with Recruiting

Responding to questions about clinical study recruitment and screening, participants in this study indicated that they look for patients who are already knowledgeable about research studies and who already understand the process and can give informed consent. Participant 005 stated, “Somebody who's really able to give informed consent.” This was of huge importance:

> That, to me is first and foremost in all of these things. I think somebody who's fully understanding of what it is that they are committed to, what the clinical trial process is like, what are the expectations of becoming a clinical trial participant. The participant continued “but you really need to understand the process and the commitment. And that's what I want, first and foremost out of anybody.”

Participant 004 indicated she looks for someone is “tech savvy” and can navigate the health care system. Participant 004 stated “They know how to navigate the system with a device, what we call them is like tech savvy people, basically, they know how to use the system, or basically, they're actually open to try something that might not work.” Study Participants 001 and 014 indicated they consider the burden to the participant when informing participants about a study.

Participant 001 stated “So often time, the discussion of how much time was going to be involved in the study was really kind of like the key thing.” Participant 014 stated,

“And we also look for, you know, as we're thinking about looking for things, when we engage a person, we want to ensure that they have transportation, childcare, it doesn't impact their job and their earnings.” Considering the needs of the population this Participant 014 works with it is important to be “very mindful of, you know, kind of that fatigue on them or taxing them already, when they’re already taxed in their own lives and stretch on different ends.” This participant employs various methods to keep them engaged. “So, trying to ensure that we have funding to help with transportation, or just to ensure that we offer compensation, or an incentive to honor the work that they’re going to partner with us to do.”

> So those are some of the things that I look out for transportation, childcare issues, that there are no like social determinants of health immediate issues, like, you know, housing or food insecurity and things like that things that we can help to intervene in to make their lives better before we just ask them for, you know, give us your blood, or give us your cell sample, really caring about that person. And I think that really helps people to optimize their experience in the trial.

Subtheme: The Role That Race and Mistrust Plays

Race and mistrust emerged as a subtheme to the knowledge of the barriers to having diverse participants in clinical research studies. Many participants alluded to what happened with the Tuskegee Syphilis studies as well as to present-day atrocities such as injustices in the judicial system, educational system, and health care. These include It is difficult to get these groups into clinical research studies when they do not trust the system. Participant 011 stated

> I would say, in my experience, it's, again, it's not only just the around clinical trials, but it's around just mistrust around physicians, or just medical setting, or being mistreated when there's often, you know, if you're looking at, we recently did a hospital wide assessment that looked at the everyday discrimination scale, and about 50% of patients said that they felt discriminated against by their physician.

Participant 004 indicated that she took a screening test to learn about her biases. Participant 004 stated "Um, I have been actually put on trial to see how I'm biased. And there are lots of studies about how bias the providers are. We are definitely biased." This highlights that if the providers are unknowingly biased, they could be adding to the problem and increasing barriers.

To address the concerns with mistrust, one of the solutions posed by the principal investigators is to increase transparency. Participant 007 stated

> You know, I just, I think, trust and honesty, and transparency are the most important things of how you can like bridge that gap of mistrust to trust, like you just have to be transparent, in which we are and any point.

Study Participant 005 expressed her concern that if a potential study participant has a bad experience once, they are reminded of that negative experience each time they visit a health care facility. Participant 005 stated "You know, once you have one bad experience at a physician's office, or in any health care setting, it's going to shape and mold and change how you view all other health care settings after that."

Principal investigators reported that their patients are frustrated with the medical system, and this is linked with the role that race and mistrust plays. Participant 003 shared

> I say like, yeah, this has to do with racism, or with racial discrimination. Part of that was also the care they were already receiving at the time that's what got them very frustrated. And now you're telling me to be on a clinical trial, screw you, you know, because they're already struggling with a lot of other things navigating the health care system, like I said earlier, and now they're going back to just another study. No, no I'm not gonna do that.

Participant 014 emphasized that while many would like to think this is something that has historical context, it still happens currently. She stated:

> And a lot of people think, oh, back in the day, no, this is happening to me currently, I'm being arrested and pulled over by the police unjustly. I'm seeing my brother getting gunned down. Like, how do I trust the system, right? And so, things are happening today in healthcare where I was just denied service, or this doctor passed me over sitting in the waiting room 10 times before I was called, things are happening today.

Participant 008 expressed hope that we can move past the historical horrors and to a place where the patients regardless of their ethnic origins can benefit. Participant 008 stated:

> But I'll still say anyway, there's a lot of bad memories and hurt, right? In groups, and rightly so. They're real. And really, in a sense, you know, unforgivable. But

> with that said, I mean, I do genuinely believe that if somehow, we could move past that the folks benefiting are our patients, right, all of our patients.

