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: Purposive 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: 4.45 years (ranging from < 1 year to 19 years).

SURVEY RESULTS

Reasons for participating
- Innovative treatments
- Close monitoring
- May be more effective
- Helps others with MBC
- Contribution to research
- Trial drugs usually free

Reasons for not participating
- Data may be missed
- May be harmful
- A lot of hassle
- Any place, any time
- Medical expenses
- Too many tests
- Side effects
- Financial burden
- May not be effective
- Survey paid $20.

Number of responses “important” and “very important”

SOLUTIONS

Exclusion and eligibility
- “Shrewd 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 resting 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 chemistry 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, deducibles, 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

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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: http://www.LBBC.org/HearMyVoice.

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.