Barriers and facilitators to Hispanic participation in cancer clinical trials as perceived by patients and clinical trial recruiters

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To my husband and best friend, Carl, for always believing in me, cheering me on, making me laugh, and knowing what to say at the exact moment I need to hear it. You are the best.

To my son, Olben, who keeps me on my toes every day, reminding me that life is one big adventure and to never take myself too seriously.

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CHAPTER 1

Introduction

1.1 Statement of the Problem

Although cancer is the leading cause of death among Hispanics in the United States (U.S.), only 2-4% of Hispanics participate in cancer clinical trials, limiting the generalization of findings and increasing treatment inequity [1]. Hispanics are the second-largest ethnic group in the U.S., accounting for nearly 20% of the population and are continuing to grow [2]. Over 125,000 new cancer cases will be diagnosed annually across the Hispanic community, with approximately 20% of men and 17% of women dying from some form of the disease during their lifetime [3]. Clinical trial participation is integral to the advancement of treatments and preventative care; however, minority ethnic groups are not participating in clinical trials at a comparable rate as White, Non-Hispanics [1]. Lack of overall diversity inhibits the efficacy of treatment options and thus increases the disparity of treatment received between diverse populations [4]. To increase engagement, and subsequent decrease in morbidity and mortality within this population, factors aiding and hindering the recruitment process must be established.

Research conducted on barriers to minority participation in clinical trials has failed to substantially represent the Hispanic oncologic population [5, 6]. Limited research exists that provides insight from Hispanic oncological patients' viewpoint regarding the barriers they encounter when enrolling in and being recruited for cancer clinical trials. Of the studies conducted that have accessed the Hispanic community, willingness to participate has been reported, yet participation remains low, raising the question of additional unknown barriers [7, 8]. To date, no known research has identified both barriers and facilitators to participation among this population, while simultaneously examining the patient and recruiter viewpoints

for similarities and differences – herein lies the gap. Securing data from both views is necessary to provide a comprehensive foundation from which intervention work can be developed in the future. Additionally, exploration of the convergence of perceived barriers and facilitators will elucidate areas in need of intervention development, while divergence will explain areas of disconnect that should be discussed and addressed.

1.2 Purpose of the Study and Long-Term Goal

The purpose of this embedded, mixed-methods cross-sectional study was to explore the perceived barriers and facilitators to participation in cancer clinical trials for Hispanic patients as perceived by both patients and recruiters. Patients can provide insight to the intrapersonal, interpersonal, and community barriers, while clinical trial recruiters can further discuss barriers beyond the patient purview, to include public policy and institutional barriers. The information elicited from this study will guide future development of interventions aimed at mitigating barriers and expanding facilitators.

My long-term goal is to improve healthcare outcomes and reduce inequities among the Hispanic oncological population. The incidence of cancer among the Hispanic population is higher than any other disease, and the care involved with the diagnosis is costly [3, 9]. Clinical trial participation can provide researchers and those providing direct patient care the evidence to implement innovative treatments, ultimately improving health outcomes and healthcare inequities among underserved populations – an objective shared by numerous health organizations [3, 4, 10]. As such, the findings of this study will provide a foundation for future intervention development aimed at increasing clinical trial participation among the Hispanic oncologic population. Increased participation in cancer clinical trials by

Hispanic populations will improve the generalization of study findings, improve treatment options, and reduce the inequities in access to care and healthcare outcomes.

1.3 Specific Aims

Research Question: What are the perceived barriers and facilitators to clinical trial participation from the perspective of Hispanics who are undergoing and who have completed cancer treatment and clinical trial recruiters?

Research Aim 1: To describe barriers and facilitators to Hispanic participation in cancer clinical trials, as perceived by Hispanics who are undergoing and who have completed cancer treatment.

Research Aim 2: To describe barriers and facilitators to Hispanic participation in cancer clinical trials, as perceived by clinical trial recruiters.

Research Aim 3: To examine the convergence and divergence of perceived barriers and facilitators to Hispanic participation in cancer clinical trials between patients who are undergoing and who have completed cancer treatment and clinical trial recruiters.

1.4 Significance of the Problem

1.4.1 Significance to Society

Cancer care has a substantial economic impact on society. In 2017 alone, 147.3 billion dollars was disbursed nationally for cancer-related treatments and care [9]. This expenditure increases when the care and treatment needed are deferred. The later the stage in which a cancer diagnosis is made, the more extensive and less efficacious treatment options become, ultimately increasing the cost of care [11]. Unfortunately, uninsured patients or those from historically disadvantaged ethnic minority groups like Hispanics have less access to care and are more likely to be diagnosed with late-stage cancer [11, 12]. Participation in cancer trials could decrease morbidity and mortality rates, which in turn would reduce the overall cost of

care [11]. Hispanic and underserved patients, however, are less likely to participate in clinical trials and are hindered by limited funding for clinical trials at local healthcare institutions [1, 3, 13, 14]. Therefore, with an underserved population not accessing care that can potentially improve their health, there is a need to explore barriers and facilitators that are influencing their decision to participate [7, 8].

1.4.2 Significance to Healthcare

Rising cancer care costs lead to poor quality of life and decreased survival rates, which are more commonly seen among the medically underserved, including the uninsured, poor, and ethnic minorities [48]. Inpatient hospitalizations, advanced disease, and end of life care create the most financial burden for those who have cancer, with new cancer drugs priced as high as $100,000 annually [48]. With these extreme costs of care, patients are faced with the decision to pursue treatment or forego potentially lifesaving medical care to deter personal bankruptcy [48]. While out-of-pocket cost-sharing steadily increases, even those insured are finding difficulty affording the care [48]. Additionally, the emotional toll of mounting medical bills and unemployment due to illness can create further deterrents from seeking treatment [48].

Clinical trial participation can provide patients with potentially efficacious therapies that may be beyond their affordability [4]. Over 27 million people lack insurance coverage in the U.S., with legal documentation status directly associated with eligibility for coverage [49]. In 2016, there were an estimated 8 million Hispanic immigrants who were undocumented living in the U.S [50]. Consequently, the Hispanic population is the least likely to have health insurance coverage of all ethnic groups [41]. Deficits in insurance coverage inhibit access to care and impact clinical trial participation as disadvantaged patients are less likely to participate in clinical trials than those with higher annual incomes [11, 13, 14]. Additionally,

funding influences care availability, as institutions in areas with limited funding suffer from decreased participation and a lower number of available clinical trials [14]. Areas with the highest per capita incomes report higher rates of engagement, but also boast more significant numbers of accredited hospitals and treating oncologists [14].

The conditions in which individuals live, work, and learn are called social determinants of health (SDOH) [78]. These determinants impact a person's well-being and contribute to disparities and healthcare inequities [78]. are The Healthy People 2020 initiative uses the social determinants of health framework to explore how an individual's health status can be affected by outside factors, several of which were noted to influence a patient's ability to participate in clinical trials, ultimately increasing the disparity of treatment options [77, 78]. Five primary constructs in this framework include: "economic stability, education, neighborhood and built environment, health and health care, and social and community context [77, 78]. The Hispanic oncologic population may be affected by one or more these constructs, which can ultimately hinder clinical trial participation [39].

Participation in cancer clinical trials can lessen the disparity of treatment received between diverse populations, improving patient outcomes [4]. It can provide the Hispanic oncologic population with innovative therapies that may not otherwise be promoted or offered to them [4]. Identifying barriers and facilitators to participation is the initial step in developing processes that will ultimately improve health inequities and health outcomes in this vulnerable population.

1.4.3 Significance to Nursing Research

Cancer clinical trials focus on studying the effectiveness of new treatments, preventative measures, diagnostic testing strategies, symptom management, predictive modeling, and interventions within the oncologic population [53]. These trials can demonstrate

relationships between nursing interventions and patient outcomes and are integral to the research process, establishing an evidence-based platform from which nursing practice may be derived [52]. Further, these trials provide nurse researchers with data utilized to guide future nursing practice aimed at improving patient outcomes [52]. Researchers in general struggle to attract and retain Hispanic participants in cancer clinical trials, regardless of the increased disease burden within the population [1, 5, 6].

Participant diversity is critical to nurse researchers seeking to apply clinical trial findings beyond those in their study, with low participation impacting the generalizability of data secured [9, 14, 39, 51]. Further, with 0.1% of all current cancer clinical trials specifically focusing on Hispanics, lack of participation is even more apparent [15]. The American Cancer Society, American Association for Cancer Research, American Society of Clinical Oncology, and the National Cancer Institute have called for increased funding opportunities of research focused on greater minority population inclusion in cancer research initiatives [54].

1.4.4 Significance to Nursing Practice

Nurses provide advocacy, psychological support, outcome evaluation, patient education, assessment, monitoring, and symptom management to patients throughout the clinical trial process [55]. As an advocate, nurses can provide opportunities and education for the underserved who may not have previously had access or knowledge of available treatment options, such as the Hispanic oncologic population [56]. Nurses play a critical role in recruitment, as they often promote potential clinical trials, educate patients and families on available studies for participation, and provide essential care to cancer patients throughout the care continuum of the clinical trial [55, 56]. Therefore, possessing an understanding of barriers that Hispanic oncology patients face when attempting to participate in clinical trials

may assist nurses in adjusting and improving processes. Increased participation allows for a wider variety of treatment options to be delivered and tested, raising the possibility of improving patient care outcomes [1, 17, 41].

Advanced Practice Providers (APPs, APRNs, ARNPs) play pivotal roles in the oncology clinical continuum, often seeing patients more frequently than physicians [57]. APPs often provide greater access to care for underserved populations by working within ethnically and geographically diverse communities [58]. APPs are critical to the clinical trial process, as they identify patients to enroll, educate on available clinical trials, provide care throughout the study, and interact and collaborate with the clinical trial team members to ensure optimal patient care [57]. Although the scope of practice differs in each state, APPs have an overarching goal of improving healthcare outcomes and have direct accountability for the management of care [59]. When access to clinical trials is impeded, APPs are unable to present their patients with all viable healthcare options. Therefore, for APPs to provide patients with comprehensive care options, barriers to access must be addressed.

In closing, this study will add to the existing literature by describing barriers and facilitators to Hispanic participation in cancer clinical trials as perceived by both patients and recruiters. Research completed to date has failed to capture this information simultaneously within both groups; therefore, a thorough examination of the convergence and divergence of the factors has not been completed. The findings from this study will be utilized as a foundation for future intervention development aimed at bolstering facilitators or mitigating barriers to clinical trial participation among this underserved population.

CHAPTER 2

Theoretical Framework and Literature Review

2.1 Scientific Premise

Several studies have explored the rationale for the lack of participation, yet many reported difficulties with the inclusion of representative samples in their studies [1, 5, 8, 17-20, 24, 29-31, 34-37, 47]. Studies conducted from the viewpoint of patients are often hampered by its inclusion criteria, such as being gender-specific, cancer-specific, or sampling in an area with a predominant population from one country of origin [1, 6-8, 17-21, 24, 26, 32-37, 47], resulting in data that lack generalizability. Limitations of the studies that focus on the perceptions of recruitment personnel include enrollment of administrative or managerial positions, rather than those interacting with potential participants directly [29, 30, 31]. The literature does not reflect a current account of both barriers and facilitators to Hispanic participation in cancer clinical trials from the perspectives of patients or recruiters [5, 6, 14, 16-18, 20-22, 24-27, 32-35, 47]. Further, no known studies have collected data from both patients and recruiters simultaneously; therefore, divergence and convergence of perceived barriers and facilitators remains unknown. As several agencies are calling for greater minority inclusion in cancer research, it is imperative to identify barriers and facilitators to participation in cancer research in this population [54].

2.1.1 Patient perspective

The patient's perspective of participation in clinical trials has been explored using methods including qualitative focus groups, one-on-one semi-structured interviews, cross-sectional surveys, retrospective case studies, longitudinal studies, as well as systematic reviews of the literature, and a prevalence study on trial data [1, 8, 16-28]. Although the

methodology is diverse, limitations in subject representation exist, as well as a lack of focus specifically on oncology clinical trials [16-17, 27]. A study conducted to explore the experiences and perceptions of ethnically diverse individuals when participating in health-related research was completed. However, they recruited an all-female sample, 28% of whom self-identified as Hispanic, with 73% of those being of Mexican origin [16]. Given the sample, findings cannot be generalized to all Hispanics or males. Another study explored perceptions of barriers to clinical trial participation among Hispanic and African American patients ages 50 to 80 but did not restrict participation to oncology trials [17]. Greater applicability and cultural competence arise from research with a more diverse sample. As such, the current state of the literature reflects the need for more diverse samples to obtain an accurate account of the barriers faced when enrolling in oncology clinical trials.

Qualitative studies conducted with minority participants reported consistent themes emerging from the patient perspective, including communication needs, relationship with providers, shared decision making, clinical trial knowledge, and trust [1, 16, 18, 21-22]. One such study exploring Mexican American perspectives on participation in clinical trials found similar themes, with the addition of clinical trial understanding and fear as potential barriers [1]. Another added concern arising from health literacy and language needs to assist patients with the decision to participate in clinical trials [21]. Participants expressed the need for a clear understanding of clinical trial processes and the resulting lack of participation due to increased uncertainty and fear experienced from the unknown [21]. Another limitation to the current literature is that much of the data were collected over a decade ago, making its applicability to the present day much more static [20, 21]. Additionally, of the few Hispanics who participated in the research, the majority was female, of specific sub-ethnicities that varied per study, and some had no history of cancer [1, 16, 21]. Exploration of these barriers

will lead to innovative solutions to mitigate barriers, which in turn improves participation, health outcomes, and health inequities among this population. However, to succeed in doing so, more recent data from a representative sample should be collected, as perceptions can vary between subethnicities from those of different countries of origin, and those inflicted with the disease.

Studies conducted using quantitative methods often fail to include a representative sample of the Hispanic oncologic population. One study used a cross-sectional design to explore barriers and facilitators to recruitment among Hispanic breast cancer patients; however, the majority of the participants were of Dominican nationality, limiting the generalizability of the findings to other Hispanic populations [19]. Another cross-sectional study explored the benefit an oncology nurse navigator had on increasing access to clinical trials for minorities. Although the intervention increased access to available trials, only African American participants were recruited, limiting the findings [22]. Similar to the qualitative studies described above, data from larger, representative samples remain outdated, affecting their present-day applicability. Finally, a cross-sectional study conducted in 2012 on 944 Latinos within nine different clinics found that 65% surveyed noted willingness to participate, after being provided education regarding cancer clinical trials [8]. The desire to participate is evident, reflecting a need to ascertain additional barriers beyond the patient perspective that are preventing enrollment.

Lastly, systematic reviews conducted on barriers and facilitators with minority participation in clinical trials further highlight the lack of representation. One such review among African Americans, Latinos, Asian Americans, and Pacific Islanders reported no distinct barriers for Latinos, which was attributed to having very limited (three) studies that focused solely on Latinos [27]. Further, only 11 of the 44 studies in the review were

oncology-related [27]. Another review focusing on barriers to participation in underrepresented populations reported barriers like those in the qualitative work, including lack of awareness of clinical trials and lack of opportunity to participate in clinical trials. However, of the 65 total articles reviewed, only 12 studies focused on Latinos/Hispanics [17].

Limited research exists that provides insight from Hispanic oncological patients' viewpoint regarding the barriers they encounter when enrolling in and being recruited for cancer clinical trials. Additionally, as the available research focuses on barriers to participation, facilitators that could aid the process remain unknown. The issue of low participation has been discussed in the literature for over a decade, yet participation rates remain low. Without this information, any interventions developed to increase participation likely lack cultural competence and relevancy. The development of improved interventions based on current, culturally competent knowledge will increase participation, which will enhance research, healthcare inequities, and healthcare outcomes in this population.

2.1.2 Recruiter Perspective

Research methodology utilized in studies conducted to explore the recruiter's perspective includes qualitative focus groups, one-on-one semi-structured interviews, cross-sectional surveys, mixed methods, and a systematic review of the literature [29-38]. Of note, as with the studies that explored the patient perspective, studies focused on the recruiter perspective also lack a representative sample. Various personnel participate in these studies, including managers, Primary Investigators, referring clinicians, cancer center leaders, and research staff [29-37], but not individuals working directly with the patients in the recruitment process. To date, no study has reported the sole view of recruiters regarding participation in

cancer clinical trials among the Hispanic population. This perspective is integral to understanding what barriers exist beyond those known to the patient.

Qualitative studies that explored the recruiter's perspective reported convergence of some major themes, including inclusion criteria, patient beliefs, training needs of recruitment staff, or language or literacy competency [29, 32-37]. Further, recruitment personnel at five NCI-designated cancer centers were interviewed and reported organizational priorities and financial support as motivators for minority recruitment [37]. In 2018, several focus groups discussed the concerns of contextual factors in the recruitment process, including immigration status, medical mistrust, and medical literacy concerns among Hispanic patients [36]. Themes arising from the recruiter perspective highlight additional barriers and facilitators to those noted within the patient's perspective – namely, at the organizational or policy level. As such, to conduct a comprehensive study to report all barriers and facilitators affecting the recruitment process, both perspectives are needed. To date, no such research exists.

Quantitative studies utilized cross-sectional surveys to discuss barriers and facilitators for minority populations, resulting in similar findings to the qualitative literature [30, 31]. After surveying 520 research professionals, enrollment of minorities in clinical trials was inversely associated with distrust, race, availability of interpreters, and translated materials [31]. Additionally, a mixed-methods study conducted described the most frequently cited barrier to participation among African Americans and those in rural communities was a lack of awareness of clinical trials [30]. While this study was not specific to the Hispanic oncologic community, it emphasizes the difficulty in attracting and retaining participation among minority populations and notes barriers as awareness, trust, and knowledge of clinical trials [30].

Although barriers have been reported in several studies, these were collected from several participants in various positions within the organization and not solely from the recruiters with direct patient interactions. The recruiter's perspective is integral to accurate reporting of barriers and facilitators, as they receive information directly from the patients and are familiar with inclusion, exclusion criteria, and protocols for each study. Professionals in positions without direct contact to the recruitment population will be further removed, and the information provided may not reflect current barriers and facilitators to participation. Additionally, the studies generalize findings to all minorities with different medical conditions. Therefore, there is a need to secure data specifically from those working directly with the Hispanic oncologic community. Gaps in the current literature reflect cultural incongruence, as most studies soliciting Hispanic participation cannot secure a substantively diverse sample that will allow findings to be generalizable to a greater Hispanic population. Aside from cultural incongruence, the available research does not reflect the perspectives of the recruiters working directly with the oncologic community; therefore, the information secured may not be reflective of what is being shared by the population of interest. Lastly, the literature highlights the issue of minimal participation among this population.

To date, there have been no known studies conducted that utilize representative samples of both Hispanic oncology patients and clinical trial recruiters. Securing the perceptions of both groups simultaneously provides current, culturally competent data from which future interventions can be developed. These interventions, aimed at increasing participation, will subsequently expand the generalizability of research findings, provide treatment alternatives to those in need, decrease health inequities in oncology care, and improve healthcare outcomes for this population.

2.2 Theoretical Framework

An adapted Socioecological Model (SEM) was utilized as the framework for the study as it depicts the hypothesized levels of barriers and facilitators impacting clinical trial participation: intrapersonal, interpersonal, institutional, community, and public policy factors [39]. Of note, the framework illustrates an individual's behavior as being influenced by multiple internal and external factors [39]. Thus, an individual's choice to participate in cancer clinical trials relies upon an intricate system of multilevel barriers that must be addressed and mitigated. This framework best depicts barriers and facilitators faced by Hispanics when enrolling in cancer clinical trials, as it reflects a comprehensive view of all applicable levels of concern [39].

The adapted framework (Figure 2.1) reflects the postulated relationship between the major constructs. Additionally, the "institutional" level was changed to "organizational" to allow for more inclusivity of types of influences in this category, including inpatient, outpatient, research facilities, cancer care centers, etc. [39].

2.2.1 Operational Definitions

Intrapersonal: factors assisting or inhibiting a patient from enrolling in clinical trials that stem from personal knowledge, attitudes, and characteristics [39]. Variables include own beliefs or biases, language barriers and literacy, and knowledge of clinical trials.

