



Reasons for declining participation in inpatient research among historically minoritized racial and ethnic communities: A scoping review

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ABSTRACT

Background: To promote equitable recruitment for studies conducted in the inpatient hospital setting, we sought to characterize reasons why individuals, both from historically minoritized racial and ethnic groups and the broader patient population, refuse participation in clinical trials within inpatient settings.

Methods: An exhaustive search of the literature was conducted in Cochrane Library, Google Scholar, Embase, MEDLINE, PubMed, Scopus, and Web of Science databases to find relevant articles published from the inception of each database to April 30, 2023. Studies recruiting patients during their inpatient stay and reporting reasons for refusing participation in clinical trials met the inclusion criteria.

Results: The search resulted in 2264 citations, of which 22 were included. Fourteen did not report data related to race, while 19 reported no ethnicity data. Reasons for refusal across trials included study burden and inconvenience (n = 16), transportation and logistical issues (n = 13), lack of interest in research (n = 12), and refusal to be randomized (n = 10). Prominent concepts included the importance of incorporating social support systems in consenting processes, lack of efforts to include data or recruitment efforts for individuals from minoritized groups, and physician involvement in recruitment.

Discussion: To enhance participation among historically minoritized communities in clinical trials, greater efforts must be made to collect demographic information and document refusal reasons to inform future recruitment methods. Strategies include proactively accounting for culture and language differences in study design and recruitment and intentionally engaging social support networks. Limiting study burden and logistics and optimizing collaborations between clinical and research teams would promote accessibility and foster patient trust.

1. Introduction

Although randomized control trials (RCT) are widely acknowledged as the gold standard for establishing evidence-based practices, there has been a significant deficiency in ensuring these trials include a diverse range of participants representative of the broader patient populations [1–3]. Notably, major landmark trials have failed to enroll adequate numbers of historically minoritized racial and ethnic groups, resulting in the establishment of clinical guidelines built upon limited evidence relevant to these populations [4,5]. Thus, the unequal inclusion of racially and ethnically diverse individuals has contributed to healthcare

disparities.

There are many ways that the institution of research has failed to address the needs of historically minoritized racial and ethnic groups, ranging from study design to recruitment and enrollment processes. Failure to address language barriers or consider cultural factors often lead to the disproportionate exclusion of these groups [6–8]. Additionally, historically minoritized and racial ethnic groups often experience higher rates of poverty and lower socioeconomic status (SES) due to systemic inequalities. Individuals from lower SES groups often face their own distinct challenges, such as access to resources and time constraints that further hinder participation in research. Furthermore, there may be

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valid individual reasons to be wary of participation in clinical trials, including lack of trust in scientific communities or the added burden of participation on caretakers and loved ones [9].

To improve representation in research, it is essential to understand the factors affecting the agreeability of an individual to participate in clinical trials. Prior studies have examined associations between characteristics such as gender, age, and study burden with the rate of refusal by participants in clinical trials [10–12]. Often, however, exploration of associations occurs without eliciting accompanying explanations, opening the door to the formulation of theories based on speculative assumptions. Inadvertently, this has created the potential to steer research efforts away from their intended objectives. These observations can be extended for studies focused on race and ethnicity data as well, many conducted within a narrow subset of clinic settings [13–16].

One context requiring further exploration as a setting for RCT recruitment is the inpatient hospital setting, particularly as an environment to reach historically minoritized racial and ethnic groups who often experience challenges accessing outpatient healthcare services. Racial and ethnic minoritized groups are less likely to seek and engage in care within outpatient primary care settings, possibly as the result of structural racism and its influences on various social determinants of health [17–19]. Particularly as it relates to intersections with low SES, long wait lists and immediate copays associated with outpatient settings often drive individuals towards more immediately accessible inpatient services. Care can also be perceived as less expensive and more comprehensive in these settings given the ease of access to all the equipment and technology to facilitate a thorough evaluation [20,21]. Structural racism often leads to the exacerbation of co-morbidities via implicit bias, discrimination, and underrepresentation of minorities in task forces, resulting in health inequities that confer an increased number of inpatient admissions [22,23]. This is particularly salient for individuals experiencing stigmatized health conditions such as mental health disorders or addiction, as well as people with serious medical or surgical illness [24]. As minority groups often have a higher incidence of conditions requiring ICU level care, as well as increased prevalence of chronic comorbidities, individuals are more likely to require hospital levels of care [25,26]. For this reason, the research community has increasingly recognized inpatient hospital settings to be critical entry points for populations both to obtain care and for inclusive research recruitment efforts [24].

