Why Women Don't Enroll in Medical Research: A Cardiovascular Case Study

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Project Background

Context

- Multiple stakeholders have identified challenges in the recruitment of female patients in medical research
- Many hypotheses explain potential participation barriers, but little evidence exists to prioritize the largest barriers

Goal

- Understand both patient and investigator perspectives to prioritize potential barriers and to identify the biggest levers for change

Activities

- Created partnership between WomenHeart and Boston Scientific to conduct market research and gain insights
- Executed market research plan with both patients and physicians with support of Fusion Hill, a market research agency
  - Quantitative survey of WomenHeart Champions (N=598)
  - Qualitative interviews with patients (N=14)
  - Qualitative interviews with trial site coordinators (N=4)
  - Qualitative interviews with physicians from the WomenHeart Scientific Advisory Committee, as well as other physicians involved in clinical research (N=12)
- Initiated physician-led, multi-stakeholder working group to develop solutions to some of the largest identified barriers

Hypotheses on Participation Barriers

Potential Barriers Along the Patient Pathway

	Patients not aware and/or not asked to participate	Patient misunderstands potential risks and benefits	Patient initially interested but does not enroll	Patient cannot execute participation logistics
Physician sources	• Physicians ask women less often • Female symptoms misdiagnosed • Women not referred to specialist or treated in a setting with no access to research	• Poor physician communication	• Patient does not meet criteria or has too many comorbidities to be a good candidate	• Clinic inefficiencies create patient burden
Patient sources	• Patients not aware of opportunities • No (or limited) access to internet • Women are older than men at disease onset	• Patients misunderstand risks and benefits • Lack of patient educational materials • Cultural biases • Intimidated by terminology (“clinical trial” vs. “health research”)	• Patient intimidated by consent form or trial materials • Insurance coverage creates financial burden • Comorbidities reduce interest • No time, logistical, burden, or caregiving responsibilities	• Caregiving responsibilities • Cost of travel, lost wages, or child care • Extra clinic visits • No time • No transportation

Market Research Results

Hypothesis #1: Patients are not aware of the opportunity to participate

- A large number of patients are not approached to consider participation
- Many patients who participated sought out the trial on their own
- PCPs and primary cardiologists are not aware of trial opportunities

Hypothesis #2: Patient misunderstands the potential risks and benefits

- Fear of randomization and/or fear of riskiness of the trial
- Women tend to consult with more friends/family members than men and may be more swayed by anyone who is nervous on their behalf