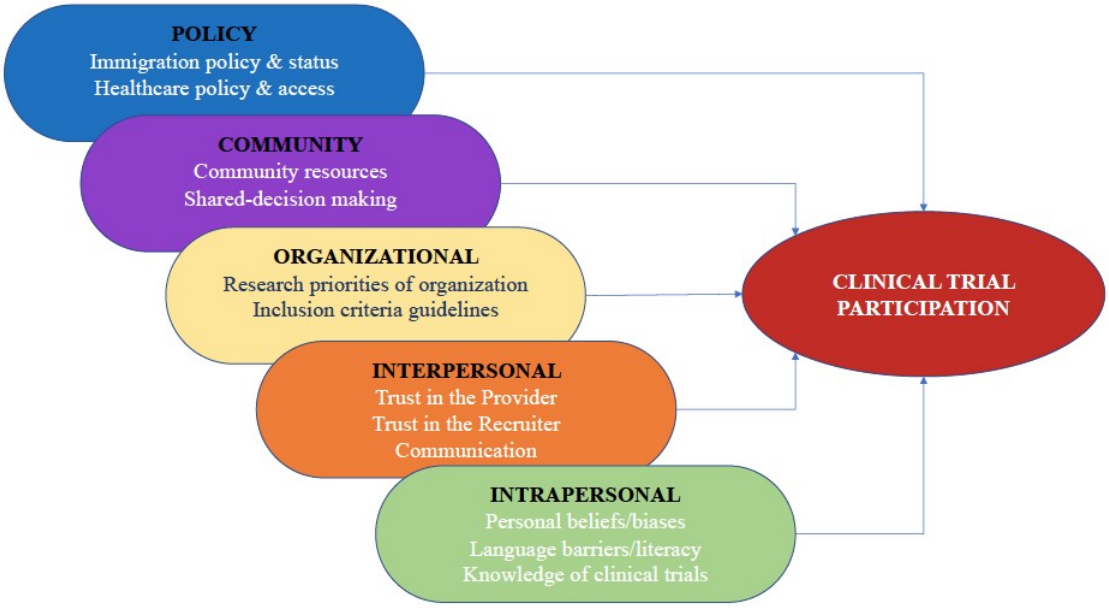
Interpersonal: factors assisting or inhibiting a patient from enrolling in clinical trials that stem from the patient-provider or patient-recruiter relationship [39]. Variables include trust in the provider, trust in the recruiter, and communication between parties.

Organizational: factors assisting or inhibiting a patient from enrolling in clinical trials stemming from institutional guidelines or study constraints [39]. Variables include research priorities of the organization and inclusion criteria guidelines.

Community: factors assisting or inhibiting a patient from enrolling in clinical trials stemming from community resources or their community network [39]. Variables include community resources and shared decision making.

Policy: factors assisting or inhibiting a patient from enrolling in clinical trials stemming from public policy guidelines [39]. Variables include healthcare policy and access, and immigration policy and status.

Figure 2.1: Adapted version of Salihu's SEM framework [39]



2.3 Preliminary Pilot Data

An exploratory, descriptive qualitative pilot study utilizing semi-structured interviews was conducted in September of 2019 to explore the perceptions of barriers and facilitators to cancer clinical trial participation among the Hispanic cancer population. The literature indicates little involvement from the Hispanic oncologic community in research [1]. The pilot study intended to aid in determining the feasibility of reaching this population.

Two participants were interviewed from each group, for a total of four interviews. Utilizing thematic analysis [67], there were four major themes identified from each group, with some convergence evident. Patients' themes identified: (1) lack of clinical trial knowledge; (2) trust issues affecting participation; (3) access issues and participation fears; and (4) altruism: desire to help others. Recruiters' themes identified: (1) clinical trial knowledge; (2) trust issues; (3) not meeting eligibility criteria; and (4) language proficiency. Theoretical concepts supported by the patient themes were (1) intrapersonal; (2) interpersonal; (3) organizational and intrapersonal; and (4) intrapersonal, respectively. Theoretical concepts supported by the recruiter themes were (1) intrapersonal; (2) interpersonal; (3) organizational; and (4) interpersonal, respectively.

In addition to the themes identified, the pilot study findings revealed several items that informed the methodology of the current proposed study. The first item, unsurprising given the topic, was the difficulty in finding patients to participate. Several revisions of the sampling protocol were completed following unsuccessful participant recruitment. Along with a very limited recruitment protocol, the pilot's inclusion criteria hindered the recruitment of participants. Six potential patients completed the web-based Research Electronic Data Capture program (REDCap®) survey, with five willing to participate in a phone interview. However, only two of the five met inclusion criteria, as the remainder did not have a present history of cancer or were not fluent in English. This situation mirrors the literature reporting that patients are willing to participate, but are unable to enroll due to outside factors, such as inclusion criteria [7, 8]. Inclusion criteria concerns was also a strong theme arising from the recruiters in the pilot, as recruiters responded needing very specific populations. Recruiters noted after screening, many potential participants didn't meet study criteria. Additionally, participants were not provided with incentives for their time. Patients

in the pilot noted that the cost of participation was a perceived deterrent and that incentives would assist in mitigating this. Lastly, recruitment may have been hindered due to language barriers, since all recruitment activities were completed in English with no translation services offered. Recruiters noted that translation services and reading materials aided in their endeavors when recruiting. Any study literature (informed consent and study protocols) written in the potential participant's native language facilitated the recruitment process.

To secure greater participation, the current study broadened sampling methods and inclusion criteria, along with providing materials and language services in both English and Spanish. With these updates, the data secured from this larger, more diverse population will aid in future intervention development aimed at increasing clinical trial participation among Hispanic oncologic patients.

CHAPTER 3

Methodology

3.1 Research Design

An embedded, mixed-methods cross-sectional study was conducted to examine the perceived barriers and facilitators to participation as described by both patients and recruiters [63]. Quantitative data were collected via a cross-sectional survey, followed by an optional qualitative semi-structured one-on-one telephone interview to explore barriers and facilitators not addressed in the survey instruments. The analyses for both collection methods were undertaken simultaneously, as the findings from each complemented and informed the other.

3.2 Sample and Setting

Purposive sampling was used to recruit the sample of the two groups of interest – Hispanic cancer patients and cancer clinical trial recruiters. The P.I. aimed to secure a total of 75 participants for the patient sample group, therefore a non-completion rate of approximately 20% was calculated due to the inherent concerns of recruitment within this population. A total of 95 accessed the survey, with a final total of 85 patients completing the survey for inclusion in the analysis.

To achieve the sample goal of 40 recruiter participants and based on an anticipated non-completion rate of 20%, the P.I. aimed to recruit 50 participants. Of the 56 participants who accessed the survey, only 30 completed the survey sufficiently to be included in the analysis.

3.2.1 Sample Size

Patients. A sample size of 85 individuals successfully completed the cross-sectional web-based survey. Every participant was asked in the survey if they wanted to participate in a one-on-one semi-structured interview via the telephone. Although the participation of each individual was requested, and an additional incentive was offered for this participation, only 15 participants noted willingness to participate in an interview. Of those 15 potential participants, only 4 completed the one-on-one interview. The P.I. reached out to each potential participant once every 2 weeks for 2 months to schedule the interview. Those who were unable to complete the interview cited current chemotherapy treatment and feeling too ill to participate; or simply never responded to the multiple attempts at contact.

Recruiters. A sample size of 30 individuals successfully completed the cross-sectional web-based survey. Everyone in the recruiter group was asked to participate in a one-on-one semi-structured interview via telephone. A total of 15 recruiter interviews were conducted, with the remainder of survey participants declining to participate in the interview for reasons unknown and undisclosed to the P.I.

3.2.2 Inclusion/Exclusion Criteria

3.2.2.1 Inclusion Criteria

Patients. Patients must: (1) have had a previous or current history of cancer within the last five years; (2) have self-identified as Hispanic; (3) have been 18 years of age or older; (4) have been verbally fluent in either English or Spanish; (5) have been able to read and write in English or Spanish; and (6) have had access to the Internet or a smartphone equipped with Internet access capability.

Recruiters. Recruiters must: (1) have been verbally fluent in English; (2) have been able to read and write in English; (3) have been employed, or previously employed, for at least

three months in a position in which research recruitment activities as a primary job duty; (4) have had experience recruiting the Hispanic population for cancer clinical trials; and (5) have had access to the Internet or a smartphone equipped with Internet access capability.

3.2.3 Methods of Subject Recruitment

3.2.3.1 Patients

After permission from the Vanderbilt University Institutional Review Board (IRB), the sample was recruited by the Primary Investigator (PI) via (1) ResearchMatch.org, (2) the community-at-large, (3) through the National Association of Hispanic Nurses (NAHN) Chapters, (4) Sigma Theta Tau International (STTI) communication channels; (5) the Vanderbilt University research listserv; (6) participating cancer centers; and (7) social media sites of cancer support groups. Recruitment materials for the patient group was available in English and Spanish to mitigate language barriers in the recruitment process.

(1) ResearchMatch.org was used as a primary recruitment tool to reach volunteers nationwide. This national health volunteer registry was created by several academic institutions and is supported by the U.S. National Institutes of Health as part of the Clinical Translational Science Award (CTSA) program. ResearchMatch.org has a large population of volunteers who have consented to be contacted by researchers about health studies for which they may be eligible [45]. This recruitment tool was successful in recruiting participants for the pilot that guided this proposed study and, thus, was utilized again.

(2) The community-at-large was accessed by the distribution of IRB-approved bilingual study flyers by the P.I. to various locations in the U.S. This included cancer centers, outpatient cancer clinics, Hispanic community centers, and individuals involved with or who had a connection to, the participant group sought, with permission. Study flyers contained

study and contact information, along with the web-based public screening survey link to access the survey online.

(3) As a current member of NAHN, the P.I. distributed the study flyer to the local Chapter Leader for distribution among their members, who may have had direct contact with the Hispanic oncologic population.

(4) As a current member of STTI, the P.I. posted the study flyer on the internal communication website to reach those who may have direct contact with the Hispanic oncologic population.

(5) VUMC IRB-approved study flyers were distributed via the Vanderbilt Medical Center communications channel, the University research listserv.

(6) The P.I. recruited patients from cancer centers in Nashville, by means of flyer dissemination and posting within those local cancer centers.

(7) Lastly, the study flyer was posted to Reddit social media sites of cancer support groups, with permission from those sites.

3.2.3.2 Recruiters

The sample was recruited via (1) ResearchMatch.org, (2) the Vanderbilt University research listserv, (3) the community-at-large, (4) the National Association of Hispanic Nurses (NAHN), (5) the Society of Clinical Research Associates (SOCRA), (6) Sigma Theta Tau International (STTI) communication channels; (7) participating cancer centers; and (8) social media sites of clinical trial recruiter organizations.

(1) ResearchMatch.org was used as a primary recruitment tool to reach volunteers nationwide.

(2) VUMC IRB-approved study flyers were distributed via the Vanderbilt Medical Center communications channel, the University research listserv.

(3) The community-at-large was accessed by the distribution of VUMC IRB-approved study flyers by the P.I. to locations in the U.S. This included individuals connected with cancer centers and interested parties that are involved with or have a connection to, the participant group sought. Study flyers contained study and contact information, along with the web-based public screening survey link to access the survey online.

(4) As a current member of NAHN, the P.I. distributed the study flyer to the local Chapter Leader for distribution among their members, who may themselves be, or have contact with, individuals that are eligible to participate.

(5) The P.I. distributed the study flyer to Chapter Leaders of SOCRA for distribution among their members. The contact listing for Chapter Leaders is readily available to the public on the organization website.

(6) As a current member of STTI, the P.I. posted the study flyer on the internal communication website to reach those who may have been eligible to participate.

(7) The P.I. recruited from cancer centers in Nashville, by means of flyer dissemination and posting within those local cancer centers.

(8) Lastly, the study flyer was posted to research professional social media sites, to include LinkedIn, by leaders of the organizations.

The P.I. kept close contact with recruitment organization leaders to continue recruitment efforts throughout the data collection phase. As the survey was distributed online, faster timing of communication and reminders was recommended, as emails are easily dismissed or forgotten [68].

3.2.4 Strategies to Ensure Human Subjects Protection

Participant protection in the form of confidentiality and informed consent was provided before, during, and following the completion of the study. The P.I. completed Human

Research Protections Training through the VUMC IRB and completed ongoing training to ensure proper protocols are known and followed.

Approval of the study by the VUMC IRB and the Scientific Review Committee (SRC) at Vanderbilt-Ingram Cancer Center was secured before the study's initiation. The VUMC IRB ensures that all approved studies protect the participants' rights, welfare, and privacy. The SRC ensures that all research conducted under the Center upholds the highest standards of scientific principles and integrity.

3.2.4.1 Informed consent (Appendix A)

A waiver of documentation for informed consent form was granted from the VUMC IRB. Informed consent was provided to each potential patient participant online in their language of choice, English, or Spanish [66]. Potential recruiter participants received informed consent online in English. Upon completion of the informed consent, the participant was directed to the study's screening questions to determine eligibility.

3.2.4.2 Confidentiality

Confidentiality is of heightened importance for minority populations, particularly undocumented individuals, for fear of repercussions, such as deportation, if sensitive information is shared or released [36]. As such, no personal health information was collected during the survey beyond what was requested in the inclusion criteria. A study ID was assigned to each participant to retain anonymity (Recruiter 1, Recruiter 2, Patient 1, Patient 2, etc.). If the participant chose to volunteer to complete the one-on-one telephone interview following the survey, only contact information was requested: email and/or phone number. At the end of the study, participant contact information was deleted.

3.2.4.3 Risk for participation

Confidentiality was maintained throughout the study as described above. As participation was entirely voluntary, if a patient or recruiter felt as though they were experiencing any risk from participation, they were free to withdraw from the study at any time. This was communicated in the informed consent information at the onset of participation. No participant reported unforeseen issues or emotional upset during or as a result of their involvement within the study.

3.2.4.4 Reporting of adverse events

No participant reported an adverse event as a result of study involvement, however if they had, the incident would have been reported immediately to the P.I., the dissertation committee, and the VUMC IRB. Each participant was provided with the contact information to the VU IRB Office should they have concerns regarding personal rights of participation or any other study-related questions or thoughts.

3.2.4.5 Study withdrawal

Participation in the study was voluntary, and participants could withdraw from the study at any time. No participants chose to withdraw during the one-on-one interviews.

3.2.4.6 Secure data storage.

Completed surveys were downloaded from a secure, web-based database and uploaded to a secured Vanderbilt University research network file on Box. Qualitative interview transcripts and coding documents were placed within a secure file on Box. The data will be kept in the Box file and maintained by the P.I. for the required ten years. At that time, all data will be destroyed.

3.3 Data Collection Methods

3.3.1 Study Overview of Procedures

An embedded, mixed-methods cross-sectional study was conducted to examine the perceived barriers and facilitators to participation as described by both patients and recruiters. Data were secured and managed via a REDCap® electronic data capture tool hosted by Vanderbilt University [44, 65]. REDCap® is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources [44, 65]. The web-based survey was followed by an optional semi-structured one-on-one telephone interview, meant to capture additional barriers and facilitators not addressed in the survey instruments.

3.3.2 Instruments

3.3.2.1 Demographic questionnaire (Appendix B)

Sample characteristics were secured through a demographic questionnaire. Data requested included age, gender, ethnicity, race, country of origin, and preferred language. Patients were asked about a history of a previous or current diagnosis of cancer, along with two additional questions regarding history of clinical trial participation ("have you ever been recruited into a cancer clinical trial?" and "have you ever participated in a cancer clinical trial?"). This additional information was utilized to provide further description of the patient participants. Omitting questions about prior clinical trial experience was noted as a limitation in a study utilizing the scale; therefore, it was added here to strengthen the insight provided by the scale itself [40].

3.3.2.2 Barriers to Clinical Trial Participation (BCTP) Scale (Appendix C) [40].

The BCTP was used to assess clinical trial participation barriers among the patient population. It is a 19-item 5-point Likert scale (1 = strongly disagree to 5 = strongly agree) that is comprised of four subscales: lack of personal benefits, lack of community support, mistrust, and lack of familiarity with clinical trials; and yields a total score for each of the subscales, with a high score of 25 per subscale. Higher scores reflect greater perceived barriers. The scale was validated in a minority population, and forward and back-translated in Spanish with reconciliation. The scale has good internal consistency, with an overall Cronbach's alpha of 0.89 [40]. Moderate internal consistency was previously reported among the four subscales ranging from 0.59-0.78, with Cronbach's alphas of 0.60 (lack of personal benefits), 0.59 (lack of community support, 0.74 (mistrust), and 0.78 (lack of familiarity with clinical trials) [40]. In the current study, the scale continued to show good internal consistency, with an overall Cronbach’s alpha of 0.93, and subscale Cronbach readings of 0.90 (lack of personal benefits), 0.80 (lack of community support, 0.80 (mistrust), and 0.74 (lack of familiarity with clinical trials).

3.3.2.3 Tanner Questionnaire (Appendix D) [30].

The Tanner questionnaire was developed to examine clinical trial recruiter experience and gain their perceptions of barriers to the recruitment of South Carolinian African American and rural communities. The questionnaire includes demographic questions, questions regarding recruitment techniques, and those regarding perceived barriers. The questions addressing perceived barriers are measured as a base 12 item, 5-point Likert (1 = strongly disagree to 5 = strongly agree) grouping that is asked separately for each population of interest. An ordinal measure for each of these 12 Likert-scale items is reported separately. No subscales exist within these 12 items. The developers have not disclosed psychometrics on the questionnaire, only noting in the one study it was used that it was developed from the

extensive literature on barriers to clinical trial participation [30]. In the absence of this psychometric data, its successful use in the original study provided face validity and feasibility of its use for the currently proposed study [30].

As the questionnaire was not originally developed to secure perceptions regarding the Hispanic population, the perceived barriers to Hispanic participation questions were added as a modification to the original questionnaire (Appendix D). The P.I. reproduced the same questions used on the instrument for the other populations (African American, rural) and added the Hispanic population heading for clarity. Additionally, since the questionnaire was sent to recruiters outside of South Carolina, and maintaining participant anonymity was essential in this study, the following question was removed: "which medical/academic center(s) are you primarily affiliated with," and replaced with "which type of healthcare or research institution are you currently affiliated with?"

3.3.2.4 One-on-one semi-structured interviews (Appendices E)

Semi-structured interviews were conducted with participants from each group, patients and recruiters. The interview guides were translated into the participants' preferred language, English or Spanish. The interviews addressed facilitators and additional barriers not measured by the BCTP scale (organizational and policy) or Tanner questionnaire (organizational) and were designed to explore the participants' perceptions of their experiences. This qualitative data added to the information collected from the quantitative measures to provide a robust account of the current barriers and facilitators to clinical trial participation among Hispanic oncology patients.

3.3.3 Protocol for Data Collection and Management

3.3.3.1 Procedure: Quantitative data collection

After VU IRB and SRC approval was obtained, participants were recruited for the study. Participants were directed by the participant link to the REDCap® site respective of their sample (patient or recruiter) to complete the Informed Consent. The Informed Consent and all study items were available in English or Spanish to patient participants, to facilitate understanding in the participant's preferred language. Materials were provided in English to the recruiter participants, as the survey instrument for this population have yet to be translated and validated in other languages.

Upon completion of the Informed Consent, the participant was asked Inclusion/Exclusion Criteria via a Screening Questionnaire to determine eligibility. If eligibility was met, the participant was provided with a survey for completion based on their respective participant group (patient or recruiter). In both sets of surveys, demographics were collected. Two additional questions were asked of the patient group regarding history of participation in clinical trials. Patients were then prompted to complete the BCTP scale. Recruiters completed the Tanner questionnaire following the demographic data.

Following the completion of their respective REDCap® survey, each participant (patient or recruiter) was provided information describing the qualitative component of the study and asked if they would consider participating in an optional, brief one-on-one semi-structured interview via telephone and why this additional information was needed. If they chose not to participate in the interview, their survey responses were saved, and the P.I.'s contact information was provided for any further questions or concerns. The participant provided a preferred email address to send the $25 e-gift card as a thank you for their time and participation.

3.3.3.2 Procedure: Qualitative data collection

If the participant chose to continue, contact information (phone number and/or email address), and preferred language was requested to set up the telephone interview at a mutually convenient time. The participant was contacted, and the interview scheduled. Upon completion of informed consent, recorded telephone interviews were completed with the P.I. Recording was completed with a handheld recorder placed near the telephone to ensure both parties were recorded clearly for transcription purposes. The interviews took no longer than 15 minutes. Once completed, the participant was provided the P.I.'s contact information for any further questions or concerns and asked their preferred email address for the appreciation $25 e-gift card to be sent for their participation.

Recordings of the telephone interviews were uploaded to a secured password-protected Vanderbilt University research network file on Box. Once uploaded securely, they were deleted from the handheld recording device and sent to the Vanderbilt Qualitative Core to be sent to Rev.com for transcription via a secured network. Upon receipt of the transcription, the P.I. matched the transcription to the recording to ensure transcription was correct. Upon validation of the transcript, member checking was conducted post-transcription for accuracy and clarification. The P.I. made any corrections on behalf of the participant and resent for approval. Only final approvals were included and uploaded to Dedoose.com for assistance with data management.

Field notes were collected during and after the one-on-one telephone interviews to aide with analysis and researcher reflection to identify and mitigate any potential bias [70]. Field notes served to further increase qualitative rigor.

3.4 Data Analysis

3.4.1 Missing data

In the case of items missed entirely at random, only those with all required items of the BCTP and Tanner questionnaire completed were included in the analysis. No information is currently available regarding validity for either the BCTP or the Tanner scale with component item responses missing nor how to handle randomly missing item responses. Therefore, item responses were required for those measures in the respective REDCap® surveys. Missing responses to other questions (e.g., demographics) were allowed and spoke to the generalizability of the results.

