An Intervention to Improve Decision Role Concordance amongst Newly Diagnosed Breast Cancer Patients

Study Protocol and Statistical Analysis Plan

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Project Summary: Role concordance among patients and providers during the decision making process can impact outcomes, but there is a lack of interventional studies in the literature aimed at improving role concordance during treatment decision making for breast cancer patients. The proposed design is a mixed methods, interventional study with concurrent controls to examine the effects of an intervention to improve role concordance on decisional outcomes and breast cancer specific quality of life among newly diagnosed breast cancer patients.

Project Description:

Rationale: This study is innovative because it is an interventional study aimed at improving role concordance in the treatment decision making process for newly diagnosed breast cancer patients. There are currently no standards of care for patient centeredness in clinical decision making. This project will provide a foundation for a research program that will change this, focusing on treatment decision making in breast cancer patients.

Overview: The proposed design is a mixed methods, interventional study with concurrent controls to examine the effects of an intervention to improve role concordance on decisional outcomes among newly diagnosed breast cancer patients. Providers will be blind to the patient's preferred decision making role in the first half of the study and then informed of the preferred role in the second half of the study. The intervention will be a short conversation that providers will have with patients at the beginning of the clinic visit where the provider identifies the patient's preferred role and their desire to help the patient achieve it. Quantitative comparisons before and after implementation of the intervention and qualitative analyses of the recorded clinical encounters will be performed to evaluate the effects of the provider directed behavioral intervention to improve role concordance. This study design was chosen because once the intervention is introduced providers may have difficulty omitting this behavior from the clinical encounter and this could confound our results. If patient-level randomization was used, providers would need much more oversight and coaching in order to not "forget" which patient is in which arm and the study effects may be biased toward the null. In this small study, if provider-level randomization was used, this could significantly bias assessments of patient involvement due to inherent differences in how the providers approach clinical interactions at baseline. Also, we do not anticipate substantial variability in the pre and post populations during the short time period of the study other than the date of their consultation and, thus, we expect that the populations will be very similar in other characteristics. We plan to examine differences between pre and post-intervention patients to evaluate this.

Objectives:

1. Investigate the impact of a brief provider-led intervention about the patients' preferred role in treatment decision making on role concordance. **We hypothesize that:**
    a. Role concordance will be improved when the preferred role is discussed with the patient at the beginning of the encounter.
    b. The provider's perception of the role achieved will be more concordant with the patient's perception when the preferred role is discussed.
2. Investigate the impact of role concordance in the treatment decision making process on short term and long term quality of life and decision outcomes. **We hypothesize that:**
    a. Patients who achieve role concordance will be more satisfied with the decision process.
    b. Patients who achieve role concordance will have better QOL and less decision regret at early (2 to 6 weeks) and later (6 months) timepoints after the clinic visit.
    c. Patients who achieve concordance will be more likely to complete or plan to complete recommended treatments.

Study Subjects: The study population will be newly diagnosed female breast cancer patients scheduled to see one of four breast surgeons at the Huntsman Cancer Hospital Breast Surgery Clinic at the University of Utah. We will exclude patients who have had breast cancer previously, cannot read or write, or have a primary language other than English.

Recruitment: All newly diagnosed patients scheduled in our clinic will be given a recruitment letter as part of their new patient materials (sent the day they scheduled their appointment). They will then be called the day before their visit to gauge interest in participation. If they express interest, they will be sent a consent form electronically so that they can familiarize themselves with the study. They will be asked to arrive at least 30 minutes early for their scheduled appointment (most patients do this anyway) and will be met by a research assistant who will explain the study again and obtain written consent. This same assistant will administer the study scales before and after the clinic visit. Providers will not consent patients nor administer any patient assessments for the study because they will also be delivering the intervention. We expect to enroll a total of 100 patients with 50 in the first year and 50 in the second. We see over 400 new breast cancer patients per year and therefore need approximately 12% of these patients per year to participate in order to reach our recruitment goals. Prior studies using similar methods have had excellent enrollment rates with 98% of eligible patients interested in enrollment.

