

Hear our voice: Patient driven solutions to increase participation in clinical trials

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BACKGROUND

- The rate of participation in clinical trials is dismally low, slowing the process of drug development and increasing cost.
- A critical gap exists in identifying actionable *solutions* to system level barriers.
- Patient-driven solutions ensure that opportunities to participate in clinical trials become more equitable, attractive and feasible for a larger, more representative pool of potential participants.

METHODS

A mixed-methods sequential explanatory design was used:

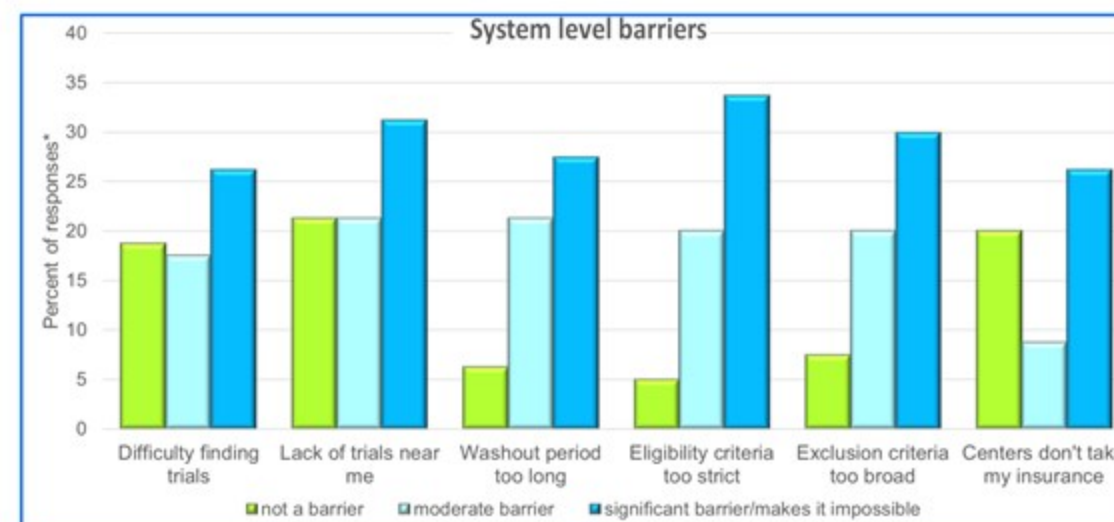
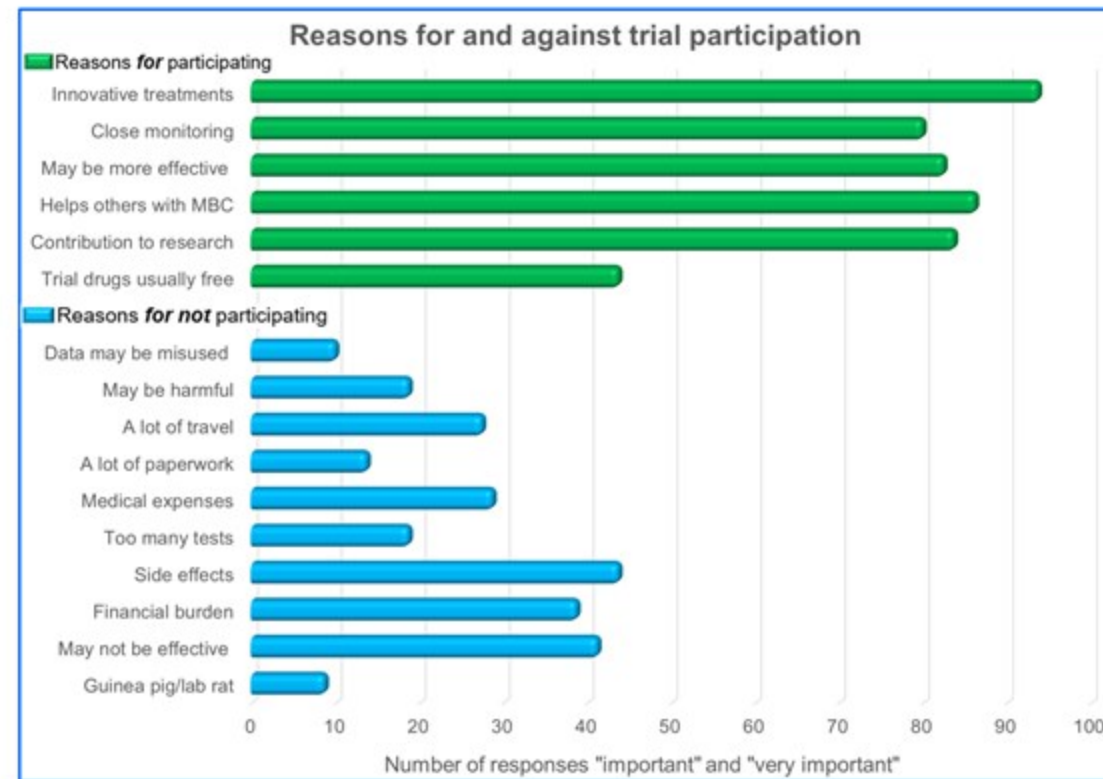
- **Interviews:** Purposeful stratified sampling to include patients, hospital administrators and payers.
 - 52 interviews conducted (28 MBC patients, 8 clinicians, 6 health care administrators, 6 researchers/research staff and 4 payers).
 - Data informed survey development and provided contextual qualitative data.
- **Surveys:** Online survey (based on Kessel *et al*, 2018)* was fielded on MBC social media groups reaching approximately 1,500 women and men. Survey measured:
 - Demographics (race, gender, age, years MBC)
 - Trial participation
 - Relative importance of reasons for/against participating in clinical trials
 - System level barriers
 - Solutions
- 496 survey respondents (88.71% white, 8.87% Black , 2.42% Asian).
- Mean age: 53 years old (34 – 74).
- Mean years with MBC: 4.6 years (ranging from < 1 year --19 years).