3.4.2 Analysis for aims

Both quantitative and qualitative data were used to address each of the study aims. Descriptive statistics were used to summarize the demographic characteristics of both the quantitative patient and recruiter samples, as well as the qualitative subsamples of patients and recruiters.

3.4.2.1 Aims 1 and 2

3.4.2.1.1 Quantitative

Descriptive statistics were used to summarize the subscales of the BCTP patient measure. If normally distributed, mean and SD were used; if not, median and IQR. Frequency distributions and median (IQR) were used to summarize the responses to the respective items on the Tanner questionnaire.

3.4.2.1.2 Qualitative

Semi-structured interview transcripts and field notes were used to analyze the qualitative data from both the patients and recruiters. Inductive content analysis was utilized to identify emerging themes [62]. Inductive content analysis is better suited for research with little to no previous studies, indicating this method was appropriate for this study [62]. Data organization and management was accomplished using the Dedoose.com software [74].

Two coders, the P.I. and an analyst consultant with over 20 years of qualitative analysis experience, had their own login to the system and independently coded for comparisons to ensure consistency.

Using content analysis, the first level analysis involved reading the transcripts followed by two coders deriving broad codes independently. A code book containing 22 codes was developed (Appendix F). Upon completion of the broad codes and using an iterative process, the coders met to discuss and reach consensus on the assigned code groups. The second and third level of analysis reconceptualized the code groups into broader, higher-order categories, to provide more meaning and description. Finally, the categories, through abstraction, were reinterpreted as salient themes, validated by participants' quotes [62]. This intercoder agreement between the P.I. and qualitative research consultant increased reliability of the interpretive coding process. Excerpts of codes, categories, and themes (Appendix G) as well as coding frequencies as reported by Dedoose.com, an app for analyzing qualitative data [74] are attached (Appendix H). Coding frequencies were utilized to determine the weight in which each barrier or facilitator carried as described by patients and recruiters (Appendix H) .

3.4.2.1.2.1 Qualitative Rigor

Rigor was established following Lincoln and Guba's evaluative criteria of credibility, confirmability, transferability, and dependability [61]. Trustworthiness was established when the results provided a rich description of the experience that is corroborated by the participants. Credibility was established by member checking to validate that; indeed, researcher interpretations had been corroborated by the participants as accurate and that the research did not silence or marginalize their voice. Additionally, interviews, audio recordings, and the transcripts, served to validate the other, ensuring that the data were

representative of their experiences. Confirmability was addressed by congruence among two people about the accuracy, relevance and meaning of the data. It was further enhanced through clear description of the analysis. Transferability was addressed through a clear description of the research process and thick, rich description of the findings, enabling the reader to transfer information to other like populations and settings. The breadth of understanding was strengthened further by including participants of varying ages, genders, cancer histories, geographic locations, and recruitment experiences (recruiters). Field notes were recorded by hand during and after each interview to enhance replicability, which served to strengthen dependability. Field noted included P.I. insights, notes, impressions, and were reviewed for relevance to the study data. Interviews were conducted by the P.I. to ensure procedure consistency and protocol compliance throughout the study.

Reflexivity was addressed by the P.I. by reflecting on personal past experiences with the study topic and how they may have shaped interpretations. As a previous oncology nurse and Hispanic female, I have cared for Hispanic oncology patients who, by their accounts and perceptions, were not provided the treatment opportunities as others in their position. These concerns fueled my interest in the topic of healthcare inequities among the Hispanic oncologic population and the need to examine perceptions of care and treatment. While I cannot forget these interactions and their impact on me and my research interest, I had to ensure that they did not cloud my judgement throughout the study. I maintained an open mind and reported the perceptions as they were presented. Interpretations of the data were made with reflection to previous literature and field notes were kept to remind me of the potential bias I may bring, as an individual that has personal connections with the population being studied. Additionally, I had frequent meetings with two faculty advisors and

conducted robust discussions to ensure I was not injecting bias during the research and analysis process.

3.4.2.2 Aim 3

To examine the convergence of the patient and recruiter reports of the relative importance of the barriers to clinical trial participation, each respective type of barrier received a rank value within each sample. For example, if the scores on the lack of mistrust subscale on the BCTP were the 3rd highest of all the subscale scores for the sample, then that subscale received a value of "3". The item responses for the respective types of barriers on the Tanner questionnaire were ranked in similar fashion for the recruiters. For example, "patients lack confidence in medical research" is the respective item on the Tanner questionnaire for the "mistrust" subscale on the BCTP.

Following the quantitative ranking, the qualitative and quantitative data sets were merged for each sample group. This data were then utilized to analyze complete data convergence and divergence between sample groups.

3.4.3 Sample size justification

This was not a hypothesis-testing study and thus, the quantitative sample sizes were based on the number of participants (patients and recruiters) that were expected to be recruited during the proposed study timeline (see sample recruitment section above). The qualitative sample sizes were based on sample sizes for data saturation recommendations in the literature and findings from qualitative investigators including those conducted in the Hispanic population [14, 21, 28-30, 33-37].

CHAPTER 4

Results

4.1 Sample Characteristics

4.1.1 Patient sample

Of the individuals solicited for enrollment in the study, a total of 95 individuals accessed the RedCap® surveys. Eighty-seven accessed the English version of the survey, while 8 accessed the Spanish version. Of the 87 who accessed the English version, one individual opened the survey but completed nothing, two individuals did not meet inclusion criteria, and four failed to continue the survey following completion of the demographic questions. Of the 8 individuals who accessed the Spanish version, one individual opened the survey but completed nothing, one individual failed to continue following the screening questions, and one failed to continue following completion of the demographic questions. Therefore, the analysis sample for the patient group is comprised of 85 participants (80 from the English version, 5 from the Spanish).

The demographic characteristics of the analysis sample are summarized in Table 4.1.1. The median age for the sample was 52 years (N=84, IQR 46-56). Slightly more males (56%) than females (43%) participated in the survey and approximately 84% (n=71) participants self-reported as White or Caucasian. All participants were Hispanic, with the majority reporting as Mexican, Mexican American or Chicano (68.2%, n=58). Sixty percent (n=51) reported that they had been recruited into clinical trials in the past, yet only 30.6% (n=26) stated that they had participated in clinical trials.

Table 4.1.1 Patient sample characteristics (N=85)

	N	%	Median	IQR
Age	84		52	46, 56

Gender				
Male	48	56.5		
Female	37	43.5		
Ethnicity				
Black or African American	1	1.2		
White or Caucasian	71	83.5		
Other	13	15.3		
Hispanic				
Mexican, Mexican American, Chicano	58	68.2		
Puerto Rican	15	17.6		
Cuban	8	9.4		
Another Hispanic, Latin(x), or Spanish Origin	4	4.7		
American Spaniard	1	1.2		
Brazilian	1	1.2		
Dominican	1	1.2		
Panamanian	1	1.2		
Preferred Language	84			
English	70	83.3		
Spanish	14	16.7		
Fluent in Spanish?				
Yes	50	58.8		
No	35	41.2		
Recruited into cancer clinical trials				
Yes	51	60.0		
No	34	40.0		
How did you hear about clinical trial?	51			
Oncologist	24	47.1		
Primary Care Provider	13	25.5		
Another Medical Provider	5	9.80		
A friend	9	17.6		
Participated in cancer clinical trials				
Yes	26	30.6		
No	59	69.4		

4.1.2 Recruiter sample

Of the recruiters solicited for enrollment in the study, a total of 56 at least opened the RedCap® survey. Of those 56, three individuals completed nothing, 15 individuals did not meet inclusion criteria, and eight failed to complete anything beyond the demographics or did not complete the scale used for analysis. Therefore, the analysis sample for the recruiter

group is comprised of 30 participants.

Demographic characteristics of the 30 recruiters are summarized in Table 4.1.2. The median age for the sample was 37 (IQR 33-52). The majority of participants were female (80%, n=24) and more than half self-reported as White or Caucasian (60.0%, n=18) Approximately two-thirds of the recruiters were not Hispanic (67%, n=20) while those who reported being Hispanic were almost dispersed evenly among country of origin. The majority of the sample was not fluent in Spanish (63%), while the other 37% were.

Table 4.1.2 Recruiter sample characteristics (N = 30)

	N	**%**	**Median**	**IQR**
Age	30		37	33, 52
Gender				
Male	6	20.0		
Female	24	80.0		
Ethnicity	29			
Native American/Native Alaskan	1	3.45		
Asian	4	13.8		
Black or African American	1	3.45		
White or Caucasian	18	62.1		
Other	5	17.2		
Hispanic				
No	20	66.7		
Yes, Mexican, Mexican American, Chicano	2	6.7		
Yes, Cuban	2	6.7		
Yes, Another Hispanic, Latin(x), or Spanish Origin	5	16.7		
Colombian	2	6.7		
Salvadorian	2	6.7		
Spanish-Brazilian	1	3.3		
Preferred Language				
English	27	90.0		
Spanish	3	10.0		
Fluent in Spanish				
Yes	11	36.7		
No	19	63.3		

4.2 Quantitative Analysis

Results from the BCTP scale, reflecting the patients' perspective on barriers to clinical

trial participation, are summarized in Table 4.2.1. The higher the score, the greater the perceived barrier to participation. The scores range from 1-5, with 5 being the highest. Perceived barriers scores were highest for mistrust (median 3.0, IQR 2.4-3.2), followed by the lack of familiarity subscale (median 2.8, IQR 2.0-3.0), lack of personal benefits subscale (median 2.5, IQR 1.7-3.0), and finally lack of community support subscale (median 2.3, IQR 1.6-3.0).

Summaries of responses to the Tanner survey, reflecting the recruiters' perspective on barriers to clinical trial participation, are summarized in Table 4.2.2. The higher the score, the greater the agreeance with the statement. Of the 12 items, a patient's lack of knowledge about the idea of clinical trials (median 4.0, IQR 4.0-5.0) scored the highest as a perceived barrier among the recruiter population. That was followed closely by a patient's lack of information about available trials (median 4.0, IQR 4.0-4.3), a patient's fear of participating in clinical trials (median 4.0, IQR 3.0-5.0), a patient's negative perception about clinical trials (median 4.0, IQR 3.0-5.0), and a patient's lack of confidence in or distrust of medical research (median 4.0, IQR 3.0-5.0). Unwillingness of local physicians/doctors to engage in accrual was the lowest perceived barrier among the group (median 3.0, IQR 2.0-4.0).

Median patient reports via the BCTP were ranked from highest to lowest; as were the individual line items from the Tanner scale that measured similar variables. These ranks are shown in Table 4.2.3 in order of greatest to least perceived barrier to clinical trial participation. Although patients perceived mistrust (median 3.0, IQR 2.4-3.2) as the greatest barrier, recruiters perceived lack of familiarity (median 4.0, IQR 4.0-5.0) as the greatest barrier to participation. Patients perceived lack of familiarity (median 2.8, IQR 2.0-3.0) as the second highest barrier, while lack of personal benefit (median 4.0, IQR 3.0-5.0) fell second for the recruiter group. Lack of personal benefit (median 2.5, IQR 1.7-3.0) was

ranked third for the patient group, while mistrust (median 4.0, IQR 3.0-5.0) ranked third among the recruiters. Lastly, lack of community support was ranked last as a barrier for both patients (median 2.3, 1.6-3.0) and recruiters (median 3.0, IQR 2.0-4.0).

Table 4.2.1 Hispanic cancer patients' perspectives on barriers to clinical trial participation, using the BCTP Scale (N=85)

	Median	IQR
Personal Benefit	2.5	1.7, 3.0
Community	2.3	1.6, 3.0
Mistrust	3.0	2.4, 3.2
Familiarity	2.8	2.0, 3.0
Total Score	2.8	2.0, 3.0

Table 4.2.2 Clinical trial recruiters' perspectives on barriers to clinical trial participation, using the Tanner measure (N=30)

	Median	IQR
Patients lack knowledge about the idea of clinical trials	4.0	4.0, 5.0
Patients lack information about available trials	4.0	4.0, 4.3
Patients have fear of participating in clinical trials (i.e., fearful about something untested, fear of randomization)	4.0	3.0, 5.0
Patients have negative perceptions about clinical trials (i.e., I will be treated like a guinea pig)	4.0	3.0, 5.0
Patients lack confidence in or distrust medical research (i.e., historical abuses of research participants)	4.0	3.0, 5.0
Patients have limited accessibility to trial sites	4.0	3.7, 4.3
Patients have low literacy or low health literacy	4.0	3.0, 4.0
Patients' insurance will not cover clinical trials procedures or drugs	4.0	2.7, 4.3
Local physicians/doctors are unaware of ongoing trials	4.0	2.7, 4.0
It is difficult to find potential participants	3.5	2.0, 4.3
Patients desire other treatments	3.0	2.0, 4.0
Local physicians/doctors are unwilling to engage in accrual	3.0	2.0, 4.0

Table 4.2.3 Barrier comparisons between patient and recruiter groups

Rank	Patients			Rank	Recruiters		
	Barrier	Median	IQR		Barrier	Median	IQR
1	Mistrust	3.0	2.4, 3.2	1	[Familiarity] "Patients lack knowledge about the idea of clinical trials"	4.0	4.0, 5.0
2	Familiarity	2.8	2.0, 3.0	2	[Personal benefit] "Patients have negative perceptions about clinical trials	4.0	3.0, 5.0

					(i.e., I will be treated like a guinea pig)"		
3	Personal benefit	2.5	1.7, 3.0	3	[Mistrust] "Patients lack confidence in or distrust medical research (i.e., historical abuses of research participants)"	4.0	3.0, 5.0
4	Community	2.3	1.6, 3.0	4	[Community] "Local physicians/doctors are unwilling to engage in accrual"	3.0	2.0, 4.0

4.3 Qualitative Analysis

Of the 85 patient participants completing the survey portion of the study, 4 completed one-on-one interviews in English. Of the 30 recruiter participants that completed the online survey, 15 participated in one-on-one interviews. Saturation was achieved at 4 patient interviews and at 8 recruiter interviews.

4.3.1 Patient themes

4.3.1.1 Theme 1: Inclusivity

The theme "inclusivity" comprises barriers and facilitators a patient may experience related to access to cancer clinical trials. The theme addresses the organizational concept in the proposed framework, as it discusses factors assisting or inhibiting a patient from enrolling in clinical trials stemming from institutional guidelines or study constraints. Patients describe transportation, clinical trial scheduling, perceived affordability, and meeting inclusion criteria as potentially problematic to their participation.

Patients voiced concerns about transportation, stating trials need to be "easily able to get to." Further, patients suggested that a trial should have flexible scheduling, because if it "interferes too much with [their] work schedule" it would make it "hard" to participate. Patients also voiced concerns regarding perceived affordability of clinical trial involvement.

Patients were concerned with potential out-of-pocket fees and believe trials made available to those with lower incomes would improve participation. Lastly, patients also mentioned the need for inclusion criteria improvement. Patients perceive clinical trials aren't being discussed or "offered" due to their cancer stage or because English is not their primary language. Patients voiced:

> *"I probably would have been open to them [clinical trials] but, again, it's just no one is reaching out to you in the cancer center, or it's not even a topic of conversation at the oncologist. Perhaps it was because I was stage one and not something like stage four…" (Patient 1)*
>
> *"…I don't think because of the language barriers that a lot of people are asked…" (Patient 3)*
>
> *[When asked about facilitators to participation]: "Yeah, that it probably wouldn't cost a whole lot out of my pocket" (Patient 3)*

4.3.1.2 Theme 2: Trial education and understanding

The theme "trial education and understanding" includes barriers and facilitators a patient may experience related to knowledge and comprehension of the clinical trial process that facilitates making an informed decision on participation. This theme addresses the intrapersonal concept within the proposed framework, as it discusses factors that stem from personal knowledge, attitudes, or characteristics. Two subthemes emerged during analysis for this theme: (a) knowledge, familiarity, and understanding, and (b) literacy.

Knowledge, familiarity and understanding describes the patient's comprehension and acquaintance with the purpose, process, and protocols involved with clinical trial participation. Patients discussed not knowing what clinical trials were, how to "become part of a trial," and not having information regarding the "efficacy rates for [their] specific

culture." Patients further described their comprehension of the clinical trial process by stating:

> *"I know that they are out there, however, I don't know how I would become part of a trial" (Patient 1)*
>
> *"I don't really know a whole let about them. I know the NIH is usually the one that I know if they have any clinical trials going on is the company that would do them…" (Patient 3)*

Literacy describes the patient's ability to read and understand information regarding the clinical trial. Patients expressed concern for the literacy level of older Hispanics, as they feel they have more trouble reading and completing clinical trial paperwork. One patient stated:

> *"…the older Hispanics, they're not quite as literate. So yes, you might be able to give them a piece of paper to read, but if they can't read, then they're not going to tell you they can't read unless you can sense from them, especially in their own language…" (Patient 3)*

4.3.1.3 Theme 3: Trust in trials.

The theme "trust in trials" encompasses the patient's confidence, or lack thereof, in any part of the clinical trial participation experience. This theme discusses factors assisting or inhibiting a patient from enrolling in clinical trials that stem from the patient-provider or patient-recruiter relationship, thus addressing the interpersonal concept in the proposed framework. Aspects aiding consideration to participate in clinical trials are included, as these may help build and promote trust in the process. Thus, the theme also addresses the intrapersonal domain of the SEM, with factors stemming from personal knowledge, attitudes, or characteristics. Three subthemes emerged during analysis: (a) trust, (b) gaining trust, and (c) participation consideration.

Trust describes a patient's confidence in the research process, to include the study protocol, recruiter, or provider. The patients described Hispanics "associat[ing] danger" with clinical trial participation, not trying new treatments because of lack of confidence, as well as having past history clouding their confidence in the process. A participant noted how confidence in clinical trials was broken by past history:

> *"… [A family member] ended up passing away from leukemia and she had participated in a clinical trial. My family kind of blamed that for it. I think it's a lot of just association with something traumatic…" (Patient 2)*

Gaining trust describes the activities that can be done to increase and maintain a patient's confidence in the research process. Patients stated that receipt of clinical trial information from a trusted source, such as their oncologist, would make them more willing to participate in clinical trials. Additionally, having someone review the clinical trial process in detail, in "layman's terms," helps with confidence in the process, comprehension, and willingness to participate. Patients appreciate follow up and help from recruiters and coordinators throughout the clinical trial process. Patients noted:

> *"Possibly something that would prevent me is not getting the information from my oncologist…" (Patient 1)*
>
> *"I did end up doing the clinical trial. I did it because a nurse at [name of facility removed for anonymity] helped explain the packet…she kind of broke it down for me in layman's terms…" (Patient 2)*
>
> *"…cancer patients are really overwhelmed. Just know that there's so many things going on, so many moving pieces…having people reach out and just follow up and make sure that it's kind of in the back of their mind, because there's so many other things going on…" (Patient 2)*

Participation consideration describes factors that patients may find helpful in building confidence in participation. Patients often review the risks and benefits to participation, which help build confidence in the clinical trials process. Patients described reviewing personal benefits to participation, benefits to other Hispanics, clinical trial incentives, efficacy of treatment and treatment type. Patients viewed perceived personal benefit in participation "to help [themselves]," benefit to others to "stop them from getting sick too," and efficacy in treatment with minimal invasiveness of procedures, as important factors to increase confidence in clinical trials. If a treatment's efficacy is low, questionable, or involves more invasive procedures, confidence in the treatment and clinical trial is diminished. Participants voiced:

> *"…if I felt the treatment that I was given wasn't going to work or was questionable, then I would want to try something else…" (Patient 1)*
>
> *"Some possible side effects would turn me off depending on what it is, if it was too broad of a treatment…" (Patient 3)*
>
> *"Any kind of invasive treatment or too invasive would probably not make me want to do it." (Patient 3)*

4.3.1.4 Theme 4: Instrumental communication.

The theme "instrumental communication" comprises the processes surrounding the utilization of language and languages services during the clinical trial process. Since this theme discussed factors that could assist or inhibit a patient from enrolling in clinical trials stemming from communication techniques between two or more entities, it addresses interpersonal concept in the proposed framework. Two subthemes that emerged from the interviews were: (a) translated materials, and (b) translator availability or deficit.

Translated material includes any documentation regarding or referring to any part of the clinical trial process in written form, to include marketing materials, protocols, trial documentation and informed consents. Participants were unaware of any bilingual written documentation offered describing clinical trials. Being able to read trial materials "in their own language" could facilitate recruitment efforts. Participants stated:

> *"…I feel like Spanish forms and flyers are huge. Having things translated into Spanish so that they understand is a big one. Just access to those information packets that typically aren't there. They're usually just in English…I think access to information is key…" (Patient 2)*
>
> *"…having information set in a bilingual way so that if there is a lack of English understanding, they can read it in their own language." (Patient 1)*

Translator availability or deficit is defined as a patient's access to translator or interpreter services during the clinical trial process. Patients described the need for interpreter services to ensure understanding of all clinical trial procedures. The availability of interpreter services was described as "hit or miss." Patients indicated:

> *"…they don't understand quite everything that's going on and they really need somebody to get them to get the whole gist of what's going on and what might happen…" (Patient 4)*
>
> *"…a lot of the Spanish speaking patients…only understand what they are either agreeing to or agreeing not to do and they don't fully, really, really comprehend the studies or the treatment…"*
>
> *(Patient 3)*

4.3.2 Recruiter themes

4.3.2.1 Theme 1: Inclusivity

The theme "inclusivity" from the recruiters' perspective comprises barriers and facilitators a patient may experience related to access to clinical trials. As with the theme discussed in the patient sample, this theme addresses the organizational concept in the proposed framework. In addition to describing the organizational concept, it adds factors assisting or inhibiting a patient from enrolling in clinical trials stemming from public policy guidelines. Therefore, the policy concept within the proposed framework is addressed as well. Three subthemes emerged from the analysis: (a) trial accessibility, (b) policy qualifiers, and (c) organizational operations.