Simultaneously, however, the hospital setting poses additional challenges for research participants. Many experience concern about research studies affecting care, heightened emotional or physical stress given underlying illness, or mistrust of clinical settings. Due to these unique considerations, the need persists to identify the factors that drive refusal to participate in research studies for individuals when admitted to the hospital, particularly those from historically minoritized racial and ethnic populations. Prior studies have synthesized reasons for study refusal in other settings [27–29]. Yet, to our knowledge, none have provided an overview of the existing literature regarding reasons for refusal in the inpatient setting or specifically focused on understanding factors that impact differential study participation among diverse racial and ethnic groups. Therefore, we sought to systematically synthesize the existing literature to inform future clinical trials in the inpatient setting to promote equitable participation.

2. Methods

This scoping review was conducted and reported in accordance with Levac et al.'s recommendations for scoping review methodology, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 and the PRISMA Extension for Scoping Reviews (Supplementary Appendix 1) [30–32]. The study protocol is available on Open Science Framework (<https://osf.io/frjw5/>).

2.1. Data sources and searches

An exhaustive search of the literature was conducted by a medical librarian (A.A.G.) in Cochrane Library, Google Scholar, Ovid Embase, Ovid MEDLINE, PubMed, Scopus, and Web of Science Core Collection databases to find relevant articles published from the inception of each database to April 30, 2023. Databases were searched using a combination of keywords and controlled vocabulary for hospital patients or health disparities, refusal to participate, and clinical trials. The search was not limited by language or year (Supplementary Appendix 2 for full search strategy). The search was peer-reviewed by a second medical librarian using the Peer Review of Electronic Search Strategies (PRESS) [33].

2.2. Study selection

Citations from all databases were imported into Endnote 20 library. Duplicates were removed using the Yale Reference Deduplicator [34]. The deduplicated results were imported into the Covidence systematic review management program for screening. Two independent screeners performed title/abstract review followed by full text review. Screening disagreements were resolved by a group discussion with a third investigator. Citation chasing was performed to identify additional relevant studies not retrieved by the database search [35].

For inclusion, the studies needed to have: 1) recruited patients during their inpatient stay at a hospital and 2) reported reasons for the patient's refusal of joining the clinical trial. Studies were excluded if they: 1) included a mixed population of inpatient and outpatient recruitment, 2) were conducted in Emergency Departments, oncology units, intensive care units, or had people who were pregnant or actively in labor/delivering, 3) had caregivers as surrogate decision makers to participants who were identified as eligible for clinical trials. As we wished to identify factors unique to inpatient settings, these criteria were developed in order to examine decision making processes specific to patients in general wards; for this reason studies in which patients were in critical condition, faced with end of life decisions, making decisions for their children, or had limited time to consider their decisions such as in an emergency setting, were excluded in an attempt to standardize patient considerations when determining participation in clinical trials. Reviews with no original data were also excluded.

2.3. Data extraction and synthesis

The data charting form was developed in Qualtrics where the data was collected. Data extraction was performed by two independent investigators. A third investigator resolved conflicts through independent review and discussion. The variables extracted included author, year of publication, country of origin, study design, study years, collection tool by which refusal reasons were elicited, population race and ethnicity proportions, age, sex, study unit, recruitment point person, reasons for refusal, healthcare disparities, and funding sources. Healthcare disparities are defined as differences in accessibility, availability, and quality of healthcare experienced by different population groups. Common factors related to access are differences in insurance coverage, geographic access or availability of healthcare facilities, and transportation issues. The collected data was organized in Microsoft Excel to portray the details of patients' reasons for refusal and study characteristics. The synthesis was presented narratively, incorporating frequencies and a descriptive analysis.

To build the conceptual framework, the multidisciplinary team identified major findings across studies and contextualized them within current enrollment and consenting practices. Based on this analysis, our interdisciplinary team generated recommendations to improve current practices.

3. Results

3.1. Study characteristics

Database searches resulted in 2264 citations (Fig. 1). After removing duplicates, 1540 citations underwent abstract screening. Of these, 143 manuscripts met criteria for full-text review, of which 122 were eliminated for outpatient recruitment (n = 63), ineligible patient population (n = 38), mixed outpatient and inpatient recruitment (n = 10), no refusal reasons (n = 7), no original data (n = 3), wrong setting (n = 1) (Supplementary Table 3). An additional one manuscript was identified through citation searching for a total of 22 manuscripts [36–57].

Among 22 manuscripts, 8 were trials that took place in the United States, 4 in Germany, 3 in India, 2 in the United Kingdom, and one each in Sweden, Switzerland, France, Amsterdam and Australia (Table 1). The most common study design types included were cross-sectional study of clinical trial data (n = 7), mock trials (i.e., simulated trials used to understand participant preference, without any intervention actually being tested) (n = 5), randomized control trials (n = 4) and secondary analysis of clinical trial data (n = 4). Trials took place in a variety of inpatient settings, including general medicine (n = 7), surgery (n = 5), psychiatry (n = 3), OBGYN (n = 3), and studies conducted across two or more inpatient units (n = 3).

