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Opportunities to advance clinical trial equity in pediatric oncology

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Disclaimers

I have no disclosures or conflicts of interests.

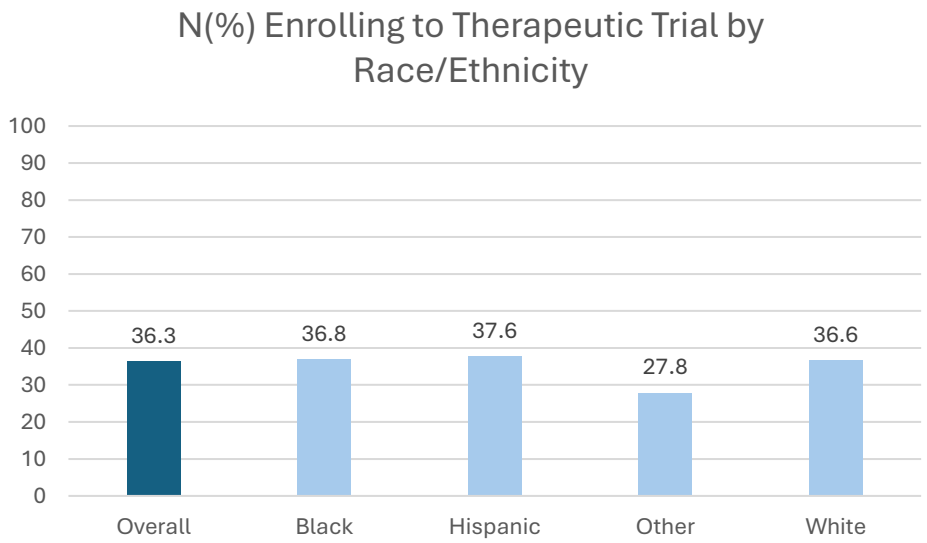
Objectives

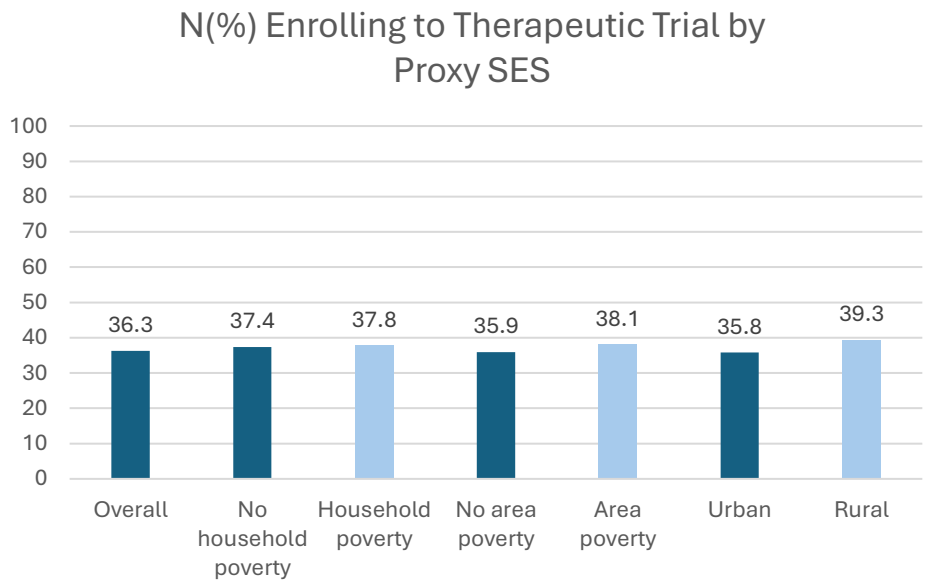
- **Enhance and maintain trial diversity is a priority:**
  - Ensures generalizability of trial results
  - Improves outcomes

- **Using pediatric oncology as a case study:**
  - Examine frontline clinical trial enrollment and participation by race, ethnicity, and poverty status
  - Examine Black and Hispanic parent perspectives regarding research participation
  - Describe interventions targeting social determinants of health in pediatric oncology