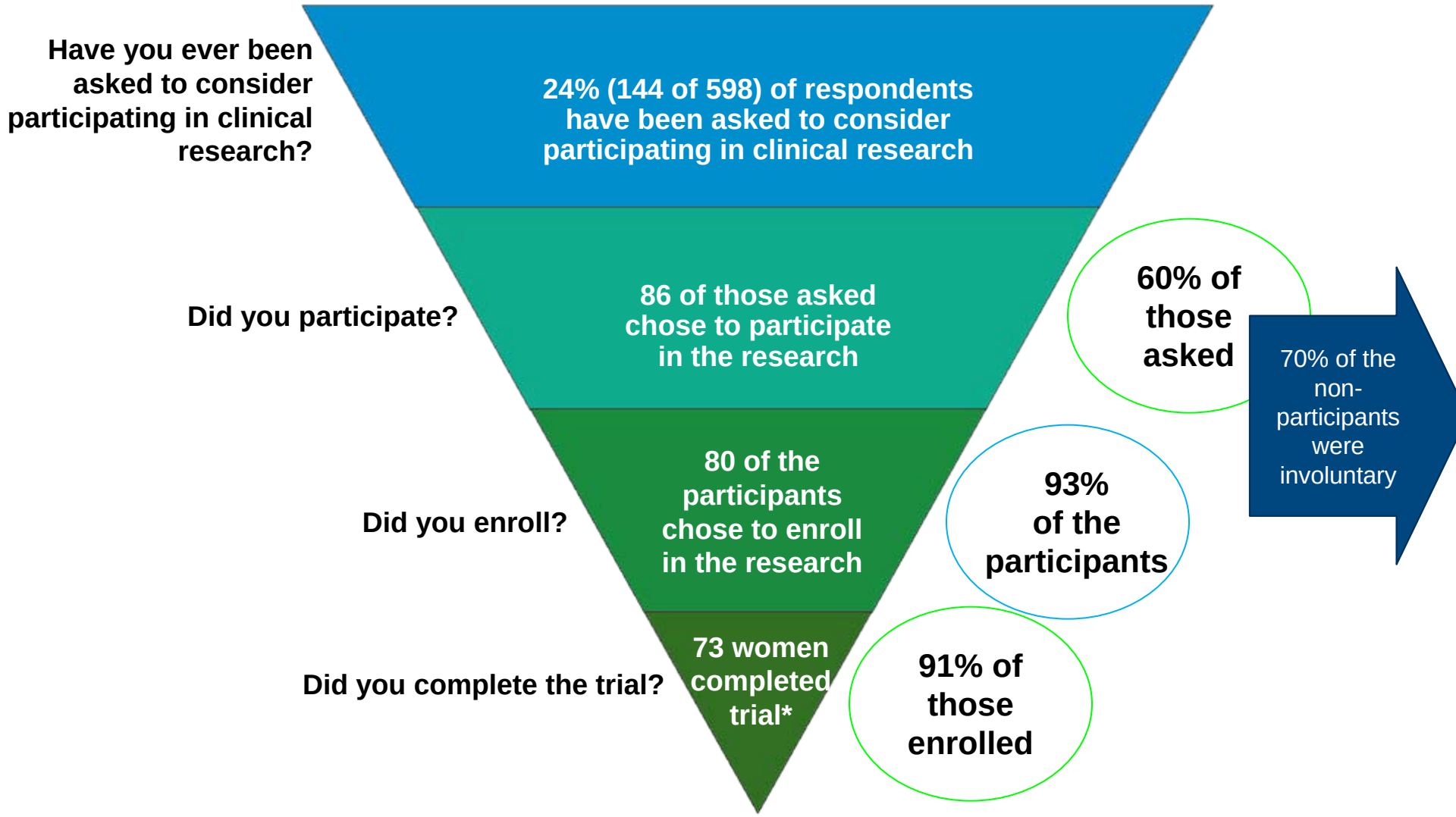
Hypothesis #3: Patient initially interested but does not enroll

- Many interested patients do not qualify due to concomitant medications, comorbities, age, or other related reasons
- Some trial sites never followed-up with patients to complete enrollment
- Fear of randomization
- Women may need more information, discussion, or time to decide and may not be receiving enough of these to convince them to enroll (and it may be cheaper/faster to enroll men)
- Logistical burden too high (travel distance, missed work, child care logistics, etc)
- Insurance coverage is an issue in many cases

Hypothesis #4: Patient cannot execute participation logistics

- Once enrolled, loss to follow-up was not a significant issue

Patient Flow: Women in Medical Research



Common Patient Characteristics

The "No" Patient

The "Yes" Patient

Source: Fusion Hill Patient Market Research, 2013

Opportunities for Change

1. Increase awareness around participation opportunities
   - Patient-focused awareness around the benefits of participation
   - Make it easier for patients to locate research opportunities (e.g. database)
   - Tools to increase awareness of participation opportunities among PCPs and General Cardiologists
   - Leverage social networks to encourage women to participate (through interaction with their peers who have participated, etc)

2. Examine trial design elements/protocols and propose changes to increase the number of women who qualify

3. Reduce the perceptions and misperceptions around participation risk
   - Patient education materials that describe the research process as well as the benefits of participation
   - Education for investigators and trial coordinators on how to more effectively approach and communicate with female patients

Each of these opportunities requires participation from multiple stakeholders

New Projects to Drive Change

Two multi-stakeholder projects were recently initiated by a physician working group, with participation from Boston Scientific, WomenHeart, and FDA

Improve trial design and execution by recommending new elements that can enhance female patient eligibility and recruitment

- Examine historical enrollment criteria and understand potential biases
- Collect and analyze trial screening logs to identify barriers and propose recommended changes to screening criteria
- Identify 10 trial site actions that predict recruitment success and pilot these in other sites to measure improvement

Design education to enhance physician-patient communication on the topic of medical research participation

- Create a prototype study kick-off kit with educational materials targeted to investigators/sites, referring physicians, and patients
- Propose content for trial kick-off meetings to educate both investigators and site coordinators on female recruitment
- Consider the role of social media in reaching referring physicians and patients