Of 22 studies, 14 did not report data related to race, while 19 reported no data related to participants' ethnic group. Three studies incorporated race and ethnicity in the analysis of factors driving refusal to participate. Five studies lacked data related to the gender or sex of participants. Some studies chose to analyze data by various healthcare disparities such as insurance status (N = 2), education or literacy status (n = 8), focusing on increasing representation from geriatric populations (n = 3), or low socioeconomic status (n = 3). Four studies mentioned the inclusion of recruitment efforts in more than one language.

3.2. Study themes

3.2.1. Reasons for refusal

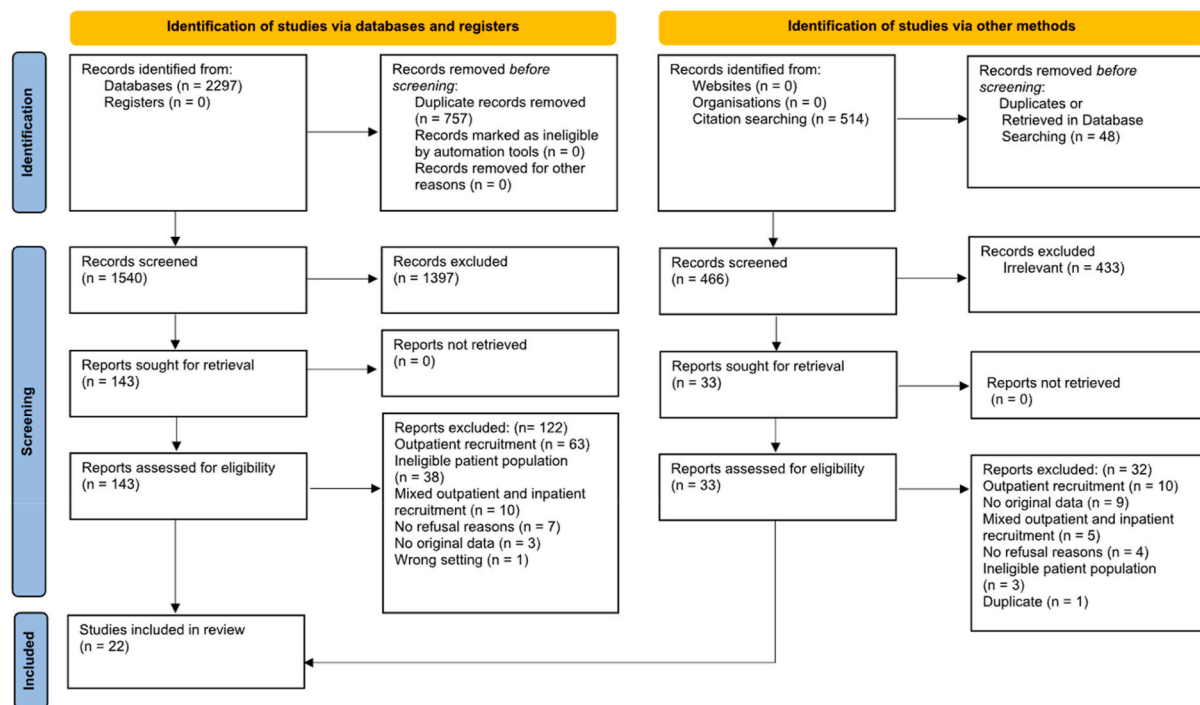
Major reasons for refusal identified across studies were study burden, added inconvenience (n = 16), transportation or logistic issues (n = 13), not interested in research (n = 12), refusing randomization (n = 10), not wanting to be a guinea pig or lack of trust with data confidentiality (n = 9). Other reasons included being too tired or sick (n = 9), fear of medical imaging, risk or side effects (n = 7), denial or fear of illness or diagnosis (n = 5), conflicting discharge schedule (n = 4), caregiver or surrogate reluctance (n = 4), or influence by others' opinions such as a family member or physician advice (n = 4). In few instances, individuals also refused to participate due to misinformation (n = 2) or for unspecified reasons (n = 3). These reasons for refusal are represented below (Fig. 2).

Tabulation of reasons for refusal included across 22 manuscripts. All reasons mentioned more than one time across studies were included for this graphical representation.

In analyzing the main reason for refusal for these studies, 5 studies listed refusal of the principal of randomization as the top reason for refusal by participants, while 4 listed lack of interest, 4 listed study burden or inconvenience, and 3 listed feeling like a guinea pig or lack of trust. For this study, burden was defined as additional demands imparted upon a participant due to participation in a clinical trial, including but not limited to time spent at trial visits, additional procedures and testing, and additional travel. Additional information regarding reasons for refusal are listed in Supplementary Table 4.