*Kessel KA, Vogel MME, Kessel C, et al. Cancer clinical trials - Survey evaluating patient participation and acceptance in a university-based Comprehensive Cancer Center (CCC). *Clin Transl Radiat Oncol*. 2018;13:44–49. Published 2018 Oct 4. doi:10.1016/j.ctro.2018.10.001

ACKNOWLEDGMENTS

Living Beyond Breast Cancer (LBBC) Hear My Voice Metastatic Breast Cancer Outreach Program. This program trains people living with metastatic disease to become advocates in their communities. For more information: lbbc.org/HearMyVoice.

SURVEY RESULTS



SOLUTIONS

Exclusion and eligibility ...*"cherry picking" participants...trials should represent us...*

- ✓ Include patient advocates in research design, protocol development and review

Finding Trials...*Clinical Trials shouldn't be a last resort...*

- ✓ Trials matching services through providers (staffed by support staff/navigator). Every restaging visit includes review of available trials.

Access to information ...*necessary information for weighing risk-benefit...*

- ✓ Preliminary findings (null, toxicities, side-effects and adverse events).

Washout period ...*Don't tell us it's for patient safety: In the real world we go from treatment to treatment without a break...*

- ✓ Base on half-life of previous drug.
- ✓ Measure in blood chemistries and statistically control.

Isolation ...*felt alone and disconnected..*

- ✓ Enable patients to connect with others if they wish.
- ✓ Direct line of communication for PRO.

Financial toxicity ...*additional expenses...*

- ✓ Consistent reimbursement for direct costs (co-pays/deductibles, travel, lodging).
- ✓ Cost of procedures/tests not covered by insurance should be met by study sponsor or negotiated with insurance without burdening the patient.

Logistical barriers ...*too much travel... too many tests and visits...*

- ✓ Limit scans and labs to minimum necessary.
- ✓ "Portable" multi-institution trials reaching a diverse/representative population.

Disparities...*data doesn't represent men or African Americans..*

- ✓ Identify and build on current community based patient led initiatives
- ✓ Federal fee schedule for clinical trials services ensuring every provider is a "participating provider" avoiding insurance discrimination

CONCLUSIONS

Patients with MBC are highly motivated to participate in clinical trials, recognizing the benefits that trials present: But are faced with significant barriers and exclusions that shut them out. There is a critical need to address these barriers using solutions-based approaches that include the patient voice.