Participant 015 shared that her institution implemented a training in implicit bias for the research staff. She stated:

> And we talk about things like implicit bias and making sure that you do your due diligence, knowing fully well what the eligibility requirements are in a study so that you don't accidentally miss someone or don't reach out to someone due to your own biases. Right. So, we do have those trainings that are now officially part of the rotation with our research department, and our research administration and their training and education series that they offer every year. So, I think in that way, you know, been admitted, happy to see that that's been part and more formalized and offered multiple times a year, and I'm happy to be able to provide that with my colleague.

Study Participant 010 shared this is a two-way street as it relates to mistrust. According to study Participant 010:

> So, I think there's mistrust on both sides, right? So, you know, we can call it racial discrimination, but a lot of times, physicians don't trust patients. And in turn, patients don't trust the physician. And, you know, oftentimes we talk about, oh, you know, there's mistrust with the patient, but I always think, too, that there's mistrust on the physician side of the patient. The physician doesn't trust that the patient will do what they're supposed to do to be an asset in a clinical trial, right?

The principal investigators who participated in this study shared that many of their patients remember the historical injustices. Participant 011 stated:

> I mean, if you think a lot of my patients who are African American, often refer to Tuskegee, you know, I think there's just so many things that have gone on, and I think even and I think that lack of communication from the physician or even from the medical team, that doesn't express that, you know, we're practicing in a different way, or we're practicing in a safe way, and that your care is our kind of primary and most concern.

Furthermore, participant 015 stated;

> And I, you know, I think what it really comes down to is, we, there has been historical injustices that communities of color have experienced in history, which is not a surprise, which does not no surprise that there's no surprise that it does impact patients and their willingness to participate in studies. And so, that can really pose a barrier.

Theme 6: Concerns That No Formal Training Exists

Study participants expressed the urgency of improving diversity in clinical research studies. The push came from their employers, pharmaceutical companies, and from government entities such as the FDA and NIH. However, they expressed frustration at being unable to find and attend a formal training on this topic. The participants expressed that they received numerous trainings to become a principal investigator but nothing on recruiting underrepresented populations. To become principal investigators,

participants expressed that they received trainings and certifications and in some instances research mentorship.

While all the participants expressed that they enroll underrepresented populations into their research studies, none have had any formal trainings on how to successfully enroll these populations into clinical research studies. For example, Participant 001 stated "I will have to be honest with you, I got zero training in that." Participant 007 stated "Ah, for the 2 years that I've been there, I have not had any training of attracting for ethnic populations that we've had any so that's, that's something that would be probably useful." Participant 014 indicated that her institution, an academic medical center recognized the need, and they developed a curriculum to train clinical research coordinators and principal investigators on the importance of implicit bias and diversity in clinical research studies. Participant 015 stated:

> Well, I didn't have any formal training in that I actually created training because I was concerned that there was a deficit. You know, I did not come across any training in my formal academic life. Nor at my institution, and at my institution, I helped to fill that gap in helping people to consider cultural beliefs, tone, you know, religious and traditional beliefs of participants, how to engage people, how to back off when something is triggering, or there might be some potential trauma related to an ask to participate in a study how to address those things. You know, and so, we didn't have any of those pieces in training, but there was no manual for that, right? And so, we just kind of had to figure it out. And so, I wanted to ensure that folks who were coming after me didn't have to figure it out. And one of the

> biggest thing I've implemented is looking at interest advice and patient recruitment in our studies, and really talking to the recruiters about who they are, what they bring to the table, what assumptions they bring, like, oh, people of color are hard to recruit like people. Like that's something that they taught you like Black people don't participate in studies. That's something that was widely taught in school, right? And so, they're never going to come up to a person of color and say, hey, you're a great candidate, because they already have those pre-assumptions, those assumptions in the back of their head. But we didn't have any formal training, you know, for how to do that.

Recognizing it is not a one-size fits all approach, the participants expressed a desire for a formalized training on how to attract and retain underrepresented populations.

Theme 7: Optimism for the Future With Strategies and Solutions

The principal investigators in this study were optimistic and hopeful that we are heading in the right direction. They expanded on strategies that could help to address increasing diversity in clinical research studies. Study Participant 013 indicated this can be addressed by addressing language barriers and improving the infrastructure. Participant 013 stated “You know, you have to have language that is available to them, and you need to have the infrastructure that they need to be enrolled in trials.” Participant 015 echoed these sentiments. She stated “Well, I think for sure, going beyond English and Spanish for us. I think we need materials fully translated in multiple languages.” According to Participant 010, we need to consider the incentives offered. She stated:

> Another piece is making sure that if you are expecting someone to come to you that you are compensating them appropriately. Like I said, I know that resources are not infinite. They can be very finite, but we have to think about what it costs a person to take a day off work to come participate in that trial. And, you know, ask ourselves the question, is it even worth it to them to come and participate? Because they need that paycheck, right?

Participant 001 stated:

> Another piece is making sure that if you are expecting someone to come to you that you are compensating them appropriately. Like I said, I know that resources are not infinite. They can be very finite, but we have to think about what it costs a person to take a day off work to come participate in that trial. And, you know, ask ourselves the question, is it even worth it to them to come and participate? Because they need that paycheck, right?"