3.3. Inclusion of diverse populations

Of the few studies that included both race and ethnicity data (n = 3), two were created to highlight and address disparities in medicine; in other words, it was rare to find data about ethnicity or race collected (Fig. 3). Overall, three studies incorporated race and/or ethnicity data into the analysis of factors driving study participation refusal. Of those, Acharya and colleagues found that race had no significant effect on rate or reason for refusal. Similarly, Jolly and colleagues found comparable



Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>

Fig. 1. PRISMA diagram.

Table 1
Main characteristics of studies on reasons for refusal to participate in inpatient settings.

| Lead author | Year published | Years of study | Country | Title | Target population | Study type | Inpatient Hospital unit | Study commitment for participants |
|-------------|----------------|----------------|---------|--|--|--|-------------------------|---|
| Acharya | 2021 | 2018–2023 | US | Perspectives of Inpatients with Cirrhosis and Caregivers on Using Health Information Technology: Cross-sectional Multicenter Study [36] | Patients with cirrhosis admitted non-electively with adult cohabitating caregivers | Secondary data analysis of RCT | Medicine | Training to use app, visits and calls 1 month post discharge |
| Apostolova | 2017 | – | Germany | Challenges in Screening and Recruitment for a Neuroimaging Study in Cognitively Impaired Geriatric Inpatients [37] | Geriatric patients with dementia and suspicion for non-Alzheimer neurodegenerative disease | Prospective | Geriatric Medicine | Baseline physical exam and lab testing, brain MRI & PET scan at various locations, optional lumbar puncture Variable (based on various cardiac trials) |
| Biswas | 2007 | 2001–2004 | US | Who refuses enrollment in cardiac clinical trials? [38] | Patients previously approached to participate in inpatient cardiac trials (cardiac catheterization, heart failure, etc.) | Cross sectional | Medicine/Surgery | Drug trial with 6 and 12 month follow up appointment |
| Comerford | 2017 | 2012–2016 | US | Challenges in Patient Enrollment and Retention in Clinical Studies for Alcoholic Hepatitis: Experience of the TREAT Consortium [39] | Patients with alcoholic hepatitis | Secondary data analysis of Observational & Experimental trials | Medicine | Take combined “polypill” of aspirin, ramipril, and atorvastatin instead of all meds separately |
| Earnot | 2020 | 2017–2018 | Germany | Factors associated with refusal or acceptance of older patients (>65 years) to provide consent to participate in clinical research in cardiology: a qualitative study [40] | Patients age 65 or older with recent acute coronary syndrome event | Cross sectional, qualitative | Medicine | 5 sessions, 1 in person week after discharge, 4 telephone over span of 4 weeks |
| Flink | 2019 | 2016–2017 | Sweden | Why patients decline participation in an intervention to reduce re-hospitalization through patient activation: whom are we missing? [41] | Patients with heart failure or COPD living at home | RCT | Medicine | Mock trial testing stress reducing drug requiring 4 week washout from current drugs and 4 weeks of inpatient care Single dose of new drug, withdrawing 1 sample of blood hourly for 8 h, collecting overnight urine sample |
| George | 2018 | – | India | Participation in randomised controlled trials: perspectives of psychiatric patients and key relatives [42] | Patients involuntarily or voluntarily admitted for a mental health condition | Mock Trial | Psych | Conservative or invasive management of NSTEMI |
| Gitanjali | 2003 | 2001 | India | Recruitment of Subjects for Clinical Trials after Informed Consent: Does Gender and Educational Status Make a Difference? [43] | Hospitalized adult patients | Mock Trial | Medicine | Home based cardiac rehabilitation program |
| Godfrey | 2019 | – | UK | Recruitment for clinical trials for elderly patients- insights from the XIMA and RINCAL trials [44] | Patients undergoing stenting for coronary artery disease age 80 or older | Secondary analysis of RCT | Surgical | Initial in hospital survey, and three additional telephone surveys conducted over 6 months. |
| Jolly | 2005 | 2002–2004 | UK | Recruitment of ethnic minority patients to a cardiac rehabilitation trial: The Birmingham Rehabilitation Uptake Maximization study [45] | Patients presenting post cardiac event | RCT | Surgical | Compare efficacy of new drug compared to established drug, with |
| Martin | 2013 | 2009–2010 | USA | Recruitment of Black and Latina Women to a Randomized Controlled Trial [46] | Women who recently delivered healthy infants, self-identified as Black/African American or Hispanic/Latina with working telephone number | RCT | OBGYN | |
| Mopuru | 2018 | 2011–2013 | India | Factors Influencing participation of psychiatry inpatients in clinical trials [47] | Psychiatry inpatients without cognitive impairment | Mock trial | Psychiatry | |

(continued on next page)