Clinical Trial Enrollment on Frontline COG Neuroblastoma Trials

- Access to center with clinical trial options
- Trial inclusion/exclusion criteria
- Offered clinical trial
- Enrolled on clinical trial
- Retention on clinical trial





No significant difference in enrollment to therapeutic trials by race, ethnicity, or proxied SES

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Umaretiya et al. PBC 2024

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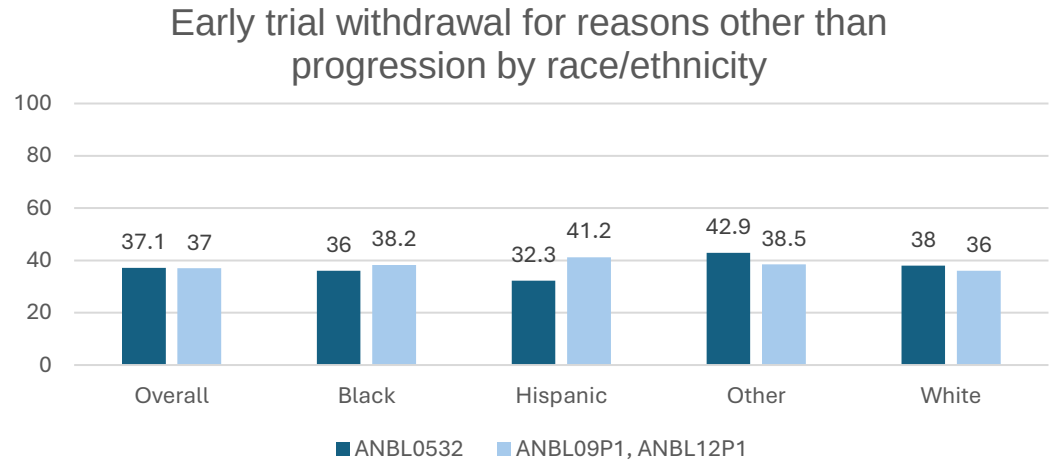

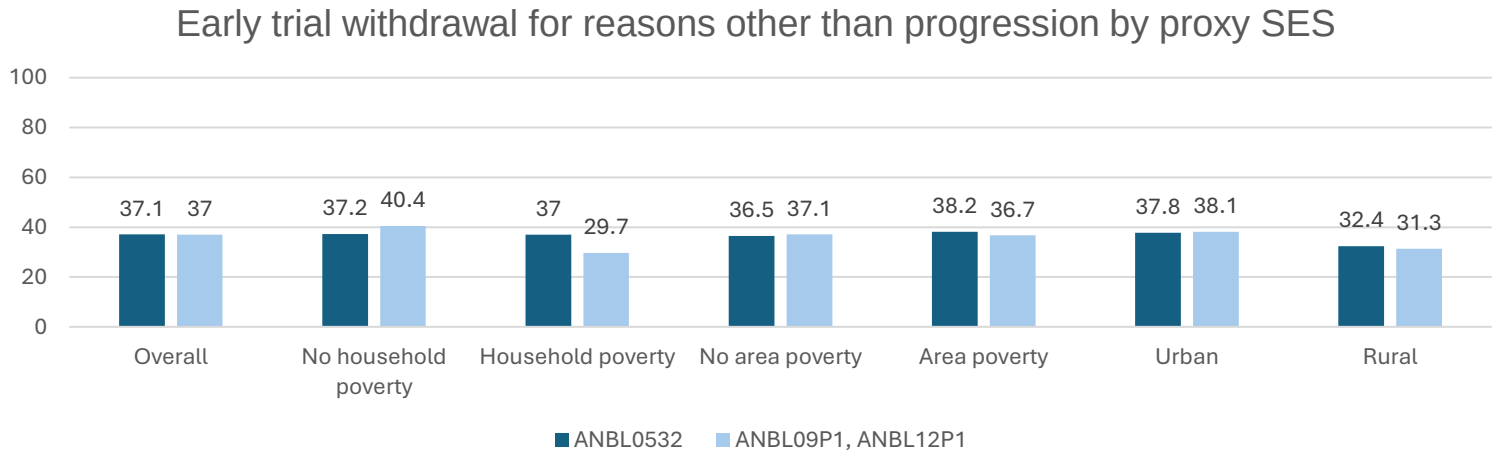

No significant difference in early withdrawal by race, ethnicity, or proxied SES

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Umaretiya et al. ASCO 2022. Manuscript under review

