

Exploring Barriers and Perceptions of Cystic Fibrosis (CF) Clinical Trial Participation Among Racial and Ethnic Minoritized Populations in the United States

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Introduction and Background

Cystic Fibrosis (CF) is an **autosomal recessive disease** that affects more than 40,000 people in the US.

Advances in **therapeutics**, **clinical care** and highly effective **CTFR modulator therapies** have significantly improved life expectancy.

Disparities in CF Outcomes

Black and Hispanic individuals represent a growing segment of the CF population but experience higher **morbidity and mortality** compared to non-Hispanic White patients.

Contributing factors include:

- Limited access to CTFR modulators
- Social determinants of health
- Structural inequities rooted in systemic racism

Health Related Quality of Life

Patients from **socioeconomically disadvantaged** and racially/ethnically minoritized groups report **lower health-related quality of life** beyond biologic outcomes.

Addressing **inequities in CF care** is essential to **improving outcomes** for all individuals living with the disease.

Project and Deliverables

1. Qualitative Research and Analysis

- Creation of qualitative codebook with detailed definitions of each code and exemplar quotes.
- Qualitative coding will be done both inductively and deductively and will use a race-conscious approach by the Public Health Critical Race Praxis (PHCRP) and the Behavioral Model for Vulnerable Populations (BMVP) to identify systemic barriers such as mistrust, access challenges and cultural factors to CF Clinical Trial Participation.

2. Action-Oriented Qualitative Data Report

- Production of detailed qualitative data report summarizing findings from interview and presenting actionable recommendations for the organization to improve inclusivity in their clinical trial recruitment efforts .

Aim and Hypothesis

Aim: To explore **perceptions of barriers** to clinical trial participation at three large CF centers using a race-conscious adaption of the **Behavioral Model for Vulnerable Populations** and semi-structured, **in-depth qualitative interviews** of minoritized people with CF.

Hypothesis: Minoritized individuals with CF perceive **multiple race-related barriers** to clinical trial participation including **healthcare discrimination**, **mistrust of the research process** and **structural inequities** which limit their participation in CF studies.