Table 1 (continued)

| Lead author | Year published | Years of study | Country | Title | Target population | Study type | Inpatient Hospital unit | Study commitment for participants |
|--------------|----------------|----------------|-------------|---|---|--------------------------------|-------------------------|---|
| Myles | 1999 | – | Australia | Randomized Trial of Informed Consent and Recruitment for Clinical Trials in the Immediate Preoperative Period [48] | Adults scheduled for elective surgery | Mock trial | Surgery | single invasive blood draw Ten minute mock study considering experimental anesthetic drug during operation |
| Nguyen-Xuan | 2016 | 2012–2014 | France | Study of the factors motivating refusal of women to participate in a randomized clinical trial in gynecological surgery [49] | Women with cystoceles previously approached for PROSPERE trial | Cross sectional | OBGYN | Laparoscopic promontofixation to vaginal prosthetic reinforcement for the treatment of cystoceles |
| Patel | 2004 | 1994–1995 | US | Patient Attitudes Toward Granting Consent to Participate in Perioperative Randomized Clinical Trials [50] | Patients who had been approached to participate in various clinical trials | Cross sectional | Surgery | Varied |
| Raue | 2010 | 2005–2008 | Germany | Problems of randomization to open or laparoscopic sigmoidectomy for diverticular disease [51] | Patients scheduled for elective sigmoidectomy for complicated diverticular disease | RCT | Surgery | Laparoscopic versus conventional sigmoidectomy for complicated diverticular disease |
| Ritcher | 2020 | 2019–2020 | Germany | Repeated Digitized Assessment of Risk and Symptom Profiles During Inpatient Treatment of Affective Disorder: Observational Study [52] | People with diagnosis of any affective disorder, mentally stable, hospitalized for 3+ days | Cohort | Any | Pre and post questionnaires, provided data on symptom severity biweekly |
| Salomons | 2002 | 1995–2000 | US | Factors associated with refusal to enter a clinical trial: epidural anesthesia is a deterrent to participation [53] | Women between 19 and 75 yr of age undergoing major gynecological procedures by laparotomy | Secondary data analysis of RCT | OBGYN | Receive epidural anesthesia |
| Tolomeo | 2008 | 2004 | US | Patient Attitudes Regarding Participation in Studies of Antimicrobial Resistance [54] | Patients who were eligible for studies regarding resistant bacteria (both approached to participate and never approached) | Cross sectional | Medicine | Answer questionnaire about attitudes towards various aspects of bacterial resistance studies |
| van den Berg | 1997 | 1993–1994 | Amsterdam | Patients' refusal to participate in clinical research [55] | Patients scheduled for eligible surgeries | Cross sectional | Surgery | Epidural vs intramuscular morphine post-op |
| Williford | 1993 | 1984–1986 | US | Comparison of Eligible Randomized Patients with Two Groups of Ineligible Patients: Can the Results of the VA Total Parenteral Nutrition Clinical Trial Be Generalized? [56] | Adults in VA Medical Centers before nonemergency laparotomy or thoracotomy | Cross Sectional | VA | Receive TPN for 7–20 days prior to operation, and for 3 days following operation. |
| Zullino | 2003 | – | Switzerland | Readiness to Participate in Psychiatric Research [57] | Patients consecutively admitted to a psychiatric hospital with visits expected to last at least 3 days | Mock trial | Psychiatry | Variable, including drugs trials, blood sampling, 1 interview, repetitive interviews, etc. |

enrollment rates among all race and ethnicity groups; however, they noted that 42.2 % of South Asians and 37.0 % of participants from other ethnicity groups selected 'no reason' for refusing to participate as compared to 18.5 % of white participants. They posited that higher proportions of minority populations may have refused for reasons differing from white participants. Lastly, Martin and colleagues did a thorough analysis of reasons for refusal. As their study focused entirely on Latinx and Black populations and recruited solely from those groups, they went further to analyze by first language of the participant, finding no significant differences in reasons of refusal between Spanish and English-speaking populations. Their study was the only to enact iterative, tailored recruitment strategies for their populations throughout the course of their study, such as creating specific messaging that

participating in research allowed improvement of systems of care for minority populations and altering emphasis placed on mental health due to its associated stigma within certain minority communities.

These overlapped significantly with the studies that reported the use of multiple languages used in recruitment materials and study design. Language barriers were reported frequently. In several studies, the unavailability of bilingual research personnel, lack of recruitment materials in multiple languages, or absence of validated tools in various languages meant that individuals were excluded from enrollment altogether. However, in other scenarios, caregivers or family members declined participation due to poor understanding of the study design. This could be attributed to using a different language than native tongue, but could also be a result of failure of research teams to make