Research perspectives of historically marginalized parents

- Single center mixed methods study to understand Black and Hispanic parent perspectives regarding clinical trial/research participation and barriers/facilitators

- Utilized intentional recruitment strategies focused on trust, transparency, and minimizing burden to enroll a cohort of N=60

94% **participation** rate
100% **completion** rate
98% **data completeness**

Perceptions of research/clinical trials

- Research and clinical trials are “experiments”
- Research and clinical trials are a way to advance medicine
- For many parents, they are both

For me [sighs], clinical trial, I can’t help but think of like experiment, for some reason. Because I mean it’s something that’s new and being done to learn about something. So for me, I guess the word would be experiment. That’s what would automatically come to mind. But not like in a bad way; in a good way to learn and hopefully advance in the treatment of whatever they’re trying to learn about.

-Mother (participant 12)

Motivations for participating in research and clinical trials

1. To access novel or the most advanced therapies
2. To have an opportunity for decreased toxicity
3. To improve care for future patients and their families
4. To represent the experiences of Black and Hispanic patients

> The majority of the research probably involves Caucasians. But I wanted to provide people with like an aspect of – from an African American family because it's not – there aren't as many. – Mother (participant 12)

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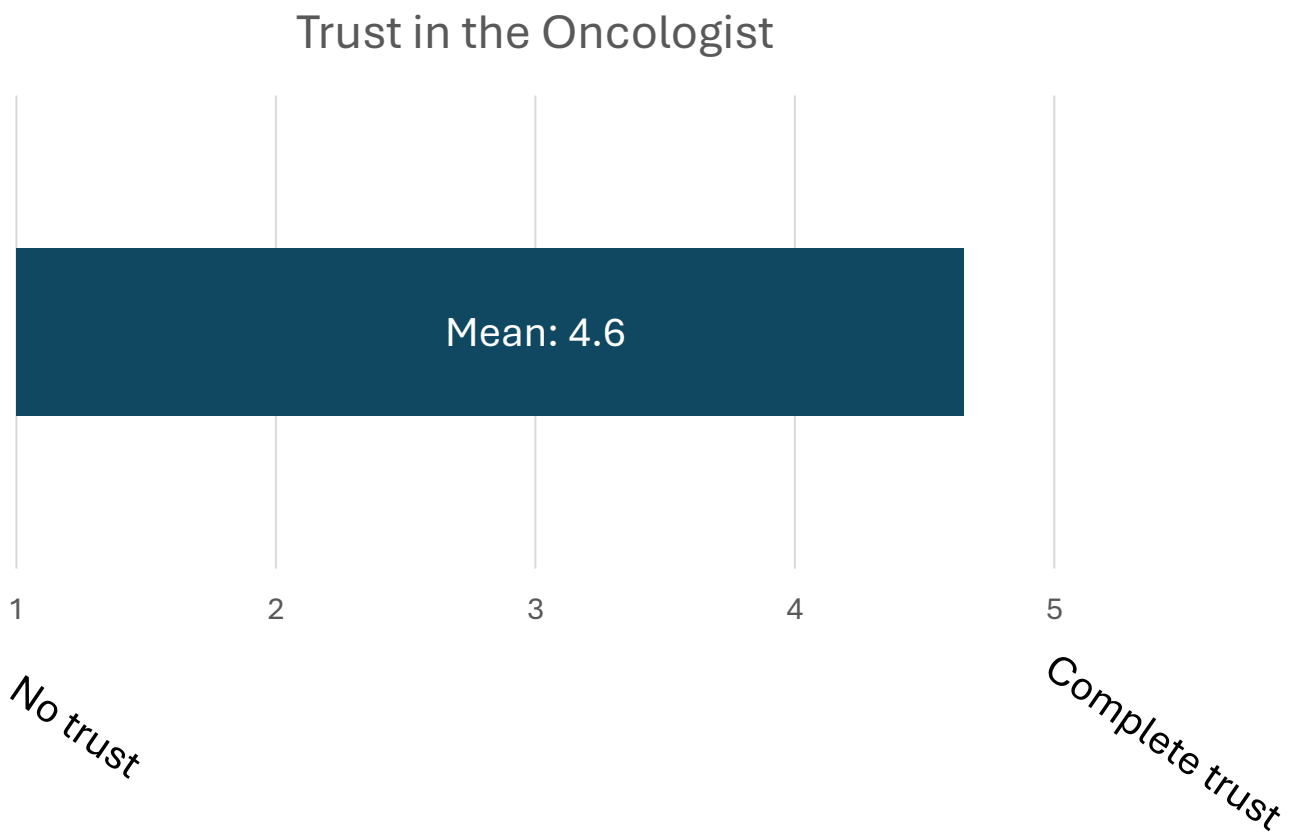
Hesitations for participating in research and clinical trials