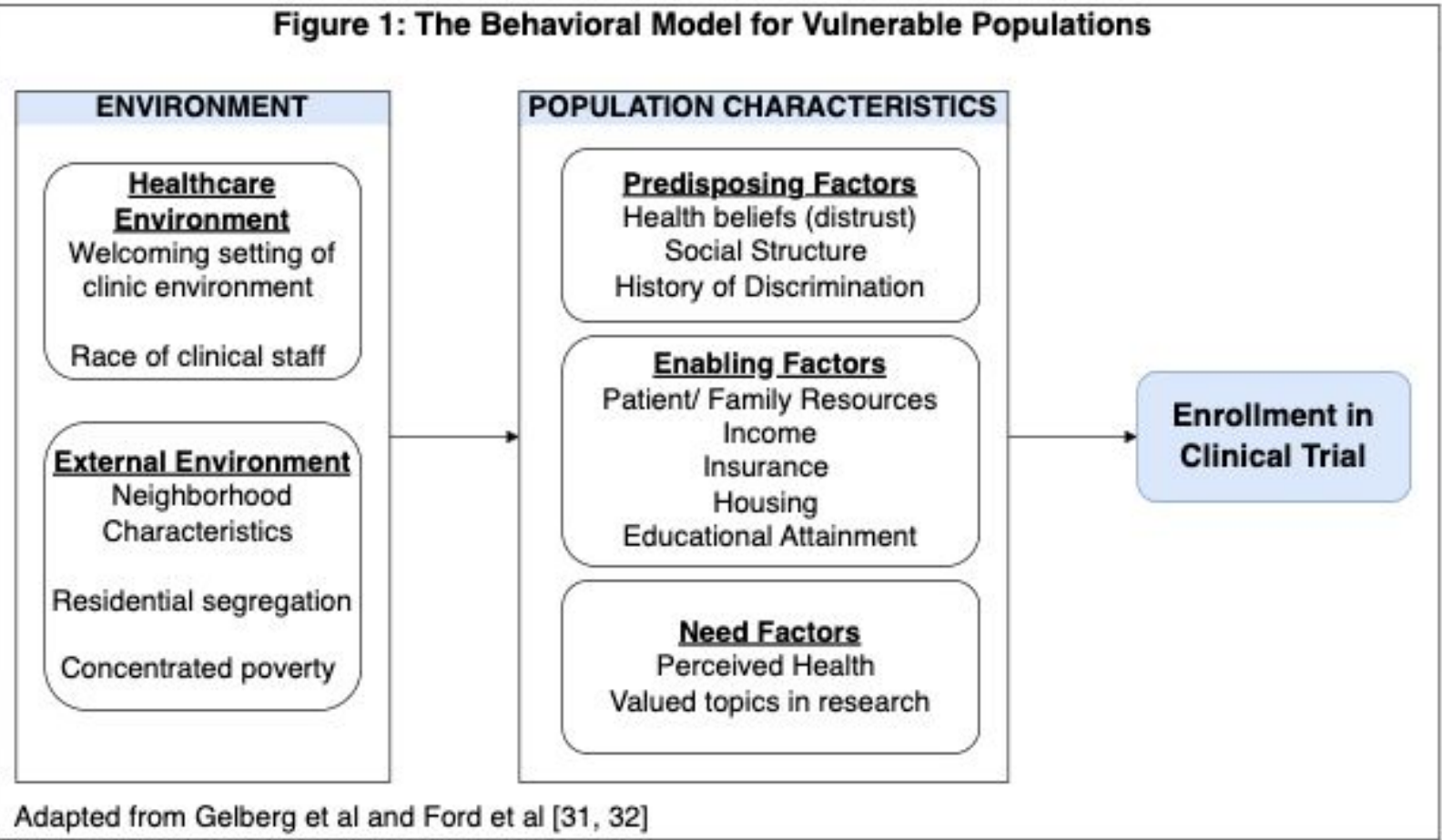


Figure 1. Behavioral Model for Vulnerable Populations

Methods

Study Design:

- **Participants:** 20 – 25 racially / ethnically minoritized adults (>18 years) from 4 CF centers (UW, UCLA, John Hopkins and University of Miami).
 - **Inclusion:** All patients, regardless of prior participation in CF clinical trials
 - **Exclusion:** FEV₁ < 25% predicted
 - **Sampling:** Purposive to achieve gender balance

Data Collection:

- **Method:** Semi-structured Zoom interviews, recorded and transcribed
- **Interview Guide:** Based on the BMVP and reviewed by a focus group of 5 – 7 CF patients
- **Focus:** Experiences will CF clinical trials, examining predisposing/enabling/need factors, healthcare interactions and social barriers.

Methods (Cont).

Data Analysis

- **Approach:** Theory driven and inductive content analysis using Dedoose.
- **Process:**
 - Initial coding guided by draft **codebook**
 - Regular team meetings to ensure consistency
 - Member checking with **focus group** to validate findings
 - Iterative refinement of **themes** with **illustrative quotes** identified

Findings

Table 1: Summary of preliminary findings of qualitative interviews with Hispanic/Latinx and Black PwCF (PID: Patient ID)		
Code	Description	Exemplar Quotes
Feelings of isolation	Participants cited feeling like lack of representation of other minoritized people at their centers (patients and staff) contributes to hesitancy to participate due to feelings of isolation	“Growing up and going to CF clinic, There were zero other people that looked like me, period.” [PID2] “And every time I would look online it always shows just white people.”[PID11]
Racialized experiences in the medical setting	Participants emphasized that racialized experiences are common, highlighting not being heard or taken seriously by medical providers	“Because nobody was listening to me, and they wouldn’t listen to me. It is because of my color. You guys do single Black folks out.” [PID5]
Need for more information	More time spent to explain risks and benefits of a study and specifically how benefits impact patient and their community.	“An informed decision on whether you want to start the trial, continue the trial and allow you to ask questions along the way, that would help with the fear of the unknown.” [PID4]
Readily available study staff	Participants highlighted the need for a study contact available to answer questions, with accessible hours of contact.	“I feel like a direct contact, someone they can -- if you have questions, call this person after.” [PID 8]
Research focusing on minoritized people	Participants expressed the need to include research that specifically addresses topics pertinent to communities of color and lived experiences of people of color with CF	“I really feel like there’s such a lack of understanding of what it’s like for people of color with CF.” [PID3]
CF physicians introducing study	Importance of CF doctors first introducing study to support information needs and engender trust	“I would like the doctors to be more involved -- start that as the first step, and then have the clinical staff then start communicating as to okay, here’s what it entails.” [PID6]

Figure 2. Example of Qualitative Findings from Codebook

Semi-structured qualitative interviews conducted with minoritized PwCF **identified gaps** in the information provided about clinical trials, expressing a desire for **more detailed** and **culturally relevant explanations** of risks and benefits of studies.