This was echoed by Participant 009 who stated, "Better site selection by the sponsor is the only answer." Participant 004 suggested expanding satellite sites and remote visits "I mean, the fact that, you know, we can do study visits, in satellite clinics, for example, that's something we need to think about, not everything has to be in one place."

Another strategy was education and raising awareness of clinical trials. Study Participant 010 stated:

> And so I think those pieces around education and having people who are part of your social stratosphere and having that social capital to enhance your ability to understand what's actually going on with a drug or trial or you know, how that

> might alter your body's blood chemistry. You know that piece is also important because you have to have people around you who you actually trust, who you know have your best interests at heart in order to help change your mind or at least educate you about enrolling in a trial or, you know, taking a new medication, or whatever it may be.

Participant 005 wished the average person was more aware of the process of how clinical trials work and how a new medication is brought to fruition. Participant 005 stated:

> I wish there was a way where somehow there was a level of introduction or education that people universally got about how medications are approved in the United States, how this process works. You know, we all talk about health care literacy and how to utilize the health care system and we invest a lot of time and effort in getting people to know how to navigate the health care system in the United States. But we never really talk about how your medications come to be. And the importance of participating in these types of trials on sort of, you know, a social level, like for, you know, all the COVID trials that we've just had, that this is also something that is really important, kind of just on a social level for everybody involved as for humanity.

Participant 014 stated:

> there should be orientation in learning and training, specifically on how we engage diverse populations in research with recognition of our own implicit bias and how it seeps in and a recognition of our history and what that means for people still.

The principal investigators in the study reported a need to see tailored recruitment strategies and advertising. It should not be a one size fits all approach because what works for one population may not work for another, and we need to meet communities where they are. Participant 001 stated "Certain pharmaceutical companies, if they were going to do any advertising for us, we would maybe kind of like request that they gear it towards like certain audiences." Participant 010 stated:

> I do understand that more resources have to be put towards recruitment efforts in populations that are more difficult to reach, simply because there are many, many, many more barriers that have to be overcome in order to pull those people into your study, and really even get in their stratosphere to gain their trust.

With that optimism came the suggestion that an increase in remote or satellite clinical research sites could help to increase diversity in clinical trials. Participant 010 stated:

> and so, I think step number one is really start thinking about equity in terms of clinical trial participation and what that really means from a principal investigator perspective. And so, taking the trial to the person would be one way to overcome some barriers when it comes to transportation, when it comes to issues around childcare and elder care.

By having home visits, it helps to alleviate barriers such as access to transportation to a research site or not having someone to take care of a dependent. Participant 004 suggested that having satellite research clinics could offer a viable

solution and stated, “we can do study visits, in satellite clinics, for example, that's something we need to think about, not everything has to be in one place.”

Subtheme: Meet the Needs of Underrepresented Populations

The principal investigators in the study asserted that based on their experiences there are certain research studies that could be appealing to members of underrepresented groups. These could be studies with great incentives, ones that meet the needs of the population or non-invasive or minimally invasive studies. Participant 005 stated:

> I find that our Hispanic population tend to do very well and benefit a lot from our metabolic disease programs. So, for us, that's, you know, our diabetes, obesity, Nash, those types of things, they, it's very endemic in their ethnicity as it is. And so usually, once we have one study participant, quite shortly, you'll find their entire family coming in, who will qualify, it only really just takes one.

To add to this, Participant 006 stated:

> Yeah, I think diseases that are more common in there, you know, that they're more common would have diabetes, obesity, things of that nature I think would be, not only because they might be the ones having the index disease, if it's a phase two or three study, but also if their family members have it, I think that kind of motivates people to try to bring about new therapies if they feel like, you know, they're familiar with it, or they have loved ones that have, you know, that have been compromised or died because of it so, so that I think those type of disease processes would probably draw more interest.

When the studies are minimally invasive, some principal investigators reported receiving more traction from underrepresented groups. Study Participant 001 stated "when we were putting eyedrops in, it was just like, glasses. So, nothing was actually entering their body, they're a little bit more open to that."

Subtheme: Link Diversity Goals to Funding

A few participants suggested that the research funding should be tied to meeting diversity goals in the studies. One participant indicated that the drug shouldn't be brought to market unless representation is achieved. Participant 014 stated:

> And so I think we're holding people more responsible for saying that, you know, we can't move forward to getting a drug to market or we're going to need you to go back and have a certain representation in your studies and interventions. And so, I think the situation is changing on a national level, we're funding more research that, you know, have requirements at the NIH that requires you to have a diverse population to get grant monies. And so, I think that having those requirements linked to dollars, linked to Rands link to funding links linked to, you know, how we approve or even getting in a peer-reviewed journal. You know, I think those hardcore requirements is going to lead us to greater and lasting changes.