1. Fear of the unknown – efficacy and side effects
2. A desire to protect their child from unnecessary treatments and tests
3. History of maltreatment of Black and Hispanic patients in research

As a black culture, we were test dummies. A lot of things were done to us in the hospitals just to get a better understanding of our race and culture, some we were aware of and some that was just – it was forced upon us…**for me as a black man, having those things done to my ancestors over time, I think when I had first heard about clinical trials, I'm like, no, thank you**. But I think with the understanding that it was happening to [child] and that we needed to gather and get more information, I agreed more so to advance her treatment and her care.
– Father (participant 26)

A priori hypotheses about barriers to participation

- Distrust



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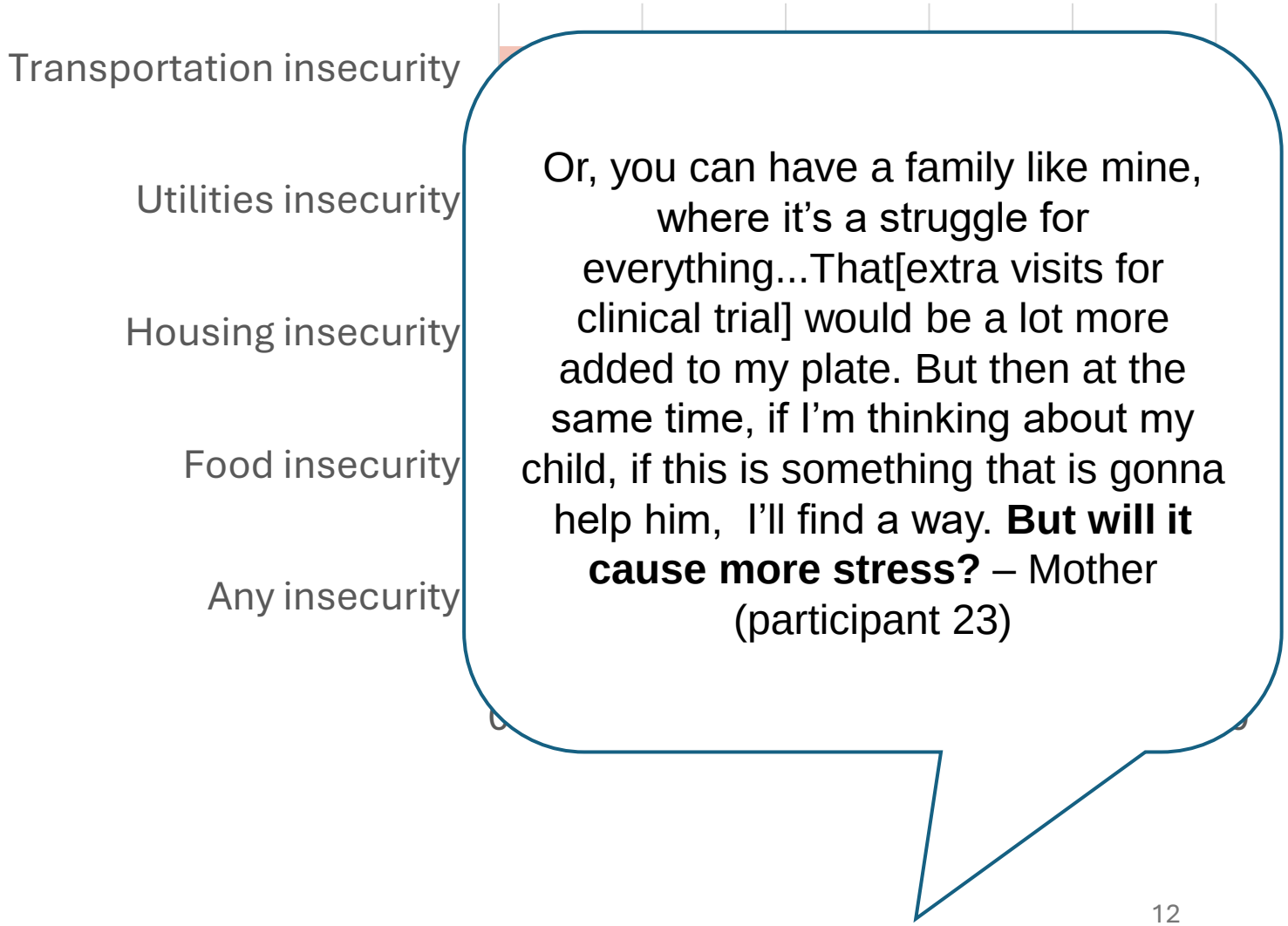
A priori hypotheses about barriers to participation

