Official Title: Optimizing Decision Making About Breast Reconstruction After Mastectomy: A Patient-Centered Approach

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Protocol

The objective of this phase of the project is to pilot test a clinical decision support tool that is risk-stratified and reflective of patients' preferences and clinical needs.

In this phase of the project, the effectiveness of the tool will be evaluated through a randomized controlled trial. Eligible patients will be identified through chart review. We will recruit patients who are scheduled for a plastic/reconstruction consultation with one of the surgeons who has agreed to participate. We will also identify patients who have completed a mastectomy, or are scheduled for one, and may be considering reconstruction, but do not have an appointment with a plastic/reconstructive surgeon. A study team member will phone the patient to determine her interest and ask her to come to their scheduled appointment 30 minutes early to meet a coordinator. These participants will also have the option of completing the study procedures at home at a time convenient for them before their scheduled appointment. Phone consent will be obtained for these individuals. For patients who have had or are scheduled for a mastectomy but do not have an appointment with a plastic/reconstructive surgeon, a study team member will phone the patient to determine their interest, and if they would like to participate, obtain phone consent. Patients will be randomized using computer random assignment, block size of 4. Patients will either interact with the decision tool (*BREASTChoice*) or the usual care American Society of Plastic Surgeons booklet “Breast Reconstruction” depending on random assignment. Both groups will be asked to answer a survey containing the same outcome measures and sociodemographic information. The pre-reconstruction Breast-Q will be administered to participants who did not complete it as part of standard of care. After the appointment, we will collect information about the duration of the consultation, decision process quality, and shared decision making measures. We will also document reconstruction outcome (receipt or not, type, and timing) from the EHR. The patient participation time is expected to be approximately 30 minutes. After the last patient is enrolled, we will ask participating surgeons to answer a short follow-up survey about their experience and offer feedback about the study.

Statistical Analysis Plan

For this clinical trial portion, 120 eligible patients, 60 per randomized group, were enrolled for evaluation of the clinical decision tool (CDT). Descriptive statistics were computed. Groups were compared across demographics and variables to ensure the randomization procedure produced balanced groups. The primary outcomes of this phase included knowledge, decision process quality subscale of the Decision Quality Index (DQI), and decisional conflict evaluated by the Decisional Conflict Scale (DCS), while all others are secondary or exploratory outcomes. Secondary outcomes included: preferences and preference concordance, quality of life as assessed by the BREAST-Q, patient activation, shared decision-making, and treatment received. Implementation outcomes included: time spent using *BREASTChoice*, clinical consultation time, and usability of the CDT. Covariates were considered including: age, education, race, ethnicity, household income, zip code of residence, stage of disease, health insurance status, and subjective health literacy. Proper transformation (e.g., logarithm and square root) will be considered for conformation to normality whenever normality is assumed. Relationship among outcomes will be evaluated based on pairwise Pearson or Spearman correlation coefficient. To determine whether the CDT increased knowledge about options and reduced the number of individuals uncertain about their choice as well as whether CDT impacts other outcomes we conducted a linear regression model examining the relationship between group (decision tool vs. usual care) and outcomes controlling for health literacy and provider. Significance of $\alpha=0.05$ was used; all tests were two-sided.

Feedback from 4 supporting physicians who allowed study team to recruit in their clinics will also be assessed.