Participant 008 shared similar sentiments:

> And if they can't get approvals until certain metrics are met, you bet, you know, then the bean counters will listen. And there's no amount of rhetoric, you know,

> pleading to the goodwill of people. So, I would say that that is really important, and to recognize that, unfortunately, how the world works.

Subtheme: Partner with Patients

Some participants recognized that the relationship with a patient and a medical professional is a two-way street. They suggest there needs to be a partnership and suggested that going this route will help increase comfort with participating in clinical research studies. This helps to build relationships and trust. Participant 015 stated, “It's a good question. I think what's been, what is helpful is really engaging with the community and engaging with diverse patient populations and going out into the community and really meeting them where they are.” This participant emphasized meeting the participants where they are and forming a liaison with the community to develop rapport and trust. This participant further shared another strategy was to address the stigma. She shared that they have partnered with patients by creating patient programs that cover research as a topic. She stated:

> Another strategy that we have used in the past is putting on patient programs that center around research, which is really more around distilling the mysteries of participating in research and kind of addressing the stigma that is often associated for communities of color with participating in research due to history, the history books that we know about things like Tuskegee, etc., and giving those spaces for patients to ask questions in a, what we hope is a safer environment for them. And share with them, okay, like, you know, our goal is to partner with you. And our goal is to, not to test on you, right, but to really develop a partnership with you,

> and speak to their concerns that they have around participating, and also really thinking about what we can do to address other barriers that might, that might, they might face in participating in this study, whether it's transportation issues, right, which wasn't the case in this particular study that I'm on.

Participant 014 shared that integrating patients into the study from conception would be a helpful approach. She shared that we need to

> talk about the patient perspective and what patients want and need and how we integrate patients in the beginning of creating and thinking and dreaming up our studies and how we engage them. So, I think all of those ways are how we get to have our patients be more engaged, because they understand more, but we have to include them from the very beginning.

Summary

Through this qualitative phenomenological research study, I sought to explore the perceptions and lived experiences of principal investigators as it relates to diversity in clinical research. The participants provided insights about their struggles to attract and retain members of underrepresented populations into their clinical research studies. They shared their challenges with language barriers, mistrust, historical injustices, unawareness, training, and myths associated with the clinical research process. When asked about training on this topic, participants responded that (a) they were unaware of any formal training and had not received any, (b) they would love to see efforts to implement training on this topic, and (c) exploring this topic made some participants aware of their own biases.

The study participants further shared their thoughts on potential solutions and strategies to mitigate the lack of diversity in clinical research studies. There are things that can be done to address this. Health care professionals need to meet patients where they are, transparency is needed, cultural competency is needed, diversity among clinical research professionals is needed, and solutions need to presented that meet the needs of the patients served. The principal investigators shared that they were attracted to the field because of the innovation and to be able to stay updated in their fields. Finally, the principal investigators shared that there should be a partnership effort between the community, the patients, and the medical researchers. Chapter 5 presents a deeper description of the data collection and analysis processes. There are discussions of the findings, interpretation of results, limitations of the study, recommendations, implications for social change and practice, and conclusions from the study's findings.

Chapter 5: Discussion, Conclusions, and Recommendations

In this qualitative study, I explored the lived experiences of clinical research principal investigators on diversity in clinical research studies. Using the conceptual framework of the SEM helped me in this exploration. Based on the data analysis, I identified seven themes that answered the research questions. The findings helped me to better understand principal investigators' challenges and achievements as they address increasing diversity among clinical research participants.

I conducted this study to address the lack of knowledge about the perspectives of principal investigators on diversity in clinical research studies. With scarce information on this topic, it was imperative that this study fill the knowledge gap and add to the research. The suggestions of government agencies, such as the FDA, to address diversity in clinical research speak to the urgency of the matter. Past studies have explored the patient and the CRC perspectives, while the present study adds the principal investigators' voices to better understand how they deal with underrepresentation in clinical research studies. In this chapter, I present my interpretation of the findings, the limitations of the study, my recommendations, and the implications for positive social change.

Interpretation of the Findings

The interviews with 15 participants yielded notable findings that emphasized that the principal investigators were aware of the insistence from government agencies such as the FDA and needed to ensure that clinical research study participants represent the intended population. They are optimistic that it can be achieved, and many have already

implemented solutions at their respective clinical research sites. They want more to be done by the pharmaceutical companies, and they want training on this topic so that they can be more competent when approaching ethnic and underrepresented populations to participate in clinical trials.

Passionate About Working in Clinical Trials

While conducting the interviews, the passion of the principal investigators about working in this field stood out to me. They were drawn to clinical trials to answer complex questions about their patients' conditions and enjoyed the innovative processes. Serving as a principal investigator requires additional training beyond medical, residency and fellowship if they choose to specialize, and they all dedicated the time to complete the required training successfully. Due to time constraints and funding, many medical schools do not routinely prepare students and physicians for clinical research (Adams et al., 2017). The fact that these principal investigators pursued the additional training exemplifies their level of commitment and dedication to the clinical research process. The principal investigators shared that they enjoyed positively impacting the lives of their patients and future generations by bringing new therapies to the market.