- Distrust
- Information sharing

As the parent finding out that your kid has cancer, you're asked to read even with all the threats that's going on at that moment, you have basically a 24-hour time limit to read all the paperwork, possibly do your own research on the paperwork in order to make a decision that affects your child's life and you've got an hour to do so.
-Father (participant 4)

A priori hypotheses about barriers to participation

- Distrust
- Information sharing
- Unmet social needs



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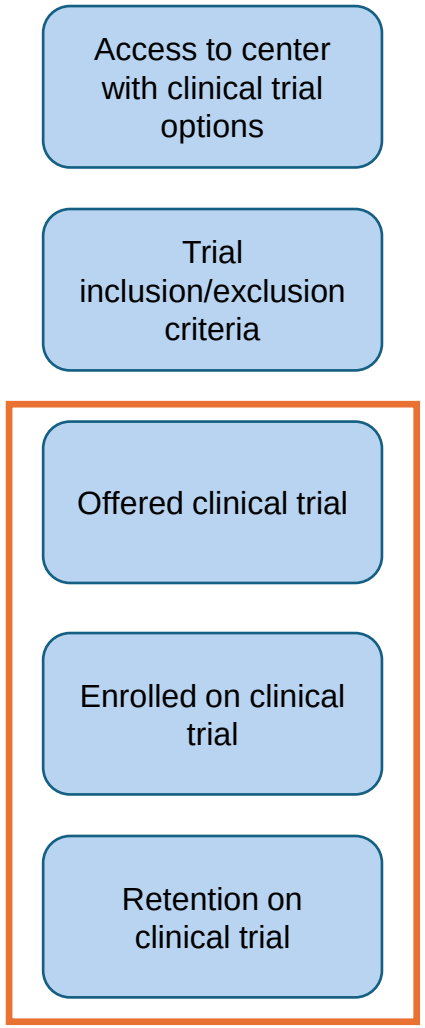
Valenzuela and Umaretiya et al. PBC 2023.