Trial accessibility is described as factors related to transportation to and from the clinical trial site, flexibility in scheduling of clinical trial procedures, perceived affordability, and meeting inclusion criteria to participate. Recruiters described location of the nearest clinical trial as a barrier to participation, as patients cannot secure transportation to attend visits required for the trial. Recruiters stated that having telehealth visits in lieu of in-person visits could assist in mitigating this common barrier. Also noted was increased flexibility in scheduling would assist with competing responsibilities, such as childcare. Recruiters stated securing reliable childcare was a great concern of their Hispanic participants. Recruiters voiced:

> *"…access in general is really bad, and with them cutting down all the bus lines…coming into downtown is a very difficult thing for people to do…because there's not really a direct route that direction…" (Recruiter 10)*
>
> *"…the biggest thing that studies can do to increase participation, is have some sort of, even if it was like a few visits or a telehealth visit…it's much easier for us*

to call them at home than them come to the hospital for an appointment…" (Recruiter 6)

"… a lot of my patients just say "Oh, I have no childcare. I have no ride to get there." A lot of my patients take public transportation to get to their appointments…" (Recruiter 6)

"…very, very limited time points. So, if a time point is very structured and it's very strict, it really, really hinders almost the eligibility of the patient. If we don't have a patient that has transportation, or means to get to the hospital, and they have to be here within one week, it really, really makes it more difficult…" (Recruiter 6)

"…access to the medical center…I see that a lot of Hispanics that go to small clinics in the community and usually those clinics are not involved in research…" (Recruiter 12)

Inclusion criteria can act as a barrier to clinical trial participants, as recruiters indicated that many studies require participants to be English-speaking. Even if the patient meets medical criteria to participate in the study, they are excluded due to not meeting primary language criteria. Recruiters stated:

"…when they want to participate, the trial is offered in English and the trial says, "Only for English-speaking participants". That immediately excluding the non-speaking English participants and that's very sad..." (Recruiter 11)

"…Some of the clinical trials are not open for Latinos, so limitations in inclusion of Latinos in clinical trials; because those trials has to be translated in Espanol and they have to be approved by the IRB and they have to hire staff." (Recruiter 11)

"…I think that the only thing that's really harmful for some of my studies, is some of the studies are literally only for English speaking patients. And that's not through any fault of the patients or anything like that. It's just based on resources that the programs have, or something like that. So maybe there's a call center and the call center may not have any Spanish speaking employees. And when that happens, I can't obviously enroll any patients that don't completely understand the English language…" (Recruiter 8)

Lastly, perceived affordability and insurance coverage may act as barriers to participation. Recruiters mentioned insurance coverage may limit inclusion to a study due to policy specifics. However, they also note that Medicaid and Medicare are more apt to cover research expenses. There is concern for those without insurance coverage, as some expenses are expected to be paid by the participant's insurance plan, thus creating an extensive out-of-pocket expense for those without. Recruiters voiced:

"…a lot of our patients, especially that are local patients, there's no insurance barriers or anything like this. Especially since a lot of patients on Medicaid or Medicare here. And those ones are very open for research, I've found…" (Recruiter 8)

"…once you go through everything and you find out that they don't have insurance and that max them out from coming here, because the only thing that's covered by the study is usually only if it's an investigational drug. Everything is expected to be paid for by the patient's insurance…" (Recruiter 5)

"…unfortunately, with our institution, we just have certain insurances that we're allowed to take here…" (Recruiter 4)

"…if the government would provide free access, I mean, would at least make them to feel like they have access to hospitals when they need, not only case of ER visits. That would be more helpful…" (Recruiter 12)

Policy qualifiers describes a participant's citizenship or immigration status. Recruiters discussed how immigration or citizenship status were barriers to participation due to the patient's concern of anonymity. However, recruiters noted if the study qualifies for social security exemption, these barriers are mitigated as participants can retain their anonymity regardless of legal status. Recruiters described:

"…minority and rural populations seem to be much more apprehensive about sharing their Social Security number with the research team. But I know there are exceptions in place. There's a team at the medical center that does Social Security exemptions for research studies...So I know there are ways around it…" (Recruiter 9)

"…being able to serve the undocumented community would be really helpful as well I think, without them being afraid to access care…" (Recruiter 10)

"…I mean, I've been in situations where maybe they're not U.S. citizens, and they are very standoffish...they don't want to give you any information that could get them into trouble…" (Recruiter 1)

Organizational operations indicate the culture of an organization and institutional guidelines that may promote or inhibit participation from the Hispanic oncologic population. Recruiters noted some institutions may be "better equipped" to handle diverse populations and thus are more successful in securing participants for clinical trials. For example, having diverse, culturally competent employees assisting the population makes the organization

more inviting to participants. Patients need to be familiar with and trust the institution where the clinical trials are being completed to consider participating.

> *"…when this information is coming from an organization that they know and trust, even if it's a very small organization, that's going to hold a whole lot more weight…" (Recruiter 13)*
>
> *"…it's Caucasian that comes in here most of the time, and I feel like that's threatening when a minority population walks in, and everybody they see is Caucasian. All the doctors are Caucasian…" (Recruiter 1)*
>
> *"…the mentality of the teams that have been focused in clinical trials for so many years - only including whites - has to change too. So it's not only the community that we need to change or the engagement, it's the internal system that we have…has to be a little bit more open, open train, have more resources, more financial resources to be able to include the community input a little bit more…" (Recruiter 11)*

4.3.2.2 Theme 2: Trial education and understanding

The theme "trial education and understanding" from the recruiters' perspective includes barriers and facilitators a patient may experience related to the knowledge or comprehension understanding of the clinical trial process that may facilitate making an informed decision on participation. This theme discusses factors assisting or inhibiting a patient from enrolling in clinical trials that stem from the patient-provider relationship, patient-recruiter relationship, personal knowledge, attitudes, or characteristics. Therefore, it addresses both the intrapersonal and interpersonal concepts of the proposed framework. Three subthemes emerged during analysis for this theme: (a) knowledge, familiarity, and understanding, (b) literacy, and (c) effective communication.

Knowledge, familiarity and understanding describes the potential participant's comprehension and acquaintance with the purpose, process, and protocols involved with clinical trial participation. Recruiters noted that many potential study participants do not know clinical trials exist or do not completely comprehend what clinical trials are, so they have greater hesitancy to participate. It was voiced if more education was available to patients, including relevant marketing to the population, patients may be more "accepting once they understand it more". Recruiters went on to state:

> *"…. I think just getting the knowledge out there about research and clinical trials is the most beneficial…" (Recruiter 3)*
>
> *"…And those minority populations don't even know research exists, so that isn't an option to them…" (Recruiter 3)*
>
> *"…Another thing that I believe would be very helpful in general, if the TV shows, especially related for the Spanish population, they would have a space just talking about research…" (Recruiter 12)*
>
> *"They just don't understand what we're going to be doing" (Recruiter 1)*

Literacy describes the patient's ability to read and understand information regarding the clinical trial. Recruiters stated the patient's ability to make an informed decision on participation could be impaired due to poor understanding of healthcare and treatment options. Translation services can assist but including family members as conversation facilitators improved this barrier. Recruiters stated:

> *"…if they're older and a child can't come with them, that usually facilitates their decision-making, they just think, "Well, let me just say no, because my child isn't here to help me decipher if I should do this or not"… (Recruiter 7)*

"…her health literacy was low and she was alone in the clinic and didn't have her daughter with her...I called the patient with a Spanish translator outside of the clinic and offered to three-way call her with the daughter, that way we could all have a discussion…" (Recruiter 7)

Effective communication describes the way the participant is provided information regarding the clinical trial to ensure understanding of the process. Potential participants need to understand and confirm that clinical trials aren't just "experiments" on them. Clear communication, at their level of understanding, facilitates the clinical trial participation process. Recruiters stated:

"If the study is not very well defined, and if the study has a lot of jargon that we have to go over, that is very difficult for others to understand... It makes them shy away from it. If it's not something that they're fully on board with, and that they fully understand completely, they're just going to run away from it…" (Recruiter 6)

"…help them understand that we're not doing experiments. This is what's been conveyed to me personally on numerous occasions. We're not doing experiments on them because they're Hispanic. We're not using them because we don't want to use a white person. We're doing it because we need to know that it works in all populations not just in the white population…" (Recruiter 9)

4.3.2.3 Theme 3: Trust in trials

The theme "trust in trials" from the recruiters' perspective encompasses the patient's confidence, or lack thereof, in any part of the clinical trial participation experience. This theme discusses factors assisting or inhibiting a patient from enrolling in clinical trials that stem from the patient-provider or patient-recruiter relationship, thus addressing the

interpersonal concept in the proposed framework. Aspects aiding consideration to participate in clinical area included, as these may help build and promote trust in the process. Thus, the theme also addresses the intrapersonal concept, with factors stemming from personal knowledge, attitudes, or characteristics. Three subthemes that were similar to the patient group emerged during analysis: (a) trust, (b) building and gaining trust, and (c) participation consideration.

Trust describes the patient's confidence in the research process, to include the study protocol, recruiter, or provider. Recruiters noted that distrust in the health care system still exists within the population, which hinders confidence of the research process, the provider, and the recruiter. Recruiters noted that potential participants have voiced concerns over getting different treatment "because they're Hispanic" or being treated as "test subjects" when dealing with their health. However, recruiters also noted that although there may be trepidation in the population to participate, if there is trust in the provider, the patient was more willing to participate in the study. Recruiters stated:

> *"…Usually, if the doctor talks to them first, they feel more comfortable with... Somehow, they have a lot of trust on the physicians…" (Recruiter 12)*
>
> *"…There's a lot of misconception of research…The common question is what are you going to do with my blood? Are you selling my blood? Why do I have to get blood work? Why do I need to get so many blood works every month or sometimes every week or every two weeks? So, I think it's just that they don't know enough about research. They distrust research and they also have misconception of research too…" (Recruiter 14)*

"…So I don't know if it's because there's some distrust between non-Hispanic and Hispanic communities, that they're not comfortable with a non-Hispanic practitioner…" (Recruiter 10)

Building and gaining trust describes the activities that can be done to promote, increase and maintain a patient's confidence in the research process. Recruiters noted difficulty in developing trust and identified ways to approach potential participants that could help build trust with the population. Recruiters stated that utilizing "culturally appropriate education materials," working with a trusted physician to recruit, and working with patients in their native language facilitate trust building and increase the likelihood of participation. Recruiters further stated:

"…it does take a longer amount of time and it's harder to build a relationship with a patient whenever you don't speak Spanish." (Recruiter 7)

"…one thing that helps with recruitment, no matter what culture you're dealing with, but if you have a physician that's on board…and that physician says, "Hey, this is [name removed for anonymity]. She's going to talk to you about this lymphedema study." That opens the door because it's almost like they trust their doctor. If she's sending you in…That's one foot in the door…" (Recruiter 1)

"…they find out about the study in their culture, whether it's their church, if it's a Jewish population, at their synagogue, whatever, they're just going to be a little bit more trusting…you have to build their trust. That may mean multiple visits, multiple phone calls, handouts, meet with them, before they will ever commit to doing your study. It may be that for the first visit or two, it's just a social visit…" (Recruiter 1)

Participation consideration from the recruiters' perspective describes factors that patients may find helpful in building confidence in participation. Potential participants utilize efficacy of treatment, treatment type, study incentives to participate, altruism, and weigh risks and benefits to treatment to build their confidence in the clinical trials process. Recruiters noted altruism as a facilitator to participation, as potential participants exhibiting altruism reported "support[ing] science" and that "advancing science is good for the community". Treatment efficacy and type can hinder participation as patients will turn down participation if there is a safety concern or if there is an "easier" treatment option that may be less invasive. Lastly, incentives may assist with potential burden of participation, however a recruiter also noted that incentivizing studies makes it seem as though the researchers must "sweeten the pot" for participation, which may cause concern. Recruiters also voiced:

> *"…the main deterrent was really just lack of research in specific to side effects, amongst certain demographics specifically in different races. I have a lot of patients that ask, is side effects increased amongst different populations, Hispanics, African -Americans, etc." (Recruiter 3)*
>
> *"…[Patients state:] No, I'll take the standard of care treatment. I'll take the quote unquote "easier route" and just have this one appointment, where it takes care of my issue, and I'm good to go for six months or a year," whatever it may be…" (Recruiter 6)*
>
> *"…Some women are all for it. And they don't have a lot of barriers, and if they do, they're willing to figure it out if the study is going to be worth their while…" (Recruiter 6)*

4.3.2.4 Theme 4: Instrumental communication

The theme “instrumental communication” from the recruiters’ perspective comprises the processes surrounding the utilization of language and languages services during the clinical trial process. As with the theme from the patient sample, this theme discusses factors assisting or inhibiting a patient from enrolling in clinical trials that stem from communication techniques between individuals, thus addressing the interpersonal concept in the proposed framework. Similarly, two subthemes emerged from the interviews: (a) translated materials, and (b) translator availability or deficit.

Translated material is defined as any documentation regarding or referring to any part of the clinical trial process that is in written form - marketing materials, protocols, trial documentation or informed consents. Several recruiters expressed having translated materials facilitates the recruitment and participation process. Several noted deficits in the availability of translated materials and informed consents, which has caused barriers within the clinical trial process. Further, one participant in the study noted never having seen a Spanish informed consent at their institution. Others noted:

> *“The one thing that I really come across is that a lot of times we don't have a Spanish consent form.” (Recruiter 1)*
>
> *“Well, on the same end, you do see some studies that right when they open they are allowing you to have a Spanish consent, fully translated. If I could think back of sometimes an institutional barrier is we would create a short form and of course, to get things translated, costs money and different times, depending on budget...So when you see a study who has translated the consent, and he has a certificate of translation, that is nice knowing that they've done the legwork for you. And so that does help…a lot of studies will say that it's difficult, again, to*

translate and get the same message across or the same question across…" (Recruiter 15)

"…So sometimes I'll get little extra materials like brochures and stuff like that. And those may only be provided to me in English, whereas if they were possibly in Spanish, that might be a little bit more helpful…" (Recruiter 8)

Translator availability or deficit is defined as a patient's access to translator or interpreter services when needed during the clinical trial process. Recruiters noted difficulty in finding interpreter and recruiter services to facilitate communication with Hispanic, Spanish-speaking participants. Further, if accessible, those services are not always readily available, which causes problems when a patient calls with questions or concerns and the recruiter cannot communicate with the patient. A recruiter expressed witnessing a "loss of enthusiasm" with potential participants when confronted with the issue of limited translation services. Lastly, when translators are available, having a third person now involved in the process can also hinder rapport. Recruiters voiced having a coordinator or recruiter who can speak Spanish is the "ideal situation". Others stated:

"When we don't have, we do need someone that has formal training as an interpreter, which sometime it can be hard to find someone that formally has the title. Our IRB don't allow us to use someone from the staff that is proficient, but don't have the official title as interpreter. That also sometimes is a issue because sometimes we find there's a potential patient right there, but we don't have any interpreters available, so then we miss the patient. I think if we could use someone that could speak Spanish, instead of someone that has formal education as interpreter, that would be helpful as well…" (Recruiter 12)

"I think the best thing that has been implemented already, and that's kind of just where my mind goes, is the use of a translator. If someone in their native tongue, isn't speaking it, like there's not a coordinator that speaks Spanish, for example, as long as there's a translator, I think patients are more inclined. And that was a policy that my institution has put in place, that the patient cannot sign a consent form without someone speaking their own language. And it's really, really helped." (Recruiter 6)

"I've been a cancer researcher for 10 years now. So I've seen a lot of patients over the course of that time, and I had very few Hispanic patients. I know that at my last facility, we didn't have any kind of translation or interpreter department. And so we didn't have the option to have any Spanish speaking patients, so that may have contributed some to that issue…" (Recruiter 10)

4.3.2.5 Theme 5: Community outreach and support

The theme "community outreach and support" encompasses Hispanic engagement, education, and support throughout the clinical trial process. Community can also be described within the Hispanic oncological population into subcommunities, such as religious affiliations and geographical areas. This theme addresses the community concept within the proposed framework, as it describes factors that assist or inhibit a patient's clinical trial enrollment stemming from community resources or the community network. Two main subthemes emerged during analysis of the data: (a) engaging and educating the community and (b) community support.

Engaging and educating the community describes the activities that researchers and recruitment personnel complete to reach the population sought for the studies. These activities can include having speakers in the community, creating community partnerships

with leaders, and completing educational activities with groups to better inform them of the clinical trial process. Several recruiters noted that going out into the community and speaking with the patients about the research, providing them with resources and information, would facilitate clinical trial recruitment. Recruiters felt that more outreach should be completed, noting greater integration into the Hispanic community being needed, along with more work with Hispanic religious communities and community centers. Additionally, recruiters and researchers need to engage and communicate with local human service agencies that the Hispanic community trusts.

> *"…You need to continue being engaged with the Hispanic community…developing those relationships help recruit in any moment for different types of clinical trials. But there is not that involvement. I don't see too many researchers in the community working with the community, gaining, doing talks, and letting the community know them. I struggle a lot finding the Spanish speaking researchers that go with me to talk about something, about any clinical trial that is specific or about cancer clinical trials…And in the other hand, from the medical system or from the research organization, they have to send everything in the language and with the respect of the culture, cultural norms, to be able to attract and to include that population…" (Recruiter 11)*
>
> *"I'm very, very lucky that I get to work with an outreach program at our institution that we partner with local hospitals and kind of the lesser fortunate areas of town to be able to offer some clinical trials to minority population." (Recruiter 3)*
>
> *"I think just that reaching the community and making them aware of... That could be something just kind of doing presentations and just kind of knowing what is*

research, who are working there, so the people there and what are the results they were having…" (Recruiter 14)

Community support details any assistance or encouragement the patient may need with participation in clinical trials, to include religious support, help with family obligations, and aid from local agencies. A recruiter mentioned greater success in participation accrual in areas that geographically have a more diverse population. Recruiters also mentioned that patients often do not want to be a burden on their community with participation scheduling, childcare, and transportation. Therefore, being a perceived burden on others in the community can hinder participation.

"…I feel like my Hispanic patients that I take care of, family is ultimately number one. I've never seen patients so well taken care of. And they just have so many people who want to help them. And it's heartwarming. And I think a lot of times they think I don't want to put my family through much, I don't want to have them come to extra visits or add this extra burden on them…" (Recruiter 15)

"…but we have had better success at other hospitals that's more in the downtown area. So that helps. It's more of a diverse population in that area than where we're at…" (Recruiter 4)

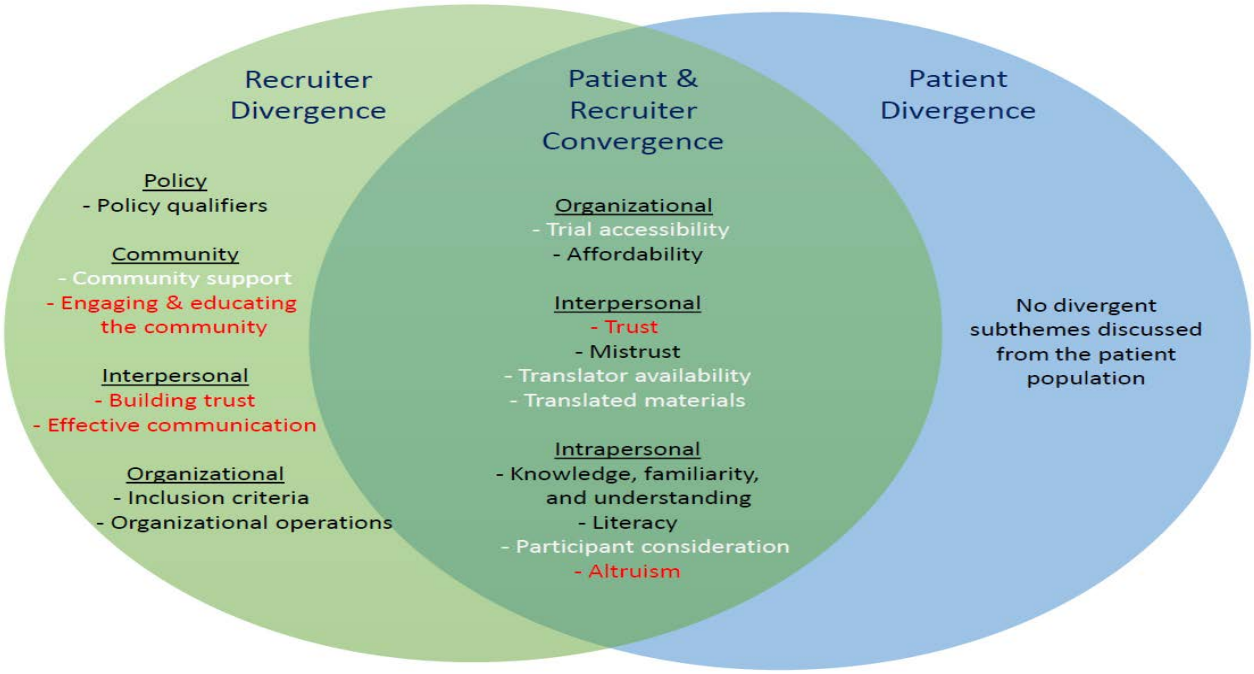
"…they need to really be included with local human service agencies that the community trusts. Those are really much more successful. You're going to be able to get much more participation for the Hispanic community when it's a small office of case managers that help…" (Recruiter 13)

4.3.3 Convergence and Divergence of Themes

Patients and recruiters both discussed barriers and facilitators within the themes of inclusivity, trial education and understanding, trust in trials, and instrumental

communications. Although some themes addressed more concepts from the proposed framework than others, convergence was seen in four of the five themes. Divergence was seen regarding community outreach and support, as this was a theme not discussed in the patient sample as it was in the recruiter sample. Figure 4.3 below highlights the convergence and divergence seen between the two samples regarding subthemes and their associated concepts. Items in red are facilitators, items in black are barriers, and items in white are both, barriers and facilitators.