Studies indicate opportunities and challenges for principal investigators conducting clinical trials (Adams et al., 2017). The principal investigators commented on the challenges faced in their profession, but they also homed in on the opportunities and appreciation of the responsibilities that came with being a principal investigator. Longevity and happiness in the clinical research profession are related to how passionate one is about the topic they are researching (Adams et al., 2017). None of the principal

investigators in the study gave any inclination that they would want to work in another profession.

Increased Awareness Over Time

The results of this study showed that over time, there has been an increase in awareness of the issue under study and the need to address the lack of diversity in clinical research. All participants discussed strategies they have implemented in their clinical research practices toward attracting underrepresented groups. The participants shared that they hear the urgency to address this from the pharmaceutical companies, sponsors, NIH, and the FDA. Many studies have shown that more and more entities are funding and prioritizing achieving representation in clinical trials and are no longer just acknowledging the problem but implementing multilevel strategies to deliver a meaningful impact (Garrick et al., 2022).

Frustration With Stringent Eligibility Criteria

The principal investigators voiced their frustration that the eligibility criteria for many clinical trials exclude the average person with the condition. The participants the clinical trials seek do not often represent those who live daily with the condition. One principal investigator also shared that laboratory test results alone often exclude her participants. The reference values of these laboratory tests were developed based on normal values for European Americans. It is not uncommon in clinical trials to exclude potential participants who previously used a particular medication; however, when appropriate, minimizing these restrictions on prior therapies could increase participant participation in clinical trials (Osarogiagbon et al., 2021).

Perception That Increased Diversity Among Staff is Needed

In this study, the principal investigators suggested that to achieve diversity in clinical research, diversity in clinical research staff is needed. Principal investigators, CRCs, and nurses all need more representation in the field if the goal is to attract and retain underrepresented populations. The principal investigators were able to meet the community's needs and successfully enroll participants in clinical trials when their ethnicity was congruent with the population served. The findings of the previous studies echo what the principal investigators in the current study suggested as a solution. There is a need to establish an advisory panel for their guidance and ongoing input into research processes and increase the recruitment of research staff from underserved groups (Bodicoat et al., 2021).

Knowledge and Awareness That There are Multifaceted Barriers to Having Diverse Participants in Clinical Research

The principal investigators are keenly aware that many layers and factors affect achieving diversity in research studies. They used various means of participant recruitment, incentives, and community partnerships to accomplish this, including developing in-house training programs when none existed. These findings confirmed and reinforced similar strategies in previous studies that facilitated recruitment and retention (see Kelsey et al., 2022). New knowledge generated in this study included using satellite research sites to prevent the need for study participants to travel long distances to a clinical research site. The principal investigators worked in different sites, including academic medical centers, dedicated clinical research facilities, private practices, and

pharmaceutical companies. They shared the multiple layers that need to be addressed, including language barriers. This aligned with the findings of Khan et al. (2022) addressing the time constraints faced by clinical research staff because conversations with interpreters often need more time. These time constraints and barriers can deter clinical research professionals from discussing clinical trials with potentially eligible participants (Khan et al., 2022).

Concerns That No Formal Training Exists

While the participants have had to complete numerous formal training courses to become a principal investigator and conduct clinical trials, they have not attended formal training on attracting and retaining underrepresented populations into clinical trials. The study participants worked in different settings, and none reported completing formal training on this. Furthermore, one participant shared that her team developed their own curriculum at her institution to address this and routinely trained the clinical research staff. There is very limited training on health care disparities across medical schools and educational programs for health care providers (Garrick et al., 2022). Studies have shown a need to improve the cultural competency and sensitivity of all clinical research personnel, which can be accomplished through formal training and ongoing development (Bodicoat et al., 2021). It is not surprising that health disparities and health equity problems are profound because there is no formalized training available to principal investigators who request it or need it. This helps to contribute to a field where the leaders are not prepared to recognize and address the needs of underrepresented populations.

Optimism for the Future with Strategies and Solutions

The principal investigators remain optimistic about the future, hoping the conversation continues and impactful strategies and solutions are implemented. Previous studies have shown power, value, and impactful results when implementing patient-centered strategies (Khan et al., 2022). The findings from the current study confirmed that the principal investigators hope that diversity and representation in clinical research studies will be achieved by raising the alarm. All participants reported being aware of the suggestions from pharmaceutical companies and government entities, such as the FDA and NIH, to implement efforts for recruiting underserved populations into clinical research studies. They were all knowledgeable about the impact on health disparities and health equity faced when access to clinical trials is unequal. They remained optimistic that things were heading in the right direction and that the situation would be improved.

Study participants shared that knowing the need to increase diversity in clinical research did not readily translate into the ability to influence underrepresented patients into participating in these studies. Principal investigators' experience ranged from 2 to 36 years, which helped to frame their optimism for the future. Many reported seeing tangible changes over time and remained enthusiastic that this will continue.