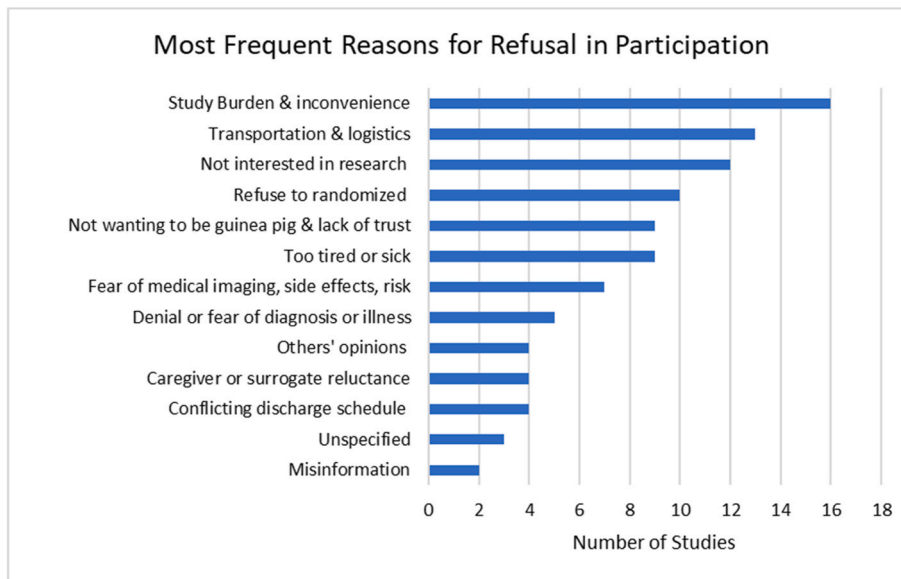


Fig. 2. Bar chart depicting major reasons for refusal.

| | Race Data | | | | | Ethnicity Data | | | Gender data | | Other disparities | | | | | | |
|--------------|------------------|------------------------|-----------------------------------|-------|-------|----------------|----------|--------------|-------------------------------|---------------|------------------------|---------------|--|----------------------------|-----|--------------------------|--|
| | White/ Caucasian | Black/African American | Native American/ Pacific Islander | Asian | Other | none reported | Hispanic | non-Hispanic | other ethnicity data reported | none reported | reported sex or gender | none reported | Insurance status (Medicaid, Medicare, other) | education status/ literacy | Age | low socioeconomic status | Included recruitment materials in more than 1 language |
| Acharya | x | x | | | x | x | | | x | x | | | x | | | | |
| Apostolova | | | | | | x | | | x | x | | | | x | | | |
| Biswas | x | x | x | x | x | | | | x | x | | x | x | | | | |
| Comerford | | | | | | x | | | x | | | | x | | | x | |
| Ecarnot | | | | | | x | | | x | | | | | x | | | |
| Flink | | | | | | x | | | x | x | | | | | | x | |
| George | | | | | | x | | | x | x | | | x | | | | x |
| Gitanjali | | | | | | x | | | x | x | | | x | | | | |
| Godfrey | | | | | | x | | | x | | | | | | x | | |
| Jolly | x | | | x | x | | | x | | x | | | | | | | x |
| Martin | | x | | | | | x | | | x** | | x | | | | | x |
| Mopuru | | | | | | x | | | x | x | | | x | | | x | |
| Myles | | | | | | x | | | x | x | | | x | | | | |
| Nguyen | | | | | | x | | | x | x** | | | | | | | |
| Patel | x | x | | x | | | x | | | x | | | x | | | | |
| Raue | | | | | | x | | | x | x | | | | | | | |
| Richter | | | | | | x | | | x | x | | | | | | | |
| Salomons | x | | | | x | | | | x | x** | | | | | | | |
| Tolomeo | x | x | | | x | | | | x | x | | | | | | | |
| van den Berg | | | | | | x | | | x | | | | | | | | |
| Williford | x | | | | | | | | x | x | | | | | | | |
| Zullino | | | | | | x | | | x | x | | | | | | | x |

Fig. 3. Inclusion of race, ethnicity, gender and/or sex, disparity and language data organized by study. ** studies conducted exclusively for female subjects.

materials approachable for populations of differing literacy levels.

3.4. The role of other's opinions

The effects of opinions from participant's social support systems

emerged as an important consideration driving patient participation. Many reasons were cited to stress the importance of engaging family or support persons. In two studies, either the hospital systems or research studies required the presence of caretakers to participate in obtaining patient care or participating in clinical trials [37,42]. One study

commented on patriarchal familial structures in various cultural contexts that held a strong influence on the decision of family members to participate in clinical trials, particularly for women from rural settings [47]. Furthermore, conditions such as cirrhosis or dementia that required increased caretaking levels meant that those individuals providing care would be directly in charge of coordinating efforts, requiring their investment into research processes such as informed consent and scheduling. In these scenarios, authors pointed out burnout and feelings of being overwhelmed to be important considerations when recruiting both patients and their caregivers [38]. Even for those who did not have a caretaker or others managing their health, it was found that many considered others opinions when deciding to engage in research (n = 4).