Figure 4.3 Convergence and Divergence of Subthemes Between Sample Groups



4.4 Convergence of Quantitative and Qualitative Data

Given the embedded research design [63], quantitative and qualitative findings were combined for the patient and recruiter participant groups and summarized in Table 4.4.1 and Table 4.4.2, respectively. Although qualitative findings were originally sought to inform the quantitative methods of this study, there is evidence of convergence in each participant group.

Within the patient participant group, qualitative and quantitative data converged among three of the four BCTP subscales: lack of personal benefit, mistrust, and lack of familiarity. Divergence was seen for lack of community support, the fourth subscale on the BCTP in that the issue was not mentioned in the qualitative responses. The qualitative data brought greater depth to the subscales, as items like mistrust were able to be further broken into subthemes of building trust and mistrust in research.

Within the recruiter participant group, qualitative and quantitative data converged among nine of the twelve items on the Tanner scale (see Table 4.4.2 below). Divergence was seen with the other three items: local physicians are unaware of ongoing trials, it is difficult to find potential participants, and local physicians are unwilling to engage in accrual, as these topics did not arise during qualitative interviews with the recruiters. Like the results in the patient group, the recruiter group also saw added value to the qualitative data secured, as areas like community outreach and support were added to the data set.

Table 4.4.1. Patient Sample Data Convergence and Divergence

Concept	Qualitative	Quantitative (BCTP)
Intrapersonal	Code: personal benefit Theme: trust in trials Exemplary Quote: *"Well, I think if I felt that the treatment that I was given wasn't going to work or was questionable, then I would want to try something else or perhaps if I had tried treatments and I was still battling cancer, I would try something else"*	Lack of personal benefit Median 2.5, IQR 1.7-3.0
Community	Not discussed	Lack of community support Median 2.3, IQR 1.6-3.0
Interpersonal	Code: mistrust in research Theme: trust in trials Exemplary Quote: *"They associated danger with that [participation]"*	Mistrust Median 3.0, IQR 2.4-3.2
Intrapersonal	Code: familiarity or knowledge	Lack of familiarity

	Theme: trial education and understanding Exemplary Quote: *"More information about what kind of clinical trials are out there for cancer research. Because unless you really go digging for it, you don't learn too much on your own"*	Median 2.8, IQR 2.0-3.0
Organizational	Code: access to trials Theme: inclusivity Exemplary Quote: *"Like work schedule because... Yeah, scheduling because if it interferes too much with my work schedule, that would be hard"*	N/A
Organizational	Code: inclusion/exclusion criteria Theme: inclusivity Exemplary Quote: *"…I don't think because of the language barriers that a lot of people aren't asked about it. They have to find out about treatment research themselves…"*	N/A
Organizational	Code: perceived cost Theme: inclusivity Exemplary Quote: *"that they'd be made available to even people of low income, that there was ways to have that done"*	N/A
Intrapersonal	Code: literacy Theme: trial education and understanding Exemplary Quote: *"…the older Hispanics, they're not quite as literate. So yes, you might be able to give them a piece of paper to read, but if they can't read, then they're not going to tell you they can't read unless you can sense from them, especially in their own language. Because that happens a lot, the illiteracy in the Hispanic population. That if they can't read what you give them, even in their own language that they have the actual translator to explain and help them through it"*	N/A
Interpersonal	Code: translated materials	N/A

	Theme: instrumental communication Exemplary Quote: *"We could try having information set in a bilingual way so that if there is a lack of English understanding, they can read it in their own language"*	
Interpersonal	Code: translator deficit Theme: instrumental communication Exemplary Quote: *"Because I know there's some translators some places, and then some it's hit or miss if I know someone"*	N/A
Interpersonal	Code: trusting communication Theme: trust in trials Exemplary Quote: *"Yeah, because if it's coming from somebody with a medical background [inaudible] that much more effective than me telling them secondhand what I heard on the call"*	N/A
Interpersonal	Code: building trust Theme: trust in trials Exemplary Quote: *"I mean, I would say cancer patients are really overwhelmed. Just know that there's so many things going on, so many moving pieces, so many, even just psychologically, a lot of things going on. Follow up, making sure that you're not leaving it in just my hands like, "Hey, here's this clinical trial packet. Let us know if you want to participate…"*	N/A
Intrapersonal	Code: type of treatment Theme: trust in trials Exemplary Quote: *"Any kind of invasive treatment or too invasive would probably not make me want to do it"*	N/A
Intrapersonal	Code: altruism Theme: trust in trials Exemplary Quote: *"…and others too. To stop them from getting sick"*	N/A

Table 4.4.2. Recruiter Sample Data Convergence and Divergence

Concept	Qualitative	Quantitative (Tanner)
Intrapersonal	Code: familiarity or knowledge Theme: trial education and understanding Exemplary Quote: *"They just don't understand what we're going to be doing"*	"Patients lack knowledge about the idea of clinical trials" Median 4.0, IQR 4.0 – 5.0
Intrapersonal	Code: available trials Theme: trial education and understanding Exemplary Quote: *"And those minority populations don't even know research exists, so that isn't an option to them"*	"Patients lack information about available trials" Median 4.0, IQR 4.0 – 4.3
Interpersonal	Code: fear/mistrust in research Theme: trust in trials Exemplary Quote: *"…I have worked with a number of patients who have expressed a distrust of the research experience. They don't want to feel like they're test subjects, or something's being tested on them. Or that they don't want to feel like they're not getting the treatment that everybody else is getting. They're getting some sort of experimental thing that they don't know what's going to happen. Those are, I think, my two biggest barriers"*	"Patients are afraid of participating in clinical trials (i.e., fearful about something untested, fear of randomization)" Median 4.0, IQR 3.0 – 5.0
Organizational	Code: inclusion / exclusion criteria Theme: inclusivity Exemplary Quote: *"Some of the clinical trials are not open for Latinos, so limitations in inclusion of Latinos in clinical trials; because those trials has to be translated in Espanol and they have to be approved by the IRB and they have to hire staff"*	N/A
Interpersonal	Code: mistrust in research Theme: trust in trials Exemplary Quote: *"I think the biggest thing, again, is just kind of that mistrust of the research process. They feel like they're test subjects or like a lab rat…"*	"Patients have negative perceptions about clinical trials (i.e., I will be treated like a guinea pig)" Median 4.0, IQR 3.0 – 5.0
		"Patients lack confidence in or distrust medical research

		(i.e., historical abuses of research participants)" Median 4.0, IQR 3.0 – 5.0
Organizational	Code: Access to trials Theme: Inclusivity Exemplary Quote: *"First, access to the medical center. At least for my experience, I see that a lot of Hispanics that go to small clinics in the community and usually those clinics are not involved in research. If they don't have access because just like the one that I work with, it makes harder for us to recruit there"*	"Patients have limited accessibility to trial sites" Median 4.0, IQR 3.7 – 4.3
Intrapersonal	Code: health literacy Theme: Trial education and understanding Exemplary Quote: *"her health literacy was low and she was alone in the clinic and didn't have her daughter with her. And so, I called the patient with a Spanish translator outside of the clinic and offered to three-way call her with the daughter, that way we could all have a discussion, that would kind of simulate what it was like pre pandemic and had better success that way. So, I think trying to include family members when possible, of course, if the patient wants a family member included"*	"Patients have low literacy or low health literacy" Median 4.0, IQR 3.0 – 4.0
Organizational	Code: insurance barriers Theme: inclusivity Exemplary Quote: *"Well, I know from our area of the diversity aspect, we have a lot of patients that aren't able to come to our clinic because of their insurance issues. So, a lot of those people are seen at other facilities where we're working with them currently to try to open a multi-site research facility so that we were able to capture minorities, but our main issue is insurance"*	"Patients' insurance will not cover clinical trials procedures or drugs" Median 4.0, IQR 2.7 – 4.3

Organizational	Not discussed	"Local physicians/doctors are unaware of ongoing trials" Median 4.0, IQR 2.7 – 4.0
Organizational	Not discussed	"It is difficult to find potential participants" Median 3.5, IQR 2.0 – 4.3
Intrapersonal	Code: personal benefit Theme: trust in trials Exemplary Quote: *"I have been declined a lot whenever the patients just desire hysterectomy and just want to solve their problem once and for all"*	"Patients desire other treatments" Median 3.0, IQR 2.0 – 4.0
Interpersonal	Not discussed	"Local physicians/doctors are unwilling to engage in accrual" Median 3.0, IQR 2.0 – 4.0
Organizational	Code: organizational culture Theme: inclusivity Exemplary Quote: *"…it's Caucasian that comes in here most of the time, and I feel like that's threatening when a minority population walks in, and everybody they see is Caucasian. All the doctors are Caucasian"*	N/A
Policy	Code: citizenship status Theme: inclusivity Exemplary Quote: *"I mean, I've been in situations where maybe they're not U.S. citizens, and they are very standoffish, and don't want to... they don't want to give you any information that could get them into trouble"*	N/A
Community	Code: community engagement Theme: community outreach and support Exemplary Quote: *"I'm very, very lucky that I get to work with an outreach program at our institution that we partner with local hospitals and kind of the lesser fortunate areas of town to be able to offer*	N/A

	some clinical trials to minority population"	
Community	Code: community support Theme: community outreach and support Exemplary Quote: *"…I feel like my Hispanic patients that I take care of; family is ultimately number one. I've never seen patients so well taken care of. And they just have so many people who want to help them. And it's heartwarming. And I think a lot of times they think I don't want to put my family through much, I don't want to have them come to extra visits or add this extra burden on them"*	N/A
Interpersonal	Code: communicating for understanding Theme: trial education and knowledge Exemplary Quote: *"communicate with them at their level so they understand it"*	N/A
Interpersonal	Code: building trust Theme: trust in trials Exemplary Quote: *"gaining that trust on the front end is just really important"*	N/A
Interpersonal	Code: mistrust of provider Theme: trust in trials Exemplary Quote: *"So I don't know if it's because there's some distrust between non-Hispanic and Hispanic communities, that they're not comfortable with a non-Hispanic practitioner"*	N/A
Interpersonal	Code: trusting communication Theme: trust in trials Exemplary Quote: *"We just tread lightly with it, as long as we're honest and open, and have just a genuine conversation. Still get the information that we need. Obviously, that's our job, but making sure that the patient feels comfortable, it's going to open a lot more doors for us with the patients,*	N/A

	because it's very, very easy for the patient just to close up and say, "Hey, I don't want to hear any more."	
Intrapersonal	Code: altruism Theme: trust in trials Exemplary Quote: *"support to science, support in the advancements of science from the Hispanic community"*	N/A
Interpersonal	Code: translated materials Theme: instrumental communication Exemplary Quote: *"the one thing that I really come across is that a lot of times we don't have a Spanish consent form"*	N/A
Interpersonal	Codes: translator deficit & translator barriers Theme: instrumental communication Exemplary Quote: *"they don't have anybody with them that can interpret it for them, and maybe we don't even have an interpreter available. A lot of our instruments have not been tested in a Hispanic version"*	N/A

4.5 Revised Conceptual Framework

The conceptual framework was updated with the findings of the study. Although the five main concepts remain unchanged, items detailed within them were updated to add qualitative and quantitative findings, such as the removal of "shared-decision making" under the community concept, as this was not perceived to be a factor from either patients or recruiters. Additionally, items such as "trust in the provider" and "communication" were updated to "trust (building, gaining, maintaining)" and "trusting communication" under the interpersonal concept, since trust was described in greater detail as an action term than simply an emotion. Further, "communication" was vague under the original interpersonal concept and thus "trusting communication" describes the form of communication needed to

facilitate participation, as perceived by patients and recruiters. The community concept was updated to include “community engagement”, as this describes the actions needed to achieve participation, rather than simply noting “community resources”. The policy concept was updated to simply note citizenship and immigration status, while the intrapersonal concept added “altruism” and “familiarity” of clinical trials. This revised framework reflects the most recent data on the subject and will guide future intervention development.

Figure 4.5 Revised Conceptual Framework

CHAPTER 5

Discussion

5.1 Meaning of Findings in Relation to Aims

The rates in which Hispanic patients participate in cancer clinical trials remains low, even with cancer being the primary cause of death within the population [1]. This study sought to elucidate barriers and facilitators of Hispanic participation in cancer clinical trials, as perceived by both patients and recruiters. Research completed previously failed to substantially represent the perceptions of Hispanic oncology patients and the recruiters working arduously to recruit them into clinical trials [5,6]. This study secured both perspectives, utilizing an embedded mixed-methods research design, to bring new light to the topic that has remained of the utmost importance. This design allowed qualitative one-on-one interviews to strengthen the discussion regarding perceptions while also addressing factors not measured by the quantitative instruments.

Patients perceived several intrapersonal, interpersonal, organizational, and community factors as barriers or facilitators to clinical trial participation, which were a reflection of the related SDOH. Recruiters perceived several of the same, with the addition of policy factors. Several factors noted in previous research, such as mistrust and clinical trial education surfaced as anticipated during the study [1,16,18,21-22]. However, other factors previously noted in research, were expounded upon, such as deficiency in translation services and materials [21]. As expected, convergence was seen between the patient and recruiter groups regarding several factors, such as trial accessibility and healthcare access concerns, however divergence was seen when discussing factors more procedural in nature, such as community engagement or inclusion criteria. These results will add to the current literature and aid in

intervention development for both patients and recruiters to increase clinical trial participation for the Hispanic oncological population as well as highlight the need to account for the impact of the SDOH experienced by this vulnerable population.

5.1.1 Aim 1

Patients identified several factors as either facilitating or impeding clinical trial participation in cancer clinical trials. Mistrust, lack of familiarity in clinical trials, lack of personal benefits, and lack of community support were reported as factors that hindered clinical trial participation, from greatest to least, respectively. These findings mirror the 2016 study in which the same instrument was utilized, correlating religiosity to clinical trial participation among Latina women, as they too placed the factors in this order [40]. Although the current study achieved a greater diversity in the patient sample group, the results were consistent.

Qualitative data collected in the current study reflected greater depth of barriers and facilitators to clinical trial participation, as patients described barriers within the themes of inclusivity, trial education and understanding, trust in trials, and instrumental communication.

Inclusivity. Patients discussed concerns with access to trials, to include transportation concerns, scheduling conflicts, and perceived out-of-pocket expense. Patients noted that clinical trials would need to be "easy to get to," and flexible to schedule, since working around a work schedule would be difficult. Also, patients expected clinical trial participation include out of pocket costs and believed more patients could participate if they were "made available" to people of "low income". These barriers are similar to what has been previously reported in the literature, as patients were concerned with work constraints and the implications of participating in clinical trials, such as missed pay and childcare [19,22,71].

Further, in a qualitative study conducted in 2005, only 50% of participants noted feeling as though they could overcome a transportation barrier to access clinical trials [20].

Trial education and understanding. Patients expressed feelings of inadequate education regarding clinical trials, as they noted that they were simply provided with a packet to read. Further, one patient noted that clinical trial information isn't readily available, and a patient would need to go research the information on their own to learn about trial processes and availability. Regarding clinical trial knowledge, understanding, familiarity, and literacy, of those participating in the interviews, only one was a previous participant in a clinical trial and spoke to that experience. Qualitative focus groups conducted in 2012 showed similar findings, as 30% of participants had previously heard of clinical trials [21].

Instrumental communication. Patients discussed concerns with instrumental communication services, especially translator deficits, and lack of translated materials. Patients noted that most information packets provided regarding cancer clinical trials are in English, thus excluding those who are Spanish speaking. Translator availability is of concern, as patients note they are not always readily available, and a patient would want this service to guide them and answer questions that may arise during and throughout the trial. A qualitative study conducted in 2005 reported that 38% of Latinas who were interviewed identified communication in Spanish or with a translator was an important factor to participation in breast cancer prevention trials [20]. Patients need clinical trial information provided in the language in which they have the most understanding.

Trust in trials. Another strong theme seen within the literature in several minority populations is that surrounding trust in any part of the research process. Participants in this study noted the need to receive information from a trusted individual, with one noting "not getting the information from [their] oncologist" would deter their participation. Therefore, a

trusted source helps build and maintain the trusting relationship needed for participation in research. Patients seek out trusted individuals for clinical trial information and many had levels of mistrust, perceiving their involvement as “guinea pigs” [1,21]. Additionally, trust can also be deterred by past experience, as one participant noted family trust was broken when a family member was perceived to be adversely affected by the clinical trial. We have seen this mistrust in the literature surrounding history of abuse of vulnerable populations in research, therefore trust must be fostered and built to facilitate participation [71].

Lastly, along with building, maintaining, and fostering trust, patients discussed personal and altruistic benefits from participation, as well as concern for invasiveness of treatment and efficacy. If patients perceived the treatment to be “questionable,” “too invasive,” or if it failed to “help” them or others in the community, participation would be declined. A study found that of 14 Latinas interviewed, the theme of perceived benefits, weighed heavily on their intent to participate. Namely, 42% of the participants thought that participation benefits were ambiguous and didn’t believe that others would benefit from their participation in the future [20]. Further, a group of 128 Mexican Americans participated in focus groups and noted a barrier to their participation was lack of knowledge of perceived benefits. However, the findings from the P.I.’s pilot study indicated participants were willing to participate in clinical trials if they perceived altruistic benefits from their participation.

It is important to note that policy factors such as immigration or citizenship status were not discussed within the patient sample. This could be that those participating were citizens and thus were not concerned with this aspect, which if accurate, causes pause as it strengthens the possibility that those concerned with this factor remain unwilling to participate. It was previously reported that a significant barrier to participation in cancer clinical trials is the fear of documentation status being divulged [72]. Given the current political climate in the

U.S., it was expected to be discussed, but ultimately was not mentioned in the patient interviews.

Patients voiced perceptions of several factors as barriers or facilitators to clinical trial participation. These perceived barriers were supported by those in the literature, and minimal differences were seen between the current study participants and those in previous studies, in some cases dating back over a decade [1, 20, 21, 71].

5.1.2 Aim 2

Recruiters reported factors that facilitate or impede clinical trial participation in cancer clinical trials similar to those reported by participants. When completing the Tanner scale, recruiters perceived lack of knowledge regarding clinical trials and lack of information about available trials as the most significant barriers to Hispanic participation in cancer clinical trials. Patients fearing participation, negative perceptions regarding clinical trials, and distrust in medical research followed in perceived severity. Recruiters gave the lowest scores, which implies lower severity, to treatment types, and providers being unaware or unwilling to engage in accrual.

Qualitative data expounded on the Tanner scale findings. Recruiters described barriers and facilitators within the themes of inclusivity, trial education and understanding, trust in trials, instrumental communication, and community outreach and support.

Inclusivity. Researchers discussed participation barriers regarding access, including transportation issues, scheduling conflicts, insurance barriers, and inclusion criteria. Researchers perceived access to clinical trials as a potential barrier to participation. Recruiters in this study noted that patients often express transportation issues, scheduling flexibility, and perceived financial expense as reasons for not participating. Having “limited time points” in the schedule for the clinical trial was a hinderance, as recruiters noted that

patients were unable to make appointments. These factors mirrored those in the literature, as logistic barriers and tight timelines were barriers expressed by recruiters [33]. However, the more these barriers could be mitigated, the more they became facilitators to enrollment. Recruiters noted that more flexible scheduling and "telehealth check-ins" instead of in-person visits have facilitated participation in current studies. In addition to logistical barriers, recruiters also confirmed Hispanic oncologic patients are often excluded from clinical trials due to strict inclusion criteria. Recruiters noted patients are being excluded due to pre-existing "co-morbidities", but one of the most common exclusions was primary language. Recruiters reported several studies require the patient to speak English, thereby immediately excluding Hispanics who are Spanish speakers. This finding was also seen in the literature, as multiple factors often exclude patients from participating in clinical trials [35].