Interpretation of the Findings and the SEM

In this study, I applied the SEM to examine and explore the lived experiences of principal investigators and their views on diversity in clinical research studies. My research questions were developed based on the SEM to explore how the principal investigators shared their lived experiences and showed multiple connected factors that

can drive the behavior change of patients toward one more accepting of participating in clinical research. The SEM was an appropriate theoretical framework for the data collection and analysis because it grounded the development of the research questions.

The use of the multidimensional SEM levels enabled the exploration of how principal investigators cope with the absence of diversity in clinical research studies. Through the qualitative lens, I explored the contributing factors to this phenomenon, including barriers, facilitators, changes over time, personnel, pharmaceutical companies, and government agencies. The exploration showed how the interconnectedness of these factors affects diversity in clinical research studies. I incorporated the five SEM levels to explore their influences on diversity in clinical research studies as reported by principal investigators.

Intrapersonal-Level Influences

At the intrapersonal level, the findings showed that the principal investigators were aware of the driving factors behind the lack of diversity in clinical research participants. Furthermore, their years of experience, combining both their years of practice and training, only helped to add to their expertise and lived experiences as principal investigators. There were significant influences from the strategies implemented and changes noticed over time. Their perceptions towards potential strategies and the lack of available resources contributed to the continued lack of diversity at their research sites. These influences made it difficult to promote a culture of awareness and acceptance of clinical trials for underrepresented groups, which is critical for moving forward.

Interpersonal-Level Influences

This level of SEM considers social networks. The social networks for the principal investigators provided opportunities for conferences and brainstorming on increasing diversity in clinical research studies. The principal investigators felt supported when in the presence of other clinical research professionals. At the interpersonal level, the principal investigators become a means for driving the change needed to address the underrepresentation seen in clinical research studies.

Community-Level Influences

At the community level, there is a strong influence from the neighborhood where the clinical research sites are located. Barriers at the clinical research sites include not having diverse research staff who can relate to the needs of underserved populations. The principal investigators stated that these barriers are contributing factors that limit the ability to recruit and retain more members of underrepresented populations in clinical research studies.

Organization-Level Influences

Organizational influences indicate the role of systems and health inequity in the principal investigators' lived experiences. The participants in this study expressed that the current system does not allow for success in recruiting underrepresented populations. They were disappointed that no formal training exists, that the strict eligibility criteria can make the average person with the condition ineligible to participate in the study, and that the laboratory results are based on normal values for European Americans.

Policy-Level Influences

Participants expected the federal government to have formal training on diversity in clinical research studies available. There are many mandates from the government, especially the FDA, to meet diversity requirements, but no formal training on this currently exists for the principal investigators. The study participants shared mixed perceptions towards the government's lack of support in addressing their training needs.

Limitations of the Study

I identified several limitations to this study. The sample size was small, consisting of 15 participants. This creates limitations in applying the study findings to all principal investigators. The eligibility criteria were strict, which enhanced limiting the findings to a selected group of principal investigator researchers who worked in the United States and spoke English. All 15 participants provided invaluable information; however, not all principal investigators had the opportunity to participate in the study.

The demographics of the study participants posed another limitation. There were only two male participants, and it is possible the results could have been different with more male participants. The predominant race of participants was Asian, and there could have been cultural biases in their responses. Another limitation was due to the use of purposeful sampling. All the study participants were volunteers, and there was no way to control self-selection bias. The results may be skewed because principal investigators who are more aware of the need to increase diversity in clinical research could have been more willing to share their experiences.

Recruitment of the participants occurred using social media. The views presented through their lived experiences could have been influenced by their ability to use social media technology. This recruitment method did not allow principal investigators not on social media to be aware of the study, which indicates a possibility that the study sample is not representative.

The COVID-19 pandemic also posed limitations to this study. With many in this field coping with the challenges brought on by the pandemic, some did not have the time to participate in the study. Many were struggling with how to remotely coordinate some of the research site visits with immunocompromised patients. There were concerns about COVID-19 exposure and the potential risks to patient safety if they had to visit the research site for a research visit. The pandemic posed limitations on the number of viable participants. Perhaps there would have been more representative volunteers had this study not been conducted during a pandemic.

The study design created limitations. As this was a qualitative research study and not quantitative, statistical significance was not needed. Large sample size was not sought to ensure generalizability and external validity. Therefore, the data were limited to the principal investigators' experiences that were collected via Zoom interviews.

Lastly, there are the limitations of my biases as a researcher. As someone passionate about this topic and as someone who has witnessed how underrepresentation in clinical trials can be detrimental, there is the possibility that my experience could have influenced my data collection and analysis. To minimize bias and the influence of my personal beliefs on the data collection and analysis, I was sure to follow the strategies for

following the interview guide, asking participants to clarify their statements, and re-stating questions if there was any confusion.

