



Alliance A231701CD: Increasing Socioeconomically Disadvantaged Patients' Engagement in Breast Cancer Surgery Decision Making Through a Shared Decision Making Intervention (A Limited Access Study)

Heather Neuman, MD

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NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

Rationale

Objective

Study Schema

Intervention

Eligibility Criteria

Follow Up

Shared decision making (SDM) may reduce health disparities by addressing barriers to patient engagement in decision making that disproportionately impact socioeconomically disadvantaged patients.[1,2] SDM interventions, e.g., decision aids, have the potential to increase patient involvement in decision making, improve health outcomes, and lower costs.[3] Decision aids may have the added benefit of reducing health disparities, since disadvantaged patients may benefit most from their use.[2] The goal of SDM is to impart knowledge while also empowering patients to engage in decision making. Decision aids increase knowledge. [2,4-6] However, barriers to patient empowerment hinder engagement, including lack of awareness about treatment choices, patients' perceptions that their personal input is not valued, and doctor-patient power imbalances.[1] There is limited understanding about how decision aids can overcome these barriers. This gap is significant as these barriers disproportionately affect disadvantaged patients.[1]

In regards to breast cancer surgery specifically, multiple clinical trials demonstrate equivalent survival between breast conservation (BCT) and mastectomy (with or without reconstruction) for women diagnosed with early stage breast cancer.[7,8] However, patient-centered outcomes differ greatly, with a higher risk of local recurrence after BCT and a greater impact on body image with mastectomy. As most women are good candidates for both procedures, patients' values and preferences should drive decision making. Increased patient engagement in decision making may mitigate existing disparities in breast cancer surgical care.[9-15] Most population-based studies demonstrate that disadvantaged women are less likely to undergo BCT or receive post-mastectomy reconstruction.[16-20] This disparity is significant, as it can

negatively impact long-term outcomes such as treatment regret, body image, and quality of life.[21-26]

The etiology of these disparities is likely multifactorial. [17,18, 27,28] However, patient engagement during the surgical consult is critical for this preference-sensitive choice.[9-15] Prior studies demonstrate that socioeconomically disadvantaged women have less understanding of treatment options.[29-31] are less likely to recall discussing a choice with their surgeon,[32,33] and participate less actively in decision making.[34] Breast cancer surgery decision aids have already been developed that could address these barriers, making breast cancer surgery an especially appropriate model for our work.

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Please use the headings above to navigate through the different sections of the poster



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Co-Primary

- Test the effectiveness of a breast cancer surgery decision aid in increasing patient engagement in decision making (measured by knowledge and power) in clinics serving a high proportion of socioeconomically disadvantaged patients
- Test the extent to which the effect of a decision aid on patient engagement is mediated through the mitigation of barriers, and determine if persistent barriers are disproportionately experienced by socioeconomically disadvantaged patients

Secondary

- Characterize how persistent barriers influence patient engagement in decision making in order to identify targets for adjunct interventions that could be implemented in clinics serving a high proportion of socioeconomically disadvantaged patients

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NCI Community Oncology Research Program

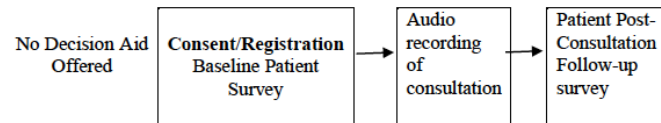
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Study Schema

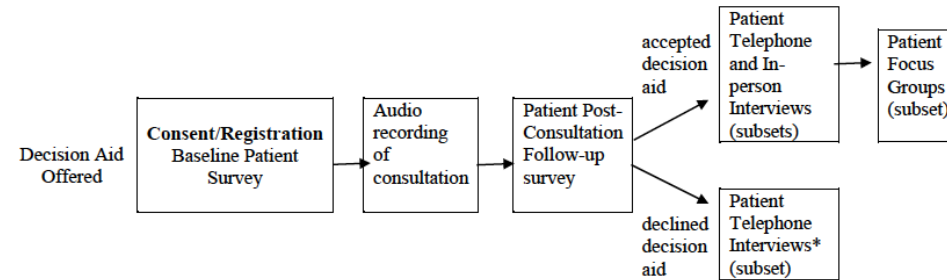
- Rationale
- Objective
- Study Schema**
- Intervention
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Please use the headings above to navigate through the different sections of the poster

For patients enrolled prior to Institutional Crossover:



For patients enrolled after Institutional Crossover:



* A subset of patients who decline the decision aid and did not participate in the surveys and audio recording of the consultation may also be approached for a telephone interview alone.



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- Rationale
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- Study Schema
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Please use the headings above to navigate through the different sections of the poster

Arm I (surgical consultation)

Prior to institutional crossover, participants receive care as per usual care.

Arm II (web-based breast cancer surgery decision aid)

Following a 10-week implementation period, at the time of institutional crossover, participants will receive a web-based decision aid prior to the surgical consultation.

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TAP TO
RETURN TO
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- Rationale
- Objective
- Study Schema
- Intervention
- Eligibility Criteria**
- Follow Up

Eligibility Criteria

Patient Eligibility

- Women newly diagnosed with stage 0-III breast cancer.
- Eligible patients must be planning breast surgery as a component of their definitive treatment.
- Patients with impaired decision-making capacity are not eligible for this study.
- Patients with hearing impairment requiring the use of an interpreter are not eligible for this study.
- Patients must be able to speak English
- Age \geq 18 years

Clinic Stakeholder (Surgeons and Clinic Staff) Eligibility

- Breast surgeon(s) and nursing staff, medical assistant, or mid-level provider at each participating clinic who participate in the care of patients newly diagnosed with breast cancer.

Institutional Eligibility

- Eligible clinics will serve a high proportion of socioeconomically disadvantaged patients, defined using two data sources. Using these data, 10 clinics that annually provide surgical care for 120-300 patients newly diagnosed with breast cancer will be selected to participate in this study. Surgeons at eligible clinics must consent to the study as a requirement for site participation.

All participating institutions will be selected by the study team prior to study activation.

Please use the headings above to navigate through the different sections of the poster



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- Rationale
- Objective
- Study Schema
- Intervention
- Eligibility Criteria
- Follow Up**

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