Trial education and understanding. Recruiters also identified patient knowledge, understanding, familiarity, education, and literacy as barriers to participant accrual. Recruiters noted patient hesitancy if the study was "not well defined" or contains a lot of "jargon." Recruiters discussed having someone on site or on staff devoted to clinical trial education that would facilitate the education process, as the process lasted "several hours" at times, due to the extent of the questions that arose during the session. Recruiters discussed that patients are "more accepting" of clinical trial participation when they understand the process more and when they are informed of the research protocol. These findings were similar to that of a qualitative study conducted on cancer program physicians in 2000. The physicians also identified lack of information regarding clinical trials along with patient fears and distrust of the medical system as barriers to participation [73].

Trust in trials. Mistrust in the medical system among minority populations is a long-standing theme in the literature surrounding minority populations. Literature reviews

regarding recruitment and retention of minorities have noted mistrust in the medical profession as a barrier, given the history of abuse among vulnerable populations in research in the past [17, 27, 71]. When discussing trust in trials, recruiters voiced mitigating distrust in the medical system by the initiation of recruitment by a trusted individual, such as a provider. When a provider introduces the recruiter to the patient, to "set the stage", the patient is more inclined to participate, as they trust the provider's judgment. Additionally, recruiters noted in-person recruiting, rather than telephonic recruiting, assists in building the trust between the recruiter and the patient. Recruiters reported greater success when the patient trusts the recruiter. Recruiters should use "honest and open" conversation with the patients to build and maintain trust with the patients. This way of adapting to the patient's needs was discussed in previous research completed with recruiters in different medical centers. The focus groups found that using culturally appropriate language, adapting to contextual factors, and adapting for mistrust of medical research were integral to the success in recruitment [36].

Recruiters noted that the way in which a participant views the risks and benefits to participation, whether they are personal – as in efficacy or invasiveness of treatment - or benefiting the community at large – as in greater research equality – play a role in accrual. Recruiters noted that patients are deterred by studies with lack of research on side effects or those that they consider a "safety concern" because the treatment may "not be beneficial" to their condition. However, if patients feel as though what they "are doing advances science for the community," they are more willing to participate. Further, according to recruiters, type of treatment can be a barrier to participation, as less invasive options are preferred. A study conducted regarding factors of influence in recruitment to research, research type was often a barrier [34]. Other factors identified as barriers by the recruiters include citizenship and immigration status. Many recruiters noted apprehension among potential participants

regarding learning citizenship or immigration status. Recruiters noted that patients are very "standoffish" and don't want to provide any citizenship details such as social security numbers to participate, for fear they will "get into trouble." Recruiters expressed that some requirements, such as securing social security numbers, are lifted in some of their studies, so those who may be undocumented need not be concerned and can proceed in participation. The barrier surrounding citizenship or immigration status has been reported in the past, as recruiters voiced the need for anonymity and adaptation to contextual factors like immigration status to recruit patients to clinical trials [36].

Instrumental communication. Recruiters voiced translation services are critical in participation facilitation. Several recruiters noted a lack of translated materials, to include the informed consent, which can cause a substantial barrier to participation, delaying the accrual process due to waiting for translation of materials, and hindering understanding of clinical trial procedures. Recruiters who reported having all materials translated also reported an improvement in the recruitment process. Additionally, concerns were raised regarding translator availability, as recruiters noted that they may not have access to translators at every moment they are in need. One recruiter noted that they offer availability to their participants 24/7, however they do not speak Spanish. As such, although they are available for the patient to call, they may not be able to communicate with the patient at the patient's time of need due to translator unavailability. Recruiters noted that in certain facilities, translation services are unavailable, therefore this excludes the ability to work with Spanish-speaking participants. The concerns of translated materials and translator unavailability has surfaced in past literature as well [31, 36]. Recruiters in the current study discussed organizational barriers, namely insurance coverages accepted and diversity of those within the organization. Many recruiters reported turning away potential participants due to specific insurance

coverage, as their institution was “very strict” with acceptable policy types. Some recruiters noted that those without insurance were not accepted at their institution, thereby increasing exclusivity of participation in the organization. Aside from institutional guidelines, recruiters also noted a barrier can be the culture of the institution. Recruiters reported feeling as though not having a diverse workforce creates significant barriers to participation, as potential patients can feel threatened when “everybody they see is Caucasian.” Additionally, information coming from a trusted organization holds a “lot more weight.”

Community outreach and support. Finally, recruiters discussed community engagement, education, and securing community support as integral components to the recruitment process. A previous study conducted reported a potential solution for distrust and lack of information is to have community physicians make personal contact with the community [73]. The recruiters in this study discussed the importance of community engagement, noting that recruiters needed to go out into the community, provide education, and do these steps in the community’s primary language. Recruiters described the need for greater community marketing and engagement at community centers and local churches, to reach potential participants. Recruiters also described community engagement efforts such as tv commercials and bilingual marketing strategies within the hospitals have facilitated the education and participation accrual. Recruiters working at institutions with outreach programs reflected that they were able to offer clinical trials to minority populations in areas of lower socioeconomic status due to these partnerships. Therefore, community engagement and outreach can play a significant role in facilitation participation among the Hispanic oncologic population.

Recruiters voiced perceptions of several factors as barriers or facilitators to clinical trial participation. Many of those expressed were similar to those in the literature, which again highlights the ongoing need for intervention development to assist in participation accrual.

5.1.3 Aim 3

Although patients and recruiters both acknowledged that mistrust, lack of familiarity, lack of personal benefit, and lack of community support are significant barriers to clinical trial participation, divergence is seen based on how these barriers are ordered in significance. Patients perceive mistrust, lack of familiarity, lack of personal benefit, and lack of community support as the most significant barriers, in that order. Recruiters, however, perceive lack of familiarity, lack of personal benefit, mistrust, and lack of community support as significant barriers to participation, in that order. Although the order of how each of the first three barriers diverged between groups, convergence was ultimately seen with lack of community support being the last of the four for both groups. The patient group did not address community outreach or support in their qualitative results, but recruiters had substantial discussions about the value of community engagement with participation accrual. It is interesting that recruiters placed community engagement at the bottom hierarchically. This could be simply due to the minimal subscales utilized and inevitably one area had to score lowest but could also symbolize the extreme importance of the other three areas regarding Hispanic oncologic patients and their recruitment activities.

Qualitative theme convergence was evident, as both groups discussed barriers and facilitators under themes of inclusivity, trial education and understanding, trust in trials, and instrumental communication. Although not all factors under each area were discussed within both groups, many factors were similar. Divergence was evident with the theme of

community outreach and support in the recruiter groups, but as this was not discussed in the patient group. Although this was a divergence among groups, it was not surprising, as this theme discussed engagement processes, which are not always evident to the patient population, so this was a challenging to ascertain, especially with the small number of patients completing the qualitative portion of this study.

5.2 Strengths and Limitations

This study sought to describe barriers and facilitators to clinical trial participation among the Hispanic oncologic population. Study strengths include research design, sample representation, study timeliness, and language services. Limitations include inclusion criteria, lack of comprehensive instrument, and low participation from patients in the qualitative interviews.

5.2.1 Strengths

Research design. The embedded mixed-methods design is an inherent strength for the study, as it allowed for simultaneous analysis of both quantitative and qualitative data [63]. As quantitative methodology can fail to factor context into its analysis, the addition of qualitative data can fill these gaps and provide rich description that would otherwise be deficient [63]. When completing research on a subject that has intrinsic contextual factors such as perceptions of barriers and facilitators to Hispanic participation in cancer clinical trials, a mixed methods approach can better assist in securing robust data to describe the phenomenon [63].

Although research has examined the barriers to Hispanic participation in the past, this is the first known study utilizing the embedded-mixed methods design and exploring barriers and facilitators as perceived by both patients and recruiters simultaneously. This study design

also allowed for the exploration of convergence and divergence of factors among both sample populations. The current literature reflects a variety of research methods, including cross-sectional surveys, systematic reviews, retrospective case studies, longitudinal studies, systematic reviews, qualitative focus groups, and qualitative one-on-one semi-structured interviews [1, 8, 16-38]. Therefore, this study is novel in that it carried out the aims using a cross-sectional survey and one-on-one semi-structured interviews. The current literature focuses on a singular population perspective (patients or recruiters), failing to explore both barriers and facilitators to Hispanic participation in cancer clinical trials as perceived by both patients and recruiters [5, 6, 14, 16-18, 20-22, 24-27, 32-35, 47]. Finally, as no studies have explored barriers and facilitator perceptions in both populations within the same study, convergence and divergence is also lacking in the literature. Therefore, the research design utilized in this study fills several gaps in the current literature.

Sample representation. The current study included a representative sample of Hispanic oncology patients and cancer clinical trial recruiters during the survey portion of the study. The inclusion criteria prevented extraneous data points from a non-representative sample. When reviewing the literature regarding patient participation in clinical trials, some studies aimed at securing Hispanic participants did not reach those with a history of cancer, so those participants were unable to speak to the specific barriers that may surround the oncologic population [16, 17]. Other studies were able to secure participants with a history of cancer, but captured a large sub-group of Hispanics, as one cross-sectional reported 77% of participants self-identified as Dominican; or another study that reported 73% of their participants self-identified as Mexican [16, 19]. Additionally, gender representation within the current literature utilizes and reports more female than male participation [1,7, 6, 20, 21, 40]. The current study was successful in securing a sample population of patients with a

history of present or previous cancer diagnosis, and a slight majority of male participants (56%). Many of the participants in the current study were Mexican (68%), however there was representation from other Hispanic sub-groups present, as the others self-reported as Puerto Rican, Cuban, Spaniard, Dominican, Panamanian, or Brazilian, which allowed for greater diversity in the overall patient sample. Securing a representative sample for this portion of the study is integral to the generalizability of the results to the Hispanic population.

Along with the Hispanic patient population, the current study was able to secure a representative sample of the recruiter population for the survey portion. Recruiters were solely sought for participation in this study, which differs from the available literature, as previous research utilized a variety of research personnel for sample groups [29-37]. Most studies explored the recruiter perspective but allowed individuals within the entire research process – managers, cancer center leaders, research staff, recruiters, clinicians, and primary investigators – to participate in the study, rather than solely with the recruiters as the current study did [29-37]. Securing the information from the individuals recruiting for the cancer clinical trials will provide much more meaningful and representative data, rather than those who may not routinely recruit or recruit at all.

Study timeliness. The current study provides updated and timely data related to perceptions of both patients and recruiters regarding barriers and facilitators to Hispanic participation in cancer clinical trials. There is a need for timely information, as many studies were conducted over a decade ago among the patient population [20, 21]. In 2017, several agencies, the American Cancer Society (ACS), the American Association for Cancer Research (AACR), the American Society of Clinical Oncology (ASCO), and the National Cancer Institute (NCI), worked jointly to administer recommendations regarding minority participation in cancer research activities, with a focus on greater inclusion [54]. Therefore,

this study provides timely information regarding participation barriers the population may be experiencing, while also meeting the call for greater minority inclusion in cancer research activities [54].

Language services. As previous studies noted that patients were concerned with translated materials or the availability of a translator, the current study ensured that these barriers were minimized [1, 17, 31]. Bilingual marketing materials to advertise recruitment, bilingual surveys validated in Spanish for patient participants, and bilingual interviewers for the qualitative portion of the study, were utilized to ensure language barriers were mitigated throughout all portions of the study.

5.2.2 Limitations

Low participation from patients for qualitative interviews. Of the 85 participants in the patient group who completed the survey, only five opted to participate in the interview, with four of the five successfully completing the interview. The fifth potential participant was completing chemotherapy during the study and was too ill to participate. Semi-structured, one-on-one telephone interviews were conducted with both samples, due to the necessity to follow COVID-19 protocols, as in-person interviews and focus groups could not be conducted due to social distancing guidelines. Focus group sessions or in-person interviews would be better utilized in this population in the future, as previous research has been successful in securing participation with these methods. It has been reported that individuals feel more comfortable discussing concerns in a group among peers, or face-to-face with someone where they can better control the data being shared [16, 21, 25-26, 60].

Lack of comprehensive instrument. The study was unable to utilize one instrument to measure all concepts. Qualitative interviews were utilized to address barriers and facilitators not measured by the BCTP scale (organizational and policy) or Tanner instrument

(organizational) [30, 40]. Therefore, a comprehensive tool should be developed that can address all concepts related to barriers and facilitators to Hispanic participation in cancer clinical trials.

Inclusion criteria. As discussed previously, a REDCap® survey was utilized to collect data from both the patient and recruiter populations with each respective instrument. Utilizing this method of data collection, the inclusion criteria required all participants to have access to the Internet or an Internet-enabled smartphone to complete the study. Lower income families in the population could encounter barriers limiting their access to the Internet [75]. Therefore, the inclusion criteria may have inadvertently excluded patients from the Hispanic oncologic population that would have met all other inclusion criteria.

5.3 Implications of Findings

The Hispanic oncologic population is not participating in cancer clinical trials at rates comparable to other populations [1]. This lack of participation leads to over generalization of results, which could lead to poor efficacy of treatment among this vulnerable population [1]. This study intended to highlight barriers and facilitators to Hispanic participation in cancer clinical trials to provide a representative, current data set in which intervention research could be based upon in the future. Through an embedded, mixed methods design, quantitative data and qualitative themes resulted in similar barriers and facilitators to those discussed in the literature [1, 16, 18, 19, 21, 22, 71]. Although the findings were similar, the literature originally did not utilize a representative sample and analyze the convergence and divergence of factors among both the patient and recruiter populations. This study was able to secure a diverse sample of patients and recruiters which improved the applicability of the study findings, given the improved representation for these populations. However, although

the science can be updated to reflect the new data secured in this study, it does highlight the concern that the issue of clinical trial participation among Hispanic oncological patients is long standing and has not improved over the decades in which research has described it. Implications for policy, practice, and research will be discussed here in detail, highlighting the findings of this study and how those can facilitate potential change.

5.3.1 Nursing Policy

In 2017, the ACS, AACR, ASCO, and NCI worked together to administer recommendations regarding minority participation in research activities [54]. This joint effort highlighted the need for greater inclusivity in research activities, including cancer clinical trials. Patients and recruiters both voiced concerns in the current study regarding insurance coverage and affordability. With the need for more participation, but with financial concerns looming, grant funding should be bolstered to offset these potential financial pitfalls. Additionally, for those insured, coverage should be extended to encompass experimental treatments to mitigate this potential barrier to participation.

Organizational level. Studies have explored the training needs of recruitment personnel to optimize minority recruitment in cancer clinical trials and reported that research personnel are often not trained adequately, as training does not focus on factors influencing participation and cultural awareness [29, 36]. The current study also supports this need, as recruiters reported “cultural competency and inclusion and trainings of unconscious bias” would be beneficial to their ability to recruit the Hispanic oncology population. Therefore, organizations can facilitate participation by providing those recruiting the patient population with culturally appropriate, in-service trainings that highlight contextual factors for the population and how to mitigate their potential unconscious bias during recruitment activities. By developing policies or guidelines to standardize training, not only will this benefit the

Hispanic oncologic population, but can also be applied to other minority populations being recruited into clinical trials.

Along with contextual trainings on minority populations, organizations should also work to employ more diverse recruiter populations. The current study highlighted the need for the recruitment and clinical personnel to "look" like the population being recruited, as having an environment with little to no Hispanic representation was thought of as potentially "threatening". Patients seek information from trusted sources, therefore having the information delivered by a provider or recruiter of the same ethnicity or cultural background, aids in the building of trust and ultimately, the willingness to participate [21, 73]. Potential participants should feel comfortable and safe in the environment in which they will be potentially seeking and receiving treatment. As such, if a patient feels threatened due to the lack of diversity in the recruitment and treatment team, organizations should take steps to increase this diversity to lessen this potential threat to participation. Organizations benefit from diverse employment, as employees bring diverse perspectives to the organization, while also providing a safe place for diverse patients.

Lastly, translator services are integral to the participation of non-English speaking clinical trial participants. This need is evident in the research surrounding participation barriers, as several studies mention translator and interpreter services as an important factor for potential participants [20, 31, 36]. Recruiters and patients in the current study consistently expressed translator deficit as a barrier to participation in cancer clinical trials, as it was the second most common code found during content analysis (Appendix H). Recruiters voiced concerns that translators are not "always available" when needed and patients voiced the need to hear about the study from someone who speaks their language. As organizations look toward building more inclusive atmospheres for their patients, they should also look to secure

representation that is bilingual to ensure that language services are readily available to those in need. This change in organizational culture can be a strong facilitator in securing diverse populations for cancer clinical trials and thus aiding in the generalizability of study findings to these populations.

Social determinants of health (SDOH). All five areas of Healthy People's 2020 social determinants of health framework were discussed in the study findings, further highlighting the contextual applicability of one's environment to their overall health outcomes. When voicing concerns over cost and insurance coverage, patients were addressing the economic stability and health and health care constructs of the SDOH framework. Areas labeled instrumental communication and knowledge and familiarity of clinical trials fall under the SDOH education construct; while inclusivity areas, such as transportation to and from clinical trials represent the neighborhood and built environments construct. Lastly, the barrier of community engagement would describe the social and community context of the SDOH framework.

5.3.2 Nursing Practice

Nurses play a critical role in recruitment, as they often promote potential clinical trials, educate patients and families on available studies for participation, and provide essential care to cancer patients throughout the care continuum of the clinical trial [55, 56]. Therefore, understanding the barriers that Hispanic oncology patients face regarding participation in clinical trials may assist nurses in revising and improving processes.

Patients need clinical trial education in terms that they can understand. Nurses that recruit patients for cancer clinical trials should be able to educate patients on the purpose of clinical trials, benefits and risks to participation, potential out-of-pocket cost, and study-specific

nuances that may be required, such as multiple visits or transportation requirements. Cancer patients have limited knowledge of clinical trials and this lack of knowledge and familiarity can cause fear of participating [1]. Patients have little familiarity or awareness of clinical trial availability indicating that purpose, need, risks, and benefits should be discussed in detail to mitigate uncertainty related to participation [17, 25, 26].

Although patients have little familiarity with clinical trials, as reflected in this study as well as those in the literature, patients do have a readiness to learn [1, 17, 25, 26]. Participants in the current study discussed willingness to participate if given the information regarding the clinical trial, however they did note not always being provided information for participation. Patients voiced the need for health literacy considerations such that information be provided in layman's terms, as they do not always understand medical terms and would need someone to explain it to them rather than simply giving them marketing materials to aid their decision.

Additionally, in the current study, patients perceived that participation in cancer clinical trials is costly, and thus make the decision to abstain from participation. This fear of clinical trial financial burden was also seen in the literature, as it was reported that patients cited cost as a barrier to their participation [17]. Nurses recruiting patients should have open dialogue with patients to discuss the concerns of financial burden. Recruitment staff, including nurses, should be aware that financial burden may be a barrier to participation and should work with their organizations to determine if financial assistance can be provided.

Recruitment nurses should also expect transportation to be a barrier to participation, as this has been reported in the literature by both participant groups [17, 20, 22, 71]. One recruiter in the current study noted that transportation barriers were mitigated slightly during the COVID-19 pandemic, as telehealth visits were utilized so that they did not require the

patient to come on-site. As such, recruitment nurses should be familiar with transportation availability in their respective locations – bus lines, bus schedules, etc. – to assist patients with overcoming this barrier, but should also look to discuss the possibility of telehealth visits with the study investigator as a way to mitigate transportation issues and the associated costs.

Aside from physical barriers to participation like transportation and cost, recruitment nurses should also be aware of the need to build and maintain a trusting relationship with the potential participant. The recruiter will remain unsuccessful in recruitment of the Hispanic population if trust is not built and maintained throughout the process. Trust has been an integral theme within the literature surrounding minority participation in cancer clinical trials, and was evident in the current study as well, as it ranked first on the BCTP barrier scale and was discussed at length in the patient and recruiter interviews, ranking the 3rd most common code during content analysis, behind translator need and engagement (Appendix H) [1, 16, 18, 21-22, 30-31, 36, 71]. Further, in the current study, patients expressed that receiving clinical trial information from a trusted source would increase their willingness to participate in cancer clinical trials. Therefore, nurses recruiting patients into clinical trials should work to build trust with the potential participant. Recruiters within the current study noted that engaging the community by providing education to the population at local community centers or churches was a way to build trust within the community. A patient in the P.I.'s 2019 pilot study noted that clear, honest communication aids in trusting recruitment professionals. Therefore, community engagement, by way of educational opportunities, discussions, and honest conversations, should be completed by those nursing professionals recruiting the population. Being present within the community and showing interest in the community aside from simply recruiting will allow for the population to begin trusting the research process and consider participation in clinical trials. As a recruiter noted in the current

study, trust is built within this population, so it must be cultivated over time and by action. Nurse recruiters can start this process by seeking out community leaders and discussing potential engagement opportunities – possibly providing education to the population that is of particular interest. These opportunities to work with the population outside of research will assist in building a foundation of trust and becoming a trusted source of information within the community.