Interpreting these data in a broader context



- **Some caveats:**
  - Pediatric cancer is rare
  - Family willingness to do anything
  - Pediatric oncology care model allows for time with patients

- **Relatively equitable trial participation is achievable**
- Distrust should not be an excuse for underrepresentation
- Information sharing and unmet social needs are real barriers that may impact enrollment and retention

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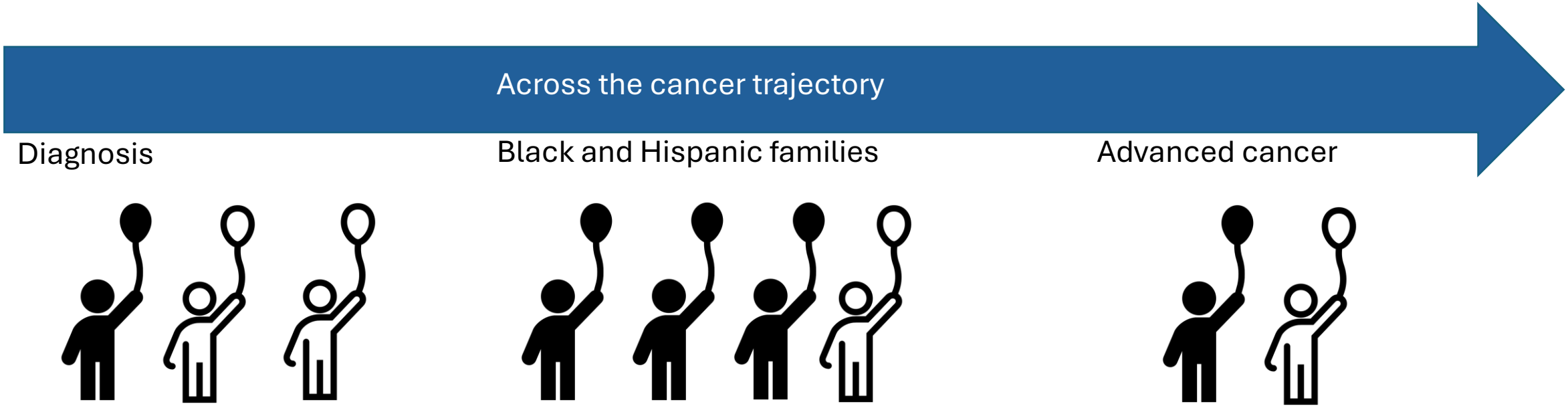
Measuring SDOH and social needs are feasible



- **Feasible** in multiple contexts: frontline national clinical trials, advanced cancer, historically marginalized populations

- Among 1000s of surveys administered: >85% consent rate, >85% completion, <2% missing data

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Aziz-Bose et al. PBC 2022.

SDOH interventions are feasible in pediatric oncology

	Intervention	Population	Duration	Stage
PediCARE	Centrally-delivered grocery & transport	Low-income families with new cancer diagnosis	6 months	Successful single-center pilot and two-center feasibility study, embedded into phase III trial for efficacy testing
Pediatric RISE (Pediatric Resource Intervention to Support Equity)	Unrestricted cash transfer	Low-income families with new cancer diagnosis or advanced cancer	6 months	Successful single-center pilot, undergoing randomized feasibility testing in a two-center pilot
CHEF (CARDIOVASCULAR HEALTH EQUITY THROUGH FOOD)	Meal kits & assisted nutrition benefits enrollment	Families with food insecurity in the first year after cancer therapy	6 months	Successful single-center pilot, plan for proof-of-concept testing
ASSIST	Means-tested benefits navigation	Low-income families with new cancer diagnosis	12 months	Developed with parent input; plan for pilot and refinement in single-center study

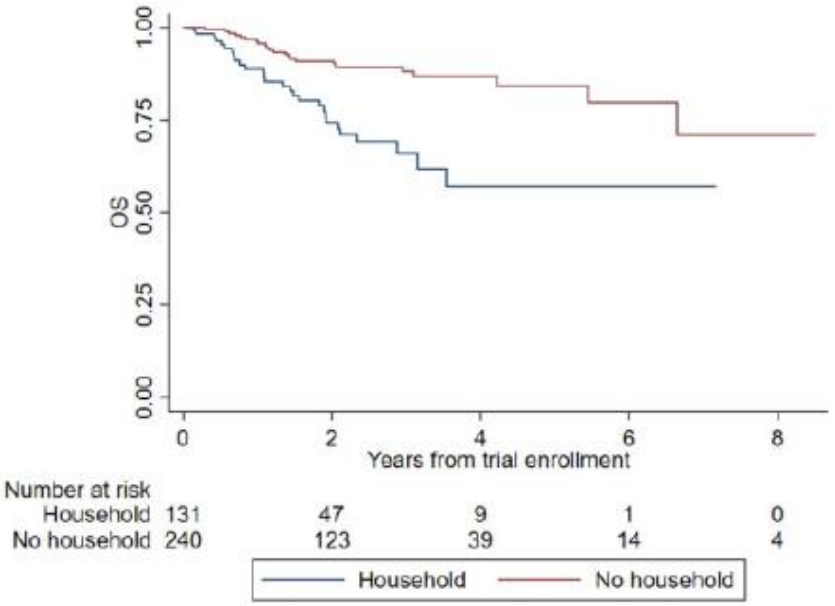
COMPRENDO: A peer clinical trial navigator