Additionally, **unique challenges** related to CF emerged including;

- **Narrow** inclusion criteria
- Pervasive sense of **isolation** among minoritized PwCF which is **intensified** by the small numbers of these individuals at certain CF centers

Recommendations

Objective

Develop and pilot a **community engagement program** to **enhance recruitment** and retention of racially/ethnically minoritized PwCF in CF clinical trials using **human-centered design (HCD)** .

Approach

- Collaborate with PwCF to understand their **unique needs** and co-produce an intervention.
- **Leverage HCD** to design inclusive solutions that prioritize the **perspectives** and **needs** of PwCF and other key stakeholders.

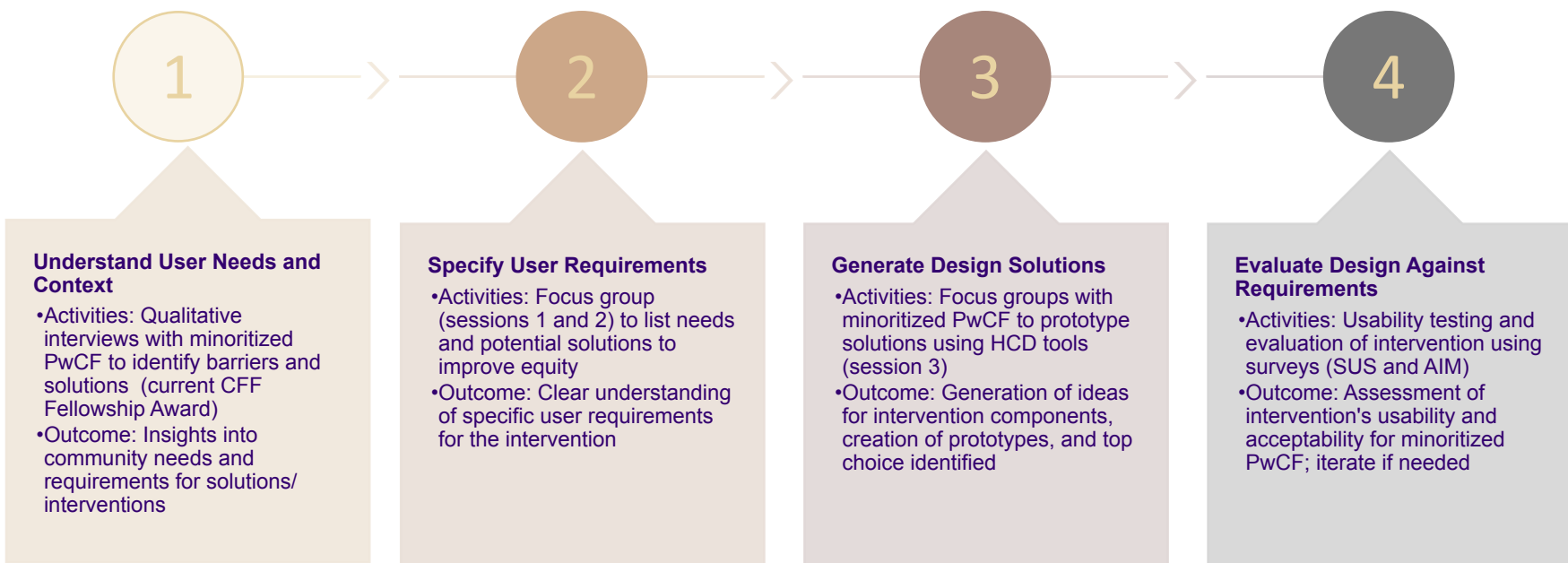


Figure 3. Example Timeline for HCD to design Inclusive Solut

Acknowledgements

Thank you to my wonderful practicum team, Tljana Milinic and Donna Denno as well as Crystal Brown and Kathleen Ramos. I would also like to thank the UW Medicine Adult Cystic Fibrosis Clinic at University of Washington Medical Center -- Montlake and Cystic Fibrosis Foundation Community Voice for feedback and ideas.