Of note, nursing practice within the realm of clinical trial recruitment is not a job solely for the nurse recruiter. Bedside oncology nurses and APRNs also play vital roles in the recruitment and retention of clinical trial participants. Bedside oncology nurses often provide care to patients during study treatment, advocate for them during clinical trial participation, and ensure that their needs are met throughout the entire clinical trial process [56]. As such, it is important for bedside oncology nurses to be aware of all potential barriers to their patient's participation in cancer clinical trials so that they can appropriately advocate for their patient.

Advanced Practice Providers (APPs, APRNs, ARNPs) play pivotal roles in the treatment and care of Hispanic oncological patients, as they often have access to underserved and ethnically diverse populations [58]. APPs assist with enrollment of patients in cancer clinical trials and are often the first step in the clinical trial participation process [8]. Recruiters in the current study noted that patients are more willing to participate when their providers introduce, educate, or refer them to studies. As such, there is no discordance between providers and patients, as patients in the current study noted that their participation hinged on the receipt of clinical trial information from their provider, thus making the APP position pivotal in the recruitment process. Trust in the provider has been noted in the literature, as patients have described needing to trust that their provider is referring them to a clinical trial

in their best interest [18]. Further, in a study conducted on patients to determine willingness to participate, 66% noted that the primary source of information regarding the clinical trial process was their provider [8]. As such, APPs can facilitate the recruitment process by collaborating with recruiters to ensure seamless transitions to the recruitment process. Further, APPs can work within the community with the nurse recruiters helping to build strong relationships with community partners and provide ongoing education as a method of engagement and trust building.

5.3.3 Nursing Research

Cancer clinical trials focus on studying the effectiveness of new treatments, preventative measures, diagnostic testing strategies, symptom management, predictive modeling, and interventions within the oncologic population [53]. Participant diversity is critical to nurse researchers seeking to apply clinical trial findings beyond those in their study, with low participation impacting the generalizability of data secured [9, 14, 39, 51]. Hispanic cancer patients are not participating at the rates required to provide enough data to generalize to the entire population [1]. Two major barriers to the clinical trial process as described by the patients and recruiters in the current study that must be considered are inclusion criteria and informed consent.

Patients in previous studies have noted inclusion criteria to be a concern, as they were unable to join clinical trials based on cancer type or medical history [17, 76]. Researchers are unintentionally creating barriers to participation, as Hispanic patients are deemed ineligible to participate given current medical conditions. As such, researchers must review potentially exclusionary participant criteria when aiming to recruit Hispanic oncology patients. Additionally, one of the main purposes of cancer clinical trials is to secure data to determine

efficacy among the population tested, therefore recruiters and primary investigators should be aware of the potential exclusion of a population based on study inclusion criteria.

In addition to inclusion criteria, patients and recruiters in the current study voiced that having no translated materials, to include marketing materials and informed consents, posted a great barrier for participation. Further, recruiters also stated that many studies they worked with did not have the option to translate informed consents, so patients had to be English speaking to participate, thereby excluding all Spanish-speakers from participation. A cross-sectional study conducted with recruiters corroborated this same barrier to clinical trial participation, that being a lack of translated materials, including informed consent [31]. As researchers aim to recruit diverse participants, they must also ensure that all study materials support the recruitment and retention of these populations. This study, for instance, mitigated this barrier by providing all study materials in Spanish for the cancer patient group, along with having a bilingual primary investigator available for questions or concerns throughout the study. Spanish materials for the recruiter group may have gained additional reach and information. As such, future studies focused on recruiting this participant population should utilize similar steps to increase inclusivity.

If barriers can be mitigated and facilitators enhanced, patients will be more inclined and able to participate in clinical trials in the future, thereby improving outcomes and the rigor of research produced. Diverse populations are required to ensure treatment efficacy, thus mitigating barriers to participation will improve participant accrual and the generalizability of treatments to these populations, ultimately reducing health inequities.

5.4 Direction for Future Research

Future research should be aimed at both the patient and recruiter populations to increase participation in cancer clinical trials among Hispanic oncologic patients. As there was convergence and divergence of barriers and facilitators noted between samples, the priority intervention developed should focus on variables that are feasible to mitigate or bolster, such as translator and translated material deficits, clinical trial knowledge and understanding, or community outreach, rather than citizenship status, which cannot be mitigated.

A 2018 randomized control trial pilot study tested the effectiveness of an intervention focused on increasing clinical trial understanding and consideration of clinical trial participation among a population of Latina breast cancer patients. They were provided an educational video, booklet, and access to a navigator for question answering. Although this was a pilot study, it is important to note that patients reported greater understanding of the clinical trial process following the intervention deliveries [7]. Clinical trial understanding, knowledge, and familiarity are reported by patients and recruiters in the current study as barriers to participation, thus a larger-scale version of an RCT aimed at a more diverse sample population should be completed.

A quasi-experimental design could be utilized to determine if the presence of translators and translated materials had greater success in recruitment of Hispanic oncology patients. Also, intervention studies aimed at community outreach would be an excellent start to improving the recruiter-patient relationship. For instance, as recruiters in the current study mentioned accessing community leaders and engaging the community were facilitators to participation, a study utilizing that engagement strategy could be developed to determine efficacy. Additionally, an RCT like that of the education intervention above could be utilized to measure effectiveness.

As many of the findings of this study fell within the SDOH framework, future research could be aimed at investigating how each SDOH area impacts participation among this population. This exploration could provide greater detail on how to properly advocate and provide culturally sensitive healthcare to this population.

Lastly, as this study was successful in achieving its aims, a reliable and valid instrument should be developed that can effectively measure all barriers and facilitators found within this study as a comprehensive tool that can be tested and validated in other minority populations to gain insight regarding clinical trial participation. The BCTP and Tanner scales utilized in this study were effective in securing the quantitative data sought in the aims, however a more comprehensive tool inclusive of qualitative themes found in this study would provide more robust data for future studies [30, 40].

5.5 Lessons Learned

Although patients were willing to participate in the survey portion of this study, they were not as willing to participate in the qualitative interviews. This could be due to several factors, some of which could be fears of anonymity compromise, scheduling conflicts, or current cancer treatment. One participant was willing to participate, however was undergoing chemotherapy at the time and thus energy level and scheduling impacted their availability to participate in an interview. Therefore, future research conducted should take into consideration the fragility of the patients participating if sample numbers are not reached.

When recruiting the Hispanic oncology population for future studies, it is recommended to make connections with community leaders and community centers prior to starting the study to educated, inform, and build trust in the research process. Building these strong foundations of trust within the community will assist in participant accrual among those who

may not be reached via online platforms. By using a nationwide survey, thereby increasing inclusivity, the study failed to reach those in the community without Internet capability. Therefore, in the future it will be important to be sensitive to inclusion criteria to ensure the study excludes only those meant to be excluded, instead of those who cannot access it.

5.6 Conclusion

In conclusion, this study sought to identify and describe barriers and facilitators to cancer clinical trial participation among Hispanic patients as perceived by patients and recruiters. The findings support previous research; however, a representative sample was recruited for both groups and was the first known study to explore the convergence and divergence of these viewpoints. Future studies should be aimed at developing interventions and instruments aimed at mitigating barriers perceived by patients and recruiters.

5.7 Dissemination of Findings

The findings of the current study will be disseminated to study participants and to the organizations assisting with recruitment activities. Manuscripts will be submitted for publication in peer-reviewed journals of interest. Copies of the manuscripts will be forwarded to the National Institute on Minority Health and Health Disparities (NIMHD).

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APPENDIX A

Informed Consent

Barriers and Facilitators to Hispanic Participation in Cancer Clinical Trials

Hello!

Would you be willing to participate in a research study exploring the reasons Hispanic/Latinx patients participate (or avoid participating) in cancer clinical trials? If so, this study may be for you.

You are being asked to take part in this research study because you can provide valuable feedback regarding Hispanic participation in cancer clinical trials. Your thoughts are vital to helping us understand how we can increase participation in clinical trials in the future.

Study Information. You do not have to be in this research study. You can stop being in this study at any time. We are asking you to spend about 10-15 minutes to complete a short survey about your experiences and thoughts about the reasons Hispanic/Latinx patients participate (or avoid participating) in cancer clinical trials. If interested, you can continue your participation with the one-on-one telephone interviews that should last no longer than 20 minutes to discuss the topic further. All responses are and will remain confidential. We are committed to maintaining your privacy throughout the study. As a thank you for your time and participation, we will provide you with a $25 e-gift card for the survey and an additional $25 e-gift card for the interview.

Contact Information. If you should have any questions about this research study, please feel free to contact Amanda Davis at (615)669-7024 or my Faculty Advisor, Dr. Jana Lauderdale at (615)343-2228. For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll-free at (866) 224-8273.

I have read and understand the information provided above. I voluntarily choose to participate in the study and understand that I am free to leave the study at any time.	◯ Yes, I AGREE to participate ◯ No, I DO NOT AGREE to participate

BCTP Patients Spanish

¡Hola!

¿Estaría dispuesto a participar en un estudio de investigación que explora las razones por las que los pacientes hispanos/latinos participan (o evitan participar) en ensayos clínicos sobre el cáncer? Si es así, podría interesarle este estudio.

Se le ha solicitado que participe en este estudio de investigación porque puede proporcionar información valiosa sobre la participación de hispanos en los ensayos clínicos sobre el cáncer. Sus opiniones son vitales para ayudarnos a entender cómo podemos incrementar la participación en los ensayos clínicos en el futuro.

Información sobre el estudio. No tiene que participar en el estudio de investigación; puede abandonarlo en cualquier momento. Le pedimos que dedique unos 10-15 minutos para completar una breve encuesta sobre sus experiencias y opiniones acerca de las razones por las que los pacientes hispanos/latinos participan (o evitan participar) en los ensayos clínicos sobre el cáncer. Si le interesa, puede continuar con las entrevistas telefónicas individuales que duran aproximadamente 20 minutos para conversar sobre el tema a más detalle. Todas las respuestas son y se mantendrán confidenciales. Nos comprometemos a mantener su privacidad durante todo el estudio y como agradecimiento por su tiempo y participación, le proporcionaremos una tarjeta de regalo electrónica de 25 dólares por la encuesta y otra de 25 dólares por la entrevista.

Información de contacto. Si tiene alguna pregunta sobre este estudio de investigación, no dude en ponerse en contacto con Amanda Davis al (615)669-7024 o con mi consejera de Facultad, la Dra. Jana Lauderdale al (615)343-2228. Para más información sobre el consentimiento o sus derechos como participante en este estudio, plantear problemas, preocupaciones y preguntas, o para ofrecer su opinión, no dude en ponerse en contacto con la Oficina de la Junta de Revisión Institucional al (615) 322-2918 o a la línea gratuita (866) 224-8273.

He leído y entiendo la información proporcionada anteriormente y por mi propia voluntad decido participar en el estudio entendiendo que puedo abandonarlo en cualquier momento.	◯ Sí, ACEPTO participar ◯ No, NO ACEPTO participar

Cancer Clinical Trials Recruiters

Hello!

Would you be willing to participate in a research study exploring the reasons Hispanic/Latinx patients participate (or avoid participating) in cancer clinical trials? If so, this study may be for you.

You are being asked to take part in this research study because you can provide valuable feedback regarding Hispanic participation in cancer clinical trials. Your thoughts are vital to helping us understand how we can increase participation in clinical trials in the future.

Study Information. You do not have to be in this research study. You can stop being in this study at any time. We are asking you to spend about 10-15 minutes to complete a short survey about your experiences and thoughts about the reasons Hispanic/Latinx patients participate (or avoid participating) in cancer clinical trials. If interested, you can continue your participation with the one-on-one telephone interviews that should last no longer than 20 minutes to discuss the topic further. All responses are and will remain confidential. We are committed to maintaining your privacy throughout the study. As a thank you for your time and participation, we will provide you with a $25 e-gift card for the survey and an additional $25 e-gift card for the interview.

Contact Information. If you should have any questions about this research study, please feel free to contact Amanda Davis at (615)669-7024 or my Faculty Advisor, Dr. Jana Lauderdale at (615)343-2228. For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll-free at (866) 224-8273.

I have read and understand the information provided above. I voluntarily choose to participate in the study and understand that I am free to leave the study at any time.

- ◯ Yes, I AGREE to participate
- ◯ No, I DO NOT AGREE to participate

APPENDIX B

Demographic Questionnaire

Barriers & Facilitators to Hispanic Participation in Cancer Clinical Trials	
What is your age?	_____
Please indicate your sex:	◯ Male ◯ Female
With what gender do you identify? (Optional):	_____
What is your ethnicity?	◯ Native American/Native Alaskan ◯ Asian ◯ Black or African American ◯ Native Hawaiian/Other Pacific Islander ◯ White or Caucasian ◯ Other ◯ Prefer not to respond
Are you Hispanic, Latin(x), or Spanish origin?	◯ No ◯ Yes, Mexican, Mexican American, Chicano ◯ Yes, Puerto Rican ◯ Yes, Cuban ◯ Yes, another Hispanic, Latin(x), or Spanish origin.
Please specify, for example: Salvadoran, Dominican, Colombian, Guatemalan, Spaniard, Ecuadorian, etc.	_____
In what country were you born?	_____
What is your preferred language?	◯ English ◯ Spanish ◯ Other language
Please specify your preferred language	_____
Are you fluent in Spanish?	◯ yes ◯ no
Are you fluent in any other languages? If so, which languages?	_____
Have you had a previous or current diagnosis of cancer?	◯ Yes ◯ No
Have you ever been recruited into a cancer clinical trial?	◯ Yes ◯ No
How did you hear about the clinical trial?	◯ Your oncologist ◯ Your primary care provider ◯ Another medical provider ◯ A friend ◯ TV ad ◯ Another resource
Have you ever participated in a cancer clinical trial?	◯ Yes ◯ No

Barreras y facilitadores para la participación hispana en ensayos clínicos de cáncer	
¿Cuál es su edad?	_____
Indique su género:	◯ Masculino ◯ Femenino
¿Con cuál género se identifica? (Opcional):	_____
¿Cuál es su etnia?	◯ Nativo americano / nativo de Alaska ◯ Asiático ◯ Negro o afroamericano ◯ Nativo de Hawái / otras islas del Pacífico ◯ Blanco o caucásico ◯ Otro ◯ Prefiero no responder
¿Es de origen hispano, latino o español?	◯ No ◯ Sí, mexicano, mexicano-americano, chicano ◯ Sí, puertorriqueño ◯ Sí, cubano ◯ Sí, otro origen hispano, latino o español.
Por favor especifique, por ejemplo: salvadoreño, dominicano, colombiano, guatemalteco, español, ecuatoriano, etc.	_____
¿Cuál es su país de nacimiento?	_____
¿Cuál es su idioma predilecto?	◯ Inglés ◯ Español ◯ Otro idioma
Por favor especifique su idioma predilecto	_____
¿Habla español con fluidez?	◯ Sí ◯ No
¿Habla otro idioma con fluidez? Si es así, ¿qué idiomas?	_____
¿Ha tenido un diagnóstico previo o actual de cáncer?	◯ Sí ◯ No
¿Alguna vez ha sido reclutado en un ensayo clínico de cáncer?	◯ Sí ◯ No
¿Cómo se enteró del ensayo clínico?	◯ Su oncólogo ◯ Su proveedor de atención primaria ◯ Otro proveedor médico ◯ Un amigo ◯ Por un anuncio de televisión ◯ Otro medio
¿Ha participado alguna vez en un ensayo clínico sobre el cáncer?	◯ Sí ◯ No

Barriers & Facilitators to Hispanic Participation in Cancer Clinical Trials	
What is your age?	_____
Please indicate your sex:	◯ Male ◯ Female
With what gender do you identify? (Optional):	_____
What is your ethnicity?	◯ Native American/Native Alaskan ◯ Asian ◯ Black or African American ◯ Native Hawaiian/Other Pacific Islander ◯ White or Caucasian ◯ Other ◯ Prefer not to respond
Are you Hispanic, Latin(x), or Spanish origin?	◯ No ◯ Yes, Mexican, Mexican American, Chicano ◯ Yes, Puerto Rican ◯ Yes, Cuban ◯ Yes, another Hispanic, Latin(x), or Spanish origin.
Please specify, for example: Salvadoran, Dominican, Colombian, Guatemalan, Spaniard, Ecuadorian, etc.	_____
What is your preferred language?	◯ English ◯ Spanish ◯ Other language
Please specify your preferred language	_____
Are you fluent in Spanish?	◯ yes ◯ no
Are you fluent in any other languages? If so, which languages?	_____

APPENDIX C

BCTP (English and Spanish Versions)

Clinical trials, also called treatment or research studies, test new treatments for people with diseases or at high risk for disease. Clinical trials test many types of treatment, such as drugs, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods such as gene therapy. Clinical trials test treatment approaches that have been tested in the laboratory and seem promising for use in humans.

People have many different reasons for choosing whether or not to be in clinical trials. We are interested in your reasons. Please circle how much you agree or disagree with each of the following reasons.

	Strongly Disagree	Disagree	Agree	Strongly Agree
There's nothing in clinical trials for me.	○	○	○	○
The leaders of my community tell us not to get involved in clinical trials.	○	○	○	○
They say everything is being done according to strict guidelines, but I don't know if anybody's checking.	○	○	○	○
It costs too much money to be in a clinical trial.	○	○	○	○
Clinical trials haven't done any good for my family.	○	○	○	○
People I know have told me not to be in clinical trials.	○	○	○	○
When I think about research, I remember Tuskegee, and think that could happen again.	○	○	○	○
I would not know how to ask for advice about getting involved in a clinical trial.	○	○	○	○
I am worried that I would not know if something went wrong in a trial I was in.	○	○	○	○
I don't know enough about clinical trials to decide.	○	○	○	○
I don't think the results of clinical trials make much difference to how my doctor treats me.	○	○	○	○
People in my community don't think it's a good idea to get involved in clinical trials.	○	○	○	○

The results will be the same whether people from minority groups take part in clinical trials or not.	○	○	○	○
If something bad happens to me, I wonder how I will know if it is because of being in the trial.	○	○	○	○
I can't think of any way that clinical trials have helped me.	○	○	○	○
Researchers sometimes say they want your information for one purpose, but then they may use it against you or your people.	○	○	○	○
You never hear anything good reported about clinical trials in the newspaper, TV or radio.	○	○	○	○
I worry that they are not telling me everything I need to know.	○	○	○	○
I can't think of any good clinical trials I've ever heard about.	○	○	○	○

Investigación clínica, también llamada tratamiento o estudios de investigación, prueban nuevos tratamientos para las personas con enfermedades o con alto riesgo de sufrir enfermedades. En la investigación clínica se prueban muchos tipos de tratamientos, tales como drogas, nuevos formas a la cirugía o a la terapia por radiación, nueva combinación de tratamientos, o nuevos métodos como la terapia génica. La Investigación Clínica prueba formas tratamientos que tienen que estar aprobados en el laboratorio y parecen prometedores para el uso en humanos.

Las personas tienen muchas razones diferentes para elegir estar o no en la investigación clínica. Estamos interesados en sus razones. Por favor señale con un círculo cuanto está de acuerdo o en desacuerdo con cada una de las siguientes razones.