Beyond personal relationships, the role of physicians in determining patient’s willingness to enroll was a recurrent subject of exploration. Some studies noted that participants with lower education status or from a rural background were more likely to defer partial or full decision-making faculties to their physicians [38,47]. Separate from education or geographic status, this consideration for physician opinion was present across the various specialty trials, noted in various psychiatry and cardiac trials [38,47]. Multiple trials noted the considerations that came with incorporating physician involvement in recruiting for trials; while some noted its efficacy in gathering support and providing patient education, others questioned the ethics and best practices surrounding physician involvement in its influence over patient participation [39, 42].

3.5. Balancing needs

Earnot and colleagues propose an idea of “balancing resources” that describes the reserve of emotional and physical capacity in order to partake in a research trial [40]. Most trials highlighting “study burden” corroborate this idea in one way or another, noting that individuals with recently increased caretaking responsibilities, new significant health diagnoses, or increased somatic symptoms are likely less able to find

“stores” of resources to participate in additional voluntary activity. Flink et al. further expanded upon this idea, mentioning the increased added tasks and time associated with managing illness for oneself [41].

3.5.1. Conceptual framework

Based off these identified themes, the interdisciplinary team consolidated common themes and contextualized concepts within current research and consenting processes. Maslow’s hierarchy of needs was found to be an informative manner to evaluate consenting processes by acknowledging that participants had specific criteria that would need to be met to consider the next stages of enrollment; for example, those who were too physically ill or sick likely would not have the energy to discuss trial details or specifics [58]. If people were healthy enough to consider engaging in conversation with research teams, those who did not have their psychological needs of trusting in research institutions or denied having an illness would likely not progress further in discussion. This idea formed the basis for categories of fulfillment identified in the figure below (Fig. 4).

This model proposes the hierarchical needs that must be addressed for participants to engage in a research trial. Physical needs must first be addressed to the extent that individuals feel well enough to engage with research staff or to learn more about the details of a trial. After this, psychological needs must be addressed to accommodate for the needs of the individual, including conversations surrounding trusting in research institutions, fear surrounding risks of participation or participation in trials. After these have been addressed, participants are more likely to engage in discussing logistical considerations for participation. They might simultaneously engage others in their support system, such as family or medical professionals, or incorporate them in conversation after the above have been addressed.

4. Discussion

To our knowledge, this is the first study to explore reasons for declining participation in inpatient clinical trials with a focus on

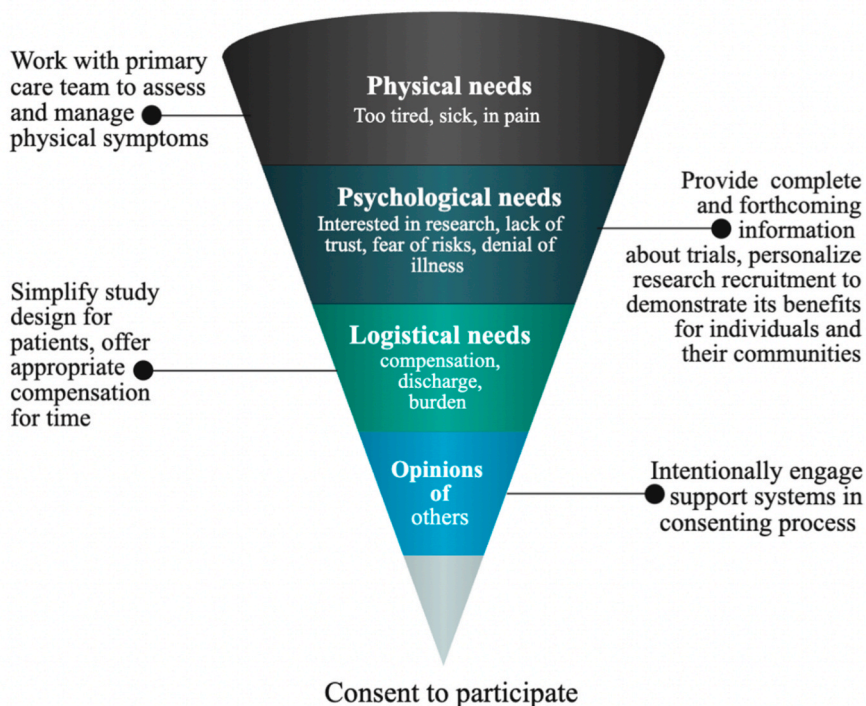


Fig. 4. Diagram categorizing fulfillment needs for participation with corresponding reasons for refusal and recommendations.

exploring differences across historically minoritized racial and ethnic groups. We found that limited studies have been conducted to elicit reasons regarding refusal to participate in trials in the inpatient setting. Moreover, even fewer have focused on the unique perspectives of participants from diverse racial and ethnic minority groups; the majority of studies did not collect demographic information, nor address the role of race and ethnicity on refusal reasons. Although the collection of demographic information may vary across country/region where the research is conducted, major reasons for refusal unique to minority groups remain ill-defined when this information is excluded. The absence of comprehensive demographic data contributes to the exclusion of minoritized populations from research as it hinders the ability to identify and address their specific needs and barriers. Moreover, our findings support the idea that patients have a balance of needs from which they can hold capacity to engage in research. Actions such as diversifying language in recruitment, better-incorporating caretakers and support systems into study design, and communicating with physicians were identified as potential targets to help promote enrollment into clinical trials in the inpatient setting.