Recommendations

This study provided insights into strategies and potential solutions for increasing diversity in clinical research studies. With the researcher applying the constructs of the SEM, principal investigators could share their lived experiences and concerns for diverse participants in clinical research. There are recommendations for future research studies, the clinical research workforce, and practice.

Future Studies

This study was limited in scope, and it would be beneficial to design a larger mixed-methods study exploring more about the principal investigators as they sought to address concerns about underrepresentation in clinical research. Future studies could include a more diverse group of principal investigators from multiple practice settings. Using a mixed-methods approach could provide the opportunity to capture hearty data from the study's qualitative elements, which could drive the understanding of quantitative data for developing and implementing new programs. Mixed-methods study designs help to understand my depth because they provide a more comprehensive picture which helps to augment description and understanding (Wasti et al., 2022). Since mixed-methods research uses quantitative and qualitative data, these study designs provide a stronger inference than either approach (Wasti et al., 2022).

The principal investigators expressed positive perceptions of the need to develop formal training on attracting and retaining underrepresented populations in clinical

research studies. None of the 15 participants received training on this topic. Many shared that they were unaware of formal training but wished they could receive it. Considering the messaging from entities such as the FDA for increased diversity and representation in clinical research, it seems impossible to identify formal training on this. Additional research could ascertain what this content should cover and the most appropriate format for delivering the training.

Additional research could expand on how to best partner with patients. This would shape what the collaboration with researchers and patients will look like. It would help address the existing mistrust and set clear expectations and boundaries. Future studies could explore how principal investigators expect pharmaceutical companies to contribute. Another recommendation is to conduct a mixed-methods study with a larger participant population. Most of the study participants in this study worked at academic medical centers. A recommendation for future exploration is for principal investigators who work in more diverse settings. Further study could explore whether principal investigators in academia have similar experiences to principal investigators in private practice or employed by a research center or research facility. Future studies can also explore the pharmaceutical industry's role in addressing the underrepresentation often seen in clinical trials.

Practice

Public health practitioners could incorporate strategies from the study into targeted, culturally congruent programs to address how participation in clinical trials can influence health equity and health disparities in underrepresented populations. Prior

researchers have explored the experiences of clinical research coordinators with limited impact on addressing underrepresented populations. Findings from this study highlight potential solutions and strategies for successfully developing and implementing programs and systems to meet the needs of underrepresented populations in clinical research.

Recommendations for Action

Recommendation 1: More Diversity in the Workforce

A major theme in the findings was the need for more diversity in the workforce. A recommendation that emerged from analyzing the experiences of the principal investigators was the need for the clinical research workforce to be representative of the population served. This study's participants called for practitioners who look like the patients they serve. They suggested it would help address the trust and mistrust issues often seen in underrepresented populations. This is echoed in recent literature. Issues of mistrust between patients and the healthcare system can be addressed by training research investigators to be more personalized with their interactions instead of a standard approach and by extending the principal investigator base to include health care practitioners and researchers who serve people of color because patients often develop more rapport with someone who shares and understands their cultural experience (Peters et al., 2022). To provide solutions to these barriers, the elephant in the room needs to be addressed, which is the lack of diversity in the clinical trial workforce (Peters et al., 2022).

Recommendation 2: Formalized Training on Attracting and Retaining Underrepresented Populations in Clinical Research Studies

The participants in this study identified the need for formalized training on reaching underrepresented populations to participate in clinical trials. The importance of increasing the recruitment of minorities into research trials is widely recognized; however, the elements r the training of clinic There is emphasis from many angles urging the principal investigators to enroll patients who represent the population affected, but any information on training on how to do so successfully is scarce or nonexistent. One participant at an academic medical center shared that her team created a curriculum to teach the clinical research staff. This study highlights the need to develop training programs in medical schools and other healthcare professionals to address these education gaps. Without the necessary training, the medical field is not adequately prepared to meet the needs of these underrepresented populations.

Clinical trials must recruit participants from diverse populations for many reasons, including ensuring generalizability, safety, and efficacy. To achieve this goal, there needs to be emphasis and efforts towards training clinical research professionals on recruiting and retaining minority patients and understanding the factors that influence minority enrollment in clinical trials (Niranjan et al., 2019). With the absence of a defined and formal training program for recruiting underrepresented populations, researchers will continue to be hindered in their efforts to study the inherent causes of racial differences and socioeconomic factors, and this can help to maintain health disparities and limit our growth in improving health equity (Niranjan et al., 2019). To

work in clinical trials, there are many formal trainings and assessments that clinical research personnel must take to comply with regulations. However, formal training on how to be efficient and successful with their recruitment and retention of underrepresented populations remains scarce or nonexistent. Findings from this study show that the principal investigators find value in having access to formal training on this topic.