	Totalmente en desacuerdo	Desacuerdo	Neutro	De Acuerdo	Totalmente De Acuerdo
No hay nada en la Investigación Clínica para mí.	○	○	○	○	○
Los líderes de mi comunidad nos dicen no formemos parte en la Investigación Clínica	○	○	○	○	○
Dicen que todo se hace de acuerdo a unas estrictas guías, pero no se si es comprobado por alguien.	○	○	○	○	○
Cuesta mucho dinero estar en investigación clínica.	○	○	○	○	○
Investigación Clínica no hacen ningún bien a mi familia.	○	○	○	○	○
Personas que conozco me han dicho no formar parte en la Investigación Clínica	○	○	○	○	○
Cuando pienso en los estudios de investigación, me acuerdo que en el pasado los investigadores le han hecho cosas malas a la gente y pienso que esto podría ocurrir otra vez.	○	○	○	○	○
No sabría pedir consejo para conseguir formar parte en la Investigación Clínica.	○	○	○	○	○
Me preocupa el no saber si algo fue mal en un ensayo en el cual participe.	○	○	○	○	○
No se lo suficiente sobre la investigación clínica para decidir.	○	○	○	○	○
No creo que los resultados de la investigación clínica sean muy distintos a como mi doctor/medico me trata.	○	○	○	○	○
Personas en mi comunidad no piensan que no es sea una Buena idea formar parte de la investigación clínica.	○	○	○	○	○
Los resultados serán los mismos, aunque la gente de grupos minoritarios participen o no, en la investigación clínica.	○	○	○	○	○
Si algo malo me sucede, me pregunto como sabré si es debido participar en el ensayo.	○	○	○	○	○
No veo ninguna forma en que los ensayos clínicos me vayan ha ayudar.	○	○	○	○	○
Los investigadores algunas veces dicen que quieren su información para un propósito, pero luego pueden utilizarla contra usted o los suyos.	○	○	○	○	○
Nunca se escucha ninguna buena información sobre investigación clínica en periódicos, TV o Radio.	○	○	○	○	○
Me preocupa que no me digan todo lo que necesito saber.	○	○	○	○	○
No recuerdo que haya oído hablar de ningún buen ensayo clínico.	○	○	○	○	○

APPENDIX D

Tanner Scale

Please indicate how much you agree or disagree with each of the following statements about BARRIERS to recruiting HISPANICS/LATINX.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
It is difficult to find potential participants.	○	○	○	○	○
Patients' insurance will not cover clinical trials procedures or drugs.	○	○	○	○	○
Local physicians/doctors are unwilling to engage in accrual.	○	○	○	○	○
Local physicians/doctors are unaware of ongoing trials.	○	○	○	○	○
Patients lack information about available trials.	○	○	○	○	○
Patients have limited accessibility to trial sites.	○	○	○	○	○
Patients desire other treatments.	○	○	○	○	○
Patients lack knowledge about the idea of clinical trials.	○	○	○	○	○
Patients have low literacy or low health literacy.	○	○	○	○	○
Patients have negative perceptions about clinical trials (e.g., "I will be treated like a guinea pig.").	○	○	○	○	○
Patients lack confidence in or distrust medical research (e.g., historical abuses of research participants).	○	○	○	○	○
Patients have fear of participating in clinical trials (e.g., fearful about something untested, fear of randomization).	○	○	○	○	○

APPENDIX E

Semi-Structured Interview Guides, Patient and Recruiter

INDIVIDUAL INTERVIEW GUIDE: PATIENT

Date: ___ / ___ / ___ Start time: ___ : ___ [AM] [PM]

Interviewee Pseudonym: _____

Introduction

"Good morning/afternoon/evening. My name is _____, and I'll be interviewing you today regarding Hispanic participation in cancer clinical trials. My role is to make sure that we cover the main topics during our conversation".

Objectives and Agenda

"As a reminder from the first part of this study that you have completed, I am conducting a study to explore the reasons why Hispanics do/do not participate in cancer clinical trials. I want to hear about your experiences and perspectives to help me understand how we can increase participation in cancer clinical trials in the future".

Ground Rules

"Before we begin, I want to confirm that you still agree to participate with this interview today [*pause 5 seconds*]. If you do not wish to participate, you are free to leave now. If you want to continue, let's talk about a few basic ground rules for our discussion.

1. This session is being recorded. This recording allows me, as the interviewer, to focus on you – instead of just writing notes the entire time. Therefore, please speak as loudly as I am so that the microphone picks up all of your comments.
2. We will write a report using the recordings. We will NOT mention your name. By ensuring and committing to your confidentiality, I'm hoping you will feel as though you can speak openly and honestly with me today.
3. The questions are meant to get your viewpoint, so there are no right or wrong answers. Feel free to give both positive and negative feedback.

Now, I want you to think of anything that you would consider a barrier or facilitator to participation among Hispanic cancer patients. A barrier is any reason that you might not want to (or cannot) participate in a clinical trial. It may include things that you can control, like no interest in the study, and things you may not be able to control, like insurance coverage. A facilitator is anything, like the ability to try a new therapy that may motivate you to participate in a clinical trial".

INTERVIEW

"Let's begin:

1. Please tell me what you know about cancer clinical trials".

   [Prompt: "can you tell me what a clinical trial is or what happens when someone is in a clinical trial?"]

   After the patient responds, the following will be read: "cancer clinical trials are research studies that people with cancer may participate in to try new therapies or medicines that researchers think may help their condition."

2. "What reasons would help you in your decision to participate in cancer clinical trials?"

   [*Prompt: "can you describe any reasons, circumstances, or procedures that may help you make a decision to participate in cancer clinical trials?"*]

3. "What reasons would prevent you from participating in cancer clinical trials?"

   [*Prompt: "can you describe any reasons, circumstances, or procedures that may prevent you from making a decision to participate in cancer clinical trials?"*]

4. "In general, what changes, if any, do you think need to be made to healthcare policy (laws, rules, or guidelines) to help Hispanics participate in cancer clinical trials?"

   [Prompt: "What rules/guidelines do you think stop Hispanic patients from participating in cancer clinical trials if any?"]

5. "How can we improve Hispanic patients' access to cancer clinical trials?"

   [*Prompt: "What changes need to be made that could make it easier for Hispanics to access clinical trials?"]*

6. "Is there anything else you would like to tell me about recruiting patients like you for clinical trials?"

Tell the patient this is the end of the interview, and thank them for their participation. Tell them they can contact _____ if they have any questions.

GUÍA DE ENTREVISTA INDIVIDUAL: PACIENTE

Fecha: ___ / ___ / ___ Hora de inicio: ___: ___ [AM] [PM]

Seudónimo del entrevistado: _____

Introducción

"Buenos días/tarde/noche. Mi nombre es _____, y lo entrevistaré hoy con respecto a la participación hispana en ensayos clínicos sobre el cáncer. Mi función es asegurarme de que cubramos los temas principales durante nuestra conversación".

Objetivos y agenda

"Como recordatorio de la primera parte de este estudio que ha completado, estoy realizando un estudio para explorar las razones por las que los hispanos participan o no en ensayos clínicos sobre el cáncer. Quiero escuchar sus experiencias y perspectivas para ayudarme a comprender cómo podemos aumentar la participación en los ensayos clínicos del cáncer en el futuro".

Reglas básicas

"Antes de comenzar, quiero confirmar que todavía está de acuerdo en participar con esta entrevista hoy [*pausa de 5 segundos*]. Si no desea participar, puede retirarse ahora. Si desea continuar, hablemos de algunas reglas básicas para nuestra discusión.

1. Esta sesión se está grabando. Esta grabación me permite, como entrevistador, a concentrarme en usted, en lugar de simplemente escribir notas todo el tiempo. Por lo tanto, hable tan alto como yo para que el micrófono capte todos sus comentarios.
2. Escribiremos un informe utilizando las grabaciones. NO mencionaremos su nombre. Al garantizar y comprometerme con su confidencialidad, espero que sienta que puede hablar abierta y honestamente conmigo hoy.
3. Las preguntas están destinadas a obtener su punto de vista, por lo que no hay respuestas correctas o incorrectas. Siéntase libre de dar comentarios tanto positivos como negativos.

Ahora, quiero que piense en cualquier cosa que considere una barrera o un facilitador para la participación de los pacientes hispanos con cáncer. Una barrera es cualquier motivo por el que no desee (o no pueda) participar en un ensayo clínico. Puede incluir cosas que puede controlar, como no tener interés en el estudio, y cosas que quizás no pueda controlar, como cobertura de seguro. Un facilitador es cualquier cosa, como la capacidad de probar una nueva terapia que pueda motivarlo a participar en un ensayo clínico".

ENTREVISTA

"Comencemos:

1. Por favor, dígame lo que sabe sobre los ensayos clínicos sobre el cáncer".

   [Mensaje: "¿puede decirme qué es un ensayo clínico o qué sucede cuando alguien participa en un ensayo clínico?"]

   Una vez que el paciente responda, se leerá lo siguiente: "Los ensayos clínicos sobre el cáncer son estudios de investigación en los que las personas con cáncer pueden participar para probar nuevas terapias o medicamentos que los investigadores creen que pueden ayudar a su afección".

2. "¿Qué razones le ayudarían en su decisión de participar en ensayos clínicos sobre el cáncer?"

   [Mensaje: "¿Puede describir alguna razón, circunstancia o procedimiento que pueda ayudarlo a tomar la decisión de participar en ensayos clínicos sobre el cáncer?"]

3. "¿Qué razones le impedirían participar en ensayos clínicos sobre el cáncer?"

   [Mensaje: "¿Puede describir alguna razón, circunstancia o procedimiento que pueda impedirle tomar la decisión de participar en ensayos clínicos sobre el cáncer?"]

4. "En general, ¿qué cambios, si los hay, cree que se deben realizar en la política de atención médica (leyes, reglas o pautas) para ayudar a los hispanos a participar en los ensayos clínicos sobre el cáncer?"

   [Mensaje: "¿Qué reglas/pautas crees que impiden que los pacientes hispanos participen en los ensayos clínicos sobre el cáncer, si los hay?"]

5. "¿Cómo podemos mejorar el acceso de los pacientes hispanos a los ensayos clínicos sobre el cáncer?"

   [Mensaje: "¿Qué cambios se deben hacer para facilitar el acceso de los hispanos a los ensayos clínicos?"]

6. "¿Hay algo más que le gustaría contarme sobre cómo reclutar pacientes como usted para ensayos clínicos?"

Dígale al paciente que este es el final de la entrevista y agradézcale su participación. Dígale que puede comunicarse con _____ si tienen alguna pregunta.

INDIVIDUAL INTERVIEW GUIDE: RECRUITER

Date: ___ / ___ / ___ Start time: ___ : ___ [AM] [PM]

Interviewee Pseudonym: _____

Introduction

"Good morning/afternoon/evening. My name is _____, and I'll be interviewing you today regarding Hispanic participation in cancer clinical trials. My role is to make sure that we cover the main topics during our conversation".

Objectives and Agenda

"As a reminder from the first part of this study that you have completed, I am conducting a study to explore the reasons why Hispanics do/do not participate in cancer clinical trials. I want to hear about your experiences and perspectives to help me understand how we can increase participation in cancer clinical trials in the future".

Ground Rules

"Before we begin, I want to confirm that you still agree to participate with this interview today [pause 5 seconds]. If you do not wish to participate, you are free to leave now. If you want to continue, let's talk about a few basic ground rules for our discussion.

1. This session is being recorded. This recording allows me, as the interviewer, to focus on you – instead of just writing notes the entire time. Therefore, please speak as loudly as I am so that the microphone picks up all of your comments.
2. We will write a report using the recordings. We will NOT mention your name. By ensuring and committing to your confidentiality, I'm hoping you will feel as though you can speak openly and honestly with me today.
3. The questions are meant to get your viewpoint, so there are not right or wrong answers. Feel free to give both positive and negative feedback.

Now, I want you to think of anything that you would consider a barrier or facilitator to participation among Hispanic cancer patients. A barrier is any reason that a patient would not participate, either within or outside of their control. A facilitator is any reason, policy or circumstance that may aid a patient to participate in clinical trials".

INTERVIEW

"Let's begin:

1. "What reasons have patients reported for accepting or declining participation in cancer clinical trials?"

   [*Prompt: "why are Hispanics declining participation?"]*

2. "What would help you in the recruitment of Hispanic patients to participate in cancer clinical trials?"

   [*Prompt: "can you describe any reasons, circumstances, or procedures that may help you recruit Hispanic patients in cancer clinical trials?"*]

3. "What do you believe prevents you from recruiting Hispanic patients to participate in cancer clinical trials?"

   [*Prompt: "can you describe any reasons, circumstances, or procedures that may prevent you from recruiting Hispanic patients to participate in cancer clinical trials?"*]

4. "What changes, if any, do you think need to be made to healthcare policy (laws, rules, or guidelines) to help Hispanics participate in cancer clinical trials?"

   [Prompt: "What rules/guidelines do you think stop Hispanic patients from participating in cancer clinical trials if any?"]

5. "In your experience, what study specifics or organizational factors prevent Hispanics from participation in cancer clinical trials?"

   [*Prompt: "Do certain studies or organizational guidelines prevent recruitment of Hispanic participants?"]*

6. "In your experience, what study specifics or organizational factors improve Hispanic recruitment for cancer clinical trials?"

   [Prompt: "Do certain studies or guidelines improve recruitment of Hispanic participants?"]

7. "Is there anything else you would like to tell me about recruiting Hispanic patients for clinical trials?"

   Tell the recruiter this is the end of the interview and thank them for their participation. Tell them they can contact _____ if they have any questions.

APPENDIX F

Qualitative Code Book

Code	Description	Example
Access to trials	Transportation, scheduling, expense, affordability.	"Patients can access clinical trials in their area" “I have/don’t have transportation to and from clinical trials”
Altruism	Participating in a clinical trial so that they can improve outcomes for others	“I want to participate to help other Hispanics” “Patients are more apt to participate if they know they are going to be helping others”
Building trust	The act of working towards improving trust between two or more people	“The recruiter has to speak to me as though they care about me to have me trust them at all” “You have to reach the patient out in the community and work hard to gain their trust”
Citizenship status	Legal status of an individual	“Patients that are undocumented are less likely to participate” "Legal status is preventing participation"
Communicating for understanding	Providing information to patients in a manner which facilitates comprehension	“I don’t know much about medicines or treatment, so I need someone to help me by breaking it down for me in terms I can understand” “I have had success recruiting when I speak to participants in their preferred language, in layman’s terms”
Community engagement	The process of going out in the community and seeking participation	“If recruiters came to my church and discussed their studies, they may get more participation” “We see more participation in areas in which we have promoted clinical trials at community centers”

Community support	Clinical trial participation is supported by friends, family, neighbors, religious affiliations, etc	"I've had friends and neighbors that have participated in CTs and they suggest them" "Friends and neighbors (church, community) support patient CT involvement"
Familiarity or knowledge	Information or knowledge (or lack thereof) re: CT or process	"I don't know what a clinical trial is" "Patients don't understand what is involved with clinical trials"
Fear (of research)	Patient is scared of research or anyone in the research process	"I am scared of what the trial may do to me"
Incentivizing	Clinical trial incentives, participation appreciation, payments	"I will participate if I am paid for my time" "Patients will participate more if they are paid for their time"
Inclusion/Exclusion Criteria	Study criteria doesn't allow participation	"I didn't meet the requirements for study" "The patient doesn't meet inclusion criteria"
Insurance barriers	Insurance causing barrier to participation	"My insurance doesn't cover Clinical Trials" "Patient insurance doesn't cover CTs"
Literacy	Patients can read/write in a preferred language	"Patients have low literacy, so they need help filling out forms" "I can't read in English, so I can't fill out forms"
Mistrust in Research	Lack of trust in research	"I worry that they are not telling me everything I need to know" "Patients don't trust the research"
Organizational culture	Items related to how the organization functions (diversity, welcoming environment, etc)	"I'll participate if I can go to a hospital that specializes in treating Hispanics" "Patients are more willing to participate if recruiters and doctors are of the same ethnicity"

Perceived cost	The patient's perception of what participation would cost them financially	"Clinical trials cost too much money" "Patients believe they would have to pay to be a part of clinical trials"
Personal benefit	The patient believes there is any benefit to themselves for participating.	"Clinical trials are beneficial and can help me" "Patients see benefit to participating"
Translated materials	Materials that are needed for the CT process (marketing, informed consent, etc) that are in translated form	"I've never seen a flyer in Spanish" "Informed consents aren't in Spanish and need to be translated"
Translator deficit	The need for translators/interpreters	"I don't participate, because I don't know anyone who speaks my language at the hospital" "We use translators to help recruitment, but don't have them with us 24/7"
Trial requirements	The requirements to participate in a clinical trial (time needed, visits required)	"I'll participate as long as I don't have to travel far too many times" "Patients would rather participate in studies with minimal visits required"
Trust in Research	Trust in the research process	"I am confident that the study will benefit me"
Trusting communication	Getting information from a trusted source	"I trust the nurse to give me all the information I need" "Patients will only work with their trusted providers to give them information"
Type of treatment	Participation based on treatment type	"If I don't need to get chemo, I'll participate" "Patient wants to participate if the treatment is easy"

APPENDIX G

Qualitative Codes, Categories, Themes, Excerpts

Access to trials	Trial accessibility	INCLUSIVITY - Trial inclusivity (access to trials - transportation, schedule; expense, affordability, inclusion/exclusion criteria)	Inability to answer the phone and say yes or no, inability to write my name yes or no. I could do it. I just have to be able to answer the phone or write my name to do it, say yes and go for it.
Access to trials			That it's easily able to get to, to get the treatments,
Access to trials			Transportation.
Access to trials			Like work schedule because... Yeah, scheduling because if it interferes too much with my work schedule, that would be hard.
Access to trials			Definitely non-flexibility of a schedule. That's a big one.
Access to trials			Yeah. I mean, make it easy to... Like this one where I missed your phone call, but I was able to call you right back. [inaudible]. Accessibility to be able to call back so that you just don't miss the opportunity. Yeah.
Access to trials			I probably would have been open to them but, again, it's just no one is reaching out to you in the cancer center, or it's not even a topic of conversation at the oncologist. Perhaps it was because I was stage one and not something like stage four, but it's just not getting the information.
Inclusion/Exclusion Criteria	Affordability and ability to participate		More, I would honestly have to say that I can guarantee that there's not... If somebody speaks Spanish that they are actually offered the clinical trials, because I don't think because of the language barriers that a lot of people aren't asked about it. They have to find out about treatment research themselves. You know what I'm saying? It's like the doctor's offices or whatever to offer it to everybody independent of their language.
Insurance barriers			Yeah, that it probably wouldn't cost a whole lot out of my pocket.
Insurance barriers			That they'd be made available to even people of low income, that there was ways to have that done.

Translated Materials	Translation	Instrumental Communication (Language service - translator issues/deficits, translated materials, communication of information)	While I have been here at Vanderbilt, I have never had a Spanish written consent.
Translated Materials			Well, having a Spanish written consent would definitely help.
Translator barriers			Well, now we have new standards where no matter what language a patient speaks, obviously there's a short form. Obviously for us, we used to do translations over the phone, that is very, very time consuming because you're basically reading that consent one sentence at a time to the person who's translating it. And medical translation is difficult. And you could tell on countless times that we've translated, they're looking on their computer for the word. What describes alopecia? What describes diarrhea? And so it's very difficult and very time consuming. And you can see that it doesn't translate the same. We've changed our policy in that we don't allow over the phone translation. The translator has to come to the clinic in person. Now it would be via Zoom because of COVID just so that they are also acknowledging that the patient isn't signing under duress. So we've changed that after a audit. So that made us feel a little bit more comfortable, but again, it all depends on the study that we're putting the patient on. And I did at one time have a research nurse who was Hispanic, but the hospital had an issue. They don't really allow staff to translate because obviously every family may have a different dialect and it may be different. And so for a while, we ran into problems because one of the hospitals that I covered was majority Hispanic community. And when joint commission came by, it was a real issue that multiple people were translating yet they all couldn't pass a language test. And so what the hospital had to do was provide, basically, a course in Spanish language that they had to pass so that they knew that everybody was on the same dialect, if you will.
Translator barriers			I just feel when I'm working with a Spanish speaking patient, I feel I'm not truly educating them as well as I would an English speaking patient. Simply because I don't know if the same in meaning that I have when I'm speaking to an interpreter is being interpreted to the patient. So, that also makes it really hard. Yeah, there's just, there's so many places where it could be so complex.
Translator barriers			Yeah. So I recently, well, not recently, I've had this study for a while, but there's a study that I run that is looking at weight loss and patients that have recovered from breast cancer. And for the first, I want to say, year, maybe year and a half, patients, they were hoping to enroll Spanish speaking patients because they had the materials. They had a Spanish translated informed consent, Spanish translated website, all of the materials and everything. But what they didn't have, was Spanish speaking health and wellness coaches. So they had to wait, I don't know, maybe a year or a year and a half, to enroll Spanish speaking patients because they did not have health and wellness coaches that spoke Spanish yet.
Translator barriers			To enroll a patient that speaks Spanish, to a clinical trial. So I can speak and understand conversational Spanish, but I don't speak medical type of Spanish. So I can conversate with people.
Translator deficit			Well, me personally, I do not speak Spanish and I feel that is a huge block for me because if I'm doing a trial that has a medical intervention, if it's involving medication, I feel as a research nurse I am available 24 hours a day, seven days a week. They can call me anytime, any day to say, "This might be a side effect I'm having. Is this a problem?" As opposed to, let's say, waiting until Monday or waiting until their physician visit. And to me with someone who speaks Spanish, if I can't communicate with them, I feel that I've lost my ability to be always available to them. It seems like in my history, if I have put someone on study, they have either lived with family members who speak majority English. So they're the ones always talking for them, but it doesn't always make me feel comfortable because I, again, don't know am I being translated correctly? Are they saying exactly what I'm saying? And so it's a little bit of me being uncomfortable, enrolling a patient who does not speak my language.

APPENDIX H

Code Frequencies

Codes	Patients	Recruiters
Access to trials	7	21
Altruism	1	2
Building trust	1	11
Citizenship status	0	12
Communicating for understanding	0	7
Community engagement	0	28
Community support	0	5
Fear of researcher	0	1
Incentivizing	0	2
Inclusion/Exclusion Criteria	1	17
Insurance access	0	22
Knowledge / familiarity	8	11
Literacy	1	1
Mistrust (in Research)	4	18
Organizational culture	0	8
Perceived cost	2	0
Personal benefit	6	1
Translated materials	3	20
Translator barriers	1	4
Translator deficit	3	25
Trial requirements	0	2
Trusting communication	4	18
Type of treatment	3	0

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