Studies that have looked more generally at recruiting historically minoritized racial and ethnic groups in a variety of contexts corroborate these findings. Particularly for individuals from minoritized populations, the importance of input and experiences from social support networks has been well explored [59,60]. In particular, cultural factors have been identified as meaningful to address when striving to incorporate caretakers and family members in the enrollment process. For example, a study by Daunt (2003) explored recruitment barriers specific to women from Latinx communities. Prevalent cultural themes of “familism,” or prioritizing time and development of others above self, as well as cultural hierarchal family structures in which women are expected to consult with their partners prior to decision making, made women feel hesitant to engage in studies that would take time away from their families for fear of being perceived as less committed mothers or partners [61,62]. Other studies have reported a lack of diverse recruitment materials excluding key family members in the decision-making process, leading to refusal [63].

The optimal manner to incorporate physicians into recruitment efforts remains controversial. As highlighted in the study by Mopuru and colleagues, populations with lower health literacy or educational background are more likely to see their physicians as all-knowing and trustworthy, agreeing with the statement “doctors can do only good.” [47] They also may be inclined to consent due to relational considerations conflating research and clinical care, such as “can’t say no to doctors” or “it will make my doctor happy.” Due to the tenuous relationship such a view creates for potentially vulnerable populations, consenting processes should allow significant time and attention to maintain integrity and trust in both the providing care team and in research practices. In a study by Black and colleagues, several points of consideration are highlighted such as the influence of a preexisting patient-doctor relationship, perception that physicians know best for their patients, and assumption that participants’ best interests are central to the research process [64]. While some noted inefficiencies created in recruitment efforts due to inclusion of physicians, as well as potential for concern for conflict of interests, they remain central in upholding ethical practice in recruitment and allow to build trust with communities that may have previous negative associations with research.

Our study’s findings should be considered in the context of its strengths and limitations. Our study’s strengths lie in generalizability to the broader context of inpatient medical floors, which allows for evaluation of factors related to culture, race, and ethnicity in the context of scenarios with high emotional and physical acuity. In contrast, as our findings were limited to inpatient medical and surgical units, our study may have limited application in settings with limited patient time to engage in informed consent processes, such as the emergency department. The study also did not include settings such as the ICU, where end of life decisions are more prominent, and therefore did not explore the

complexity of such scenarios.

Based on these findings and to inform future efforts, we propose a model to illustrate the hierarchy of needs and considerations that must be addressed to empower patients to make informed decisions with respect to participation in inpatient trials. (Fig. 4). Patients who are preoccupied with somatic symptoms likely need these addressed prior to being able to fully consider trial; for this reason, research teams should coordinate their efforts with treatment teams to ensure they time their efforts in a way that limits distress. Psychological needs should be met in tandem; if individuals lack trust in their physician, in confidentiality measures taken by the research community, or in the hypothesis or interventions being tested, they are less likely to want to consider logistical details related to studies. Once these first two are met, patients can properly weigh the pros and cons of study participation concerning the length or type of treatment in the context of their own life. To that end, researchers must continue their efforts in simplifying participant considerations, such as limiting travel and number of follow up appointments, and offering flexible scheduling options when appropriate. Lastly, incorporating others in the support system, either by diversifying recruitment material language, timing efforts for when others are present, and ensuring all have comprehended the study objectives is crucial. Within the research community, systematically increasing the collection of refusal reasons in clinical studies, particularly alongside race and ethnicity data, will enable us to better identify and address this important gap in the field.

5. Conclusions

As a research community, there remains a need to adapt recruitment efforts to better incorporate historically minoritized communities and avoid the perpetuation of substandard evidence basis for treatment. This includes documenting reasons for refusal to participate in clinical trials, collection of demographic data across participants, and including various languages intentionally in study design and recruitment goals.

CRedit authorship contribution statement

Poyani Bavishi: Writing – review & editing, Writing – original draft, Visualization, Project administration, Investigation, Formal analysis, Conceptualization. **Alyssa A. Grimshaw:** Writing – review & editing, Visualization, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Oscar F. Rojas Perez:** Writing – review & editing. **Brian D. Kiluk:** Writing – review & editing, Funding acquisition. **E. Jennifer Edelman:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cctc.2024.101386>.

[org/10.1016/j.conctc.2024.101386](https://doi.org/10.1016/j.conctc.2024.101386).

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