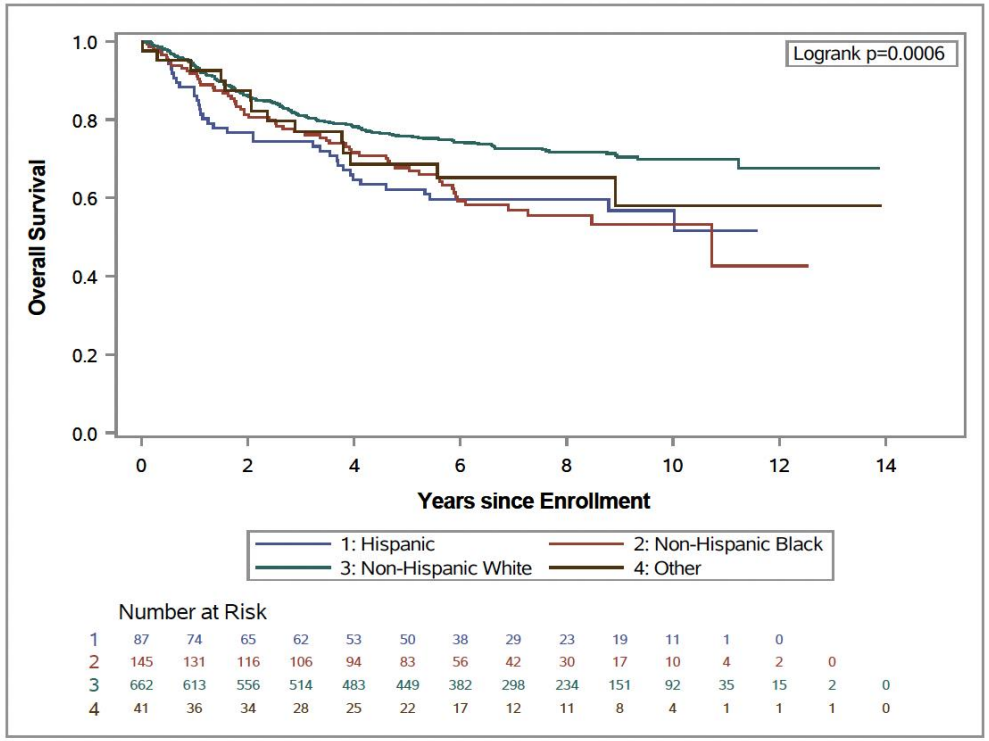
- Intervention: Culturally and linguistically appropriate peer navigator at the time of an informed consent conference for clinical trial participation

- Pilot testing results (N=137):
  - Improved comprehension of therapeutic trial components (purpose, randomization, risk/benefits, alternatives, voluntariness)
  - Greater improvements in parents who are Hispanic or who speak a language other than English

- Current stage: Undergoing multicenter RCT across 4 centers

Despite access to trials, survival inequities exist





Access alone may be insufficient to achieve equitable outcomes

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Bona et al. JNCI 2021 Umaretiya et al. ASCO 2022

Conclusions

- Equitable trial participation is achievable
- This is the first (but not only) step to ensuring equitable outcomes
- Pediatric oncology provides proof-of-concept that SDOH measurement and interventions are feasible and can be embedded in clinical trials