Recommendation 3: Clinical Trial Eligibility Criteria That Reflect Patient Populations

The participants in this study identified the need to have clinical trial eligibility criteria that reflect real-world patients. They shared that the laboratory results criteria used to determine eligibility are based on White males. Therefore, they often exclude minority patients from participating because their lab results do not fall into the accepted eligibility criteria range. Frequently patients are excluded from participation because of having common other medical conditions or using certain medications. There are often very narrow definitions of the study population. Current clinical trial eligibility criteria are often very strict, which causes enrollment limitations and screen failures for patients in clinical trials (Al-Baimani et al., 2018). The eligibility criteria often seek participants who represent a small percentage of those with the medical condition, which helps to exclude even members of underrepresented populations from participating in the clinical trials. It may be worthwhile for eligibility criteria to be reviewed and relaxed depending on the therapy and its safety and efficacy profile (Al-Baimani et al., 2018).

Implications

This study has implications for positive social change. The knowledge of specific strategies and the recommendations for creating training programs could contribute to designing programs and training that are relevant and culturally appropriate for increasing diversity in clinical research studies. The impacts of such implementations would be having more representation in the research studies, having more data and safety and efficacy profiles of many therapies for ethnic minority groups, improving health equity, and reducing health disparities. Furthermore, this study's participants revealed innovative recommendations for future researchers and public health practitioners to promote positive outcomes and social change.

Conclusions

This was the first study to explore principal investigators' lived experience of diversity in clinical research. Findings show that principal investigators are passionate about their work and being a part of the process of making new medications available to the patients they serve but face multi-faceted barriers to having diverse participants in clinical research. They are nevertheless optimistic that clinical research is heading in the right direction and offered strategies to achieve representation. These interviews highlighted the passion of these principal investigators to drive care forward but also their pleas for help. Principal investigators are innovative and problem solvers. They want their study participants to reflect the real world and they want formal training on how to properly address increasing diversity in clinical research studies.

This situation of underrepresentation in clinical trials is critical. Diversity in clinical trials is needed and it is needed now. Government entities such as the NIH and FDA have recognized the urgency. The advancement of care, medicine, and science for underrepresented groups depend on increasing awareness and having more represented populations in the clinical trials. It is possible for mankind to live in a world where certain groups are not disproportionately affected by certain conditions. A world without health disparities can exist. A world with health equity can exist. It would not happen overnight. Clinical trials can help to get to that world. The findings from this study can be used to drive social change by creating programs to raise awareness of clinical trials and to develop formal trainings for principal investigators.

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Appendix: Questionnaire and Interview Guide

The purpose of this questionnaire it to obtain basic demographic information about the participants in this study.

1. Name
2. Email address
3. Employer
4. Medical specialty
5. What diseases do you study and recruit participants for?
6. How many years have you been a principal investigator?
7. Race
8. Gender
9. Where do you conduct your clinical research studies?

□ Private Medical Practice

□ Academic Medical Center

□ Clinical Research Center/Facility

□ Other (specify)

RQ1. What are the lived experiences of clinical research principal investigators on diversity in clinical research?

RQ2. What do clinical research principal investigators identify as concerns for diverse participants in clinical trials?

Introduction: Thank you for agreeing to participate in this study. My name is Nadine Spring and I am a doctoral student at Walden University in the PhD in Public Health program. The purpose of this study is to understand your perceptions and lived experiences on diversity in clinical research studies as a principal investigator. I will be taking notes throughout our interview. I will also record our interview and it will be transcribed. I will share the transcript with you when it has been created. If you have any corrections or additions at that point, you can send them to me via email. Thank you again, for participating in this study.

Warm-up questions: These questions are not meant to collect demographic information but they were created to help provide me with a context for their work as a principal investigator.

1. How long have you been a principal investigator on clinical trials?
2. What are some of the challenges you have faced when it comes to recruiting diverse populations into clinical research studies?

Interview Questions:

1. Please tell me about your role as a principal investigator on clinical research studies
    a. Possible follow up question: How long have you been a principal investigator on clinical trials?

2. Tell me what attracted you to become a principal investigator on clinical research studies?
3. Please tell me about the training you received to become a principal investigator
4. Please tell me about your responsibilities for recruiting participants into research studies
5. Please share what you look for in potential participants in your research studies
6. In your experience, tell me about challenges towards recruiting diverse populations into clinical research studies
7. Please share any trainings you have had on attracting and enrolling underrepresented minorities into research studies
8. If you think there might not be enough diversity in clinical research, what can you do to increase it?
9. Tell me about some of the strategies you have personally implemented towards increasing diversity in clinical research studies
10. Tell me about the strategies you would like to see implemented to increase diversity in clinical research studies
11. Based on your experience, are there specific clinical trials that members of underrepresented populations are more likely to be interested in and potentially enroll in if given the opportunity?
    a. Follow up with a why or why not?
12. Do you have any concerns about diversity in clinical research studies? If yes, can you explain what they are? If no, why not?

13. Is there anything else you would like to share or tell me?

Conclusion: Thank you again for sharing your perspectives and experiences with me. Once I have the transcript of our interview, I will send it to you. After you have reviewed it, you can contact me via email to add any revisions or additional thoughts you have.