Methodology*:* The Patient Preference Scale is the initial scale used in the study and identifies 5 different roles in decision making (Fig. 1). Following completion of the consent process, participants will be asked just prior to the first clinic visit with the surgeon to identify their most preferred role for treatment decision making during that encounter. This will be designated as the preferred role for evaluation of role concordance. For the first 50 patients, the providers will be blinded to the preferred role. After the clinic visit, the participants will complete the Patient Perception Scale which measures patients' perception of the achieved role in the treatment decision making process. After the clinic visit, providers will also complete the Provider Perception Scale which measures the provider's perception of the role achieved by the patient. These three scales are shown in Table 1. The Patient Perception Scale and the Provider Perception Scale will be compared to evaluate the degree of patient-provider concordance between achieved roles. Analysis will also be performed to establish the proportion of patients with perfect role concordance between their preferred and achieved roles. The degree of discordance can also be measured by comparing the number of roles between the preferred role and the achieved role on the 5-point Likert-type scales

Table 1.

Patient Preference Scale (prior to clinic visit)	**Patient Perception Scale (after clinic visit)**	**Provider Perception Scale (after clinic visit)**
I prefer to make the final selection about which treatment I will receive	I made the final decision about which treatment I would receive.	The patient made the final decision about which treatment she would receive.
I prefer to make the final selection of my treatment after seriously considering my doctor's opinion.	I made the final selection of my treatment after seriously considering my doctor's opinion	The patient made the final decision about which treatment she would receive after seriously considering my opinion.
I prefer that my doctor and I share responsibility for deciding which treatment is best for me.	My doctor and I shared responsibility for deciding which treatment was best	I shared responsibility with the patient for making the final decision about

	for me.	treatment she would receive.
I prefer that my doctor make the final decision about which treatment will be used but seriously consider my opinion.	My doctor made the final decision about which treatment would be used but seriously considered my opinion.	I made the final decision about which treatment the patient would receive after seriously considering the patient's opinion.
I prefer to leave all decisions regarding my treatment to my doctor.	My doctor made all the decisions regarding my treatment.	I made the final decision about which treatment the patient would receive.

Recording of clinical consultations has been well-studied as a tool for determining patient-centered communication [1-3]. Therefore, all clinic encounters will be digitally recorded, transcribed, and analyzed using the OPTION scale for patient involvement, which is described below. The transcriptions will be de-identified and coded by independent raters (paid graduate students).

Assessments of QOL and decision regret will be performed at early (2 to 6 weeks) and later (6 months) timepoints after the clinic visit. These scales will be distributed electronically and patients will receive a phone call from the study coordinator to remind them to complete the measures. If they have not completed the measures by one week from the reminder phone call, a second call will be placed with an offer to complete the surveys over the phone with the study coordinator.

Chart review of all participants will be reviewed at the 6 month time point to assess for decisions ultimately made and completion or intention to complete recommended therapies. This timeframe was selected because the majority of patients will have completed their surgery, chemotherapy (if needed), and radiation (if needed) or at least have the initiation of these therapies planned. Radiation is always given last and this therapy is the most likely to still be in the planning stages. Also at this time point, endocrine therapy will have been initiated by some patients and may be planned by others.

Intervention: The intervention will take place in the second half of the study, where the research assistant will inform the provider of the patient's preferred role based on the Patient Preference Scale prior to the clinic visit. The provider will then have a brief conversation at the beginning of the clinic visit where they state "I see that you prefer to have treatment decisions made (*together, by yourself, by me*) today. I appreciate knowing this information." The rest of the encounter will proceed as per the provider's usual practice. All other study procedures will be the same and the same perception scales will be used after the clinic visit and concordance and discordance will be examined as described in the study flow diagram.

Outcomes*:* The primary outcomes will be role concordance and patient satisfaction with the decision process. Secondary outcomes will be role perception concordance between provider and patient, quality of life at 2 to 6 weeks and 6 months after initial clinic visit, decision regret at 2 to 6 weeks and 6 months after initial clinic visit, and completion or planned completion of recommended therapies at 6 months. These time points were chosen to provide an early assessment of the impact of the intervention and to see if the results are durable after a longer period of time while still allowing us to conclude the study within the funding timeframe. There is evidence that decision regret is stable over time out to 4 years after diagnosis [4]. We will also correlate role

preference and concordance with surgical procedure performed or planned to look for associations between these measures and type of surgery received or planned, controlling for ineligibility for breast conservation.

Risks and Benefits of Participation*:* Participation is completely voluntary and may be withdrawn at any time. This is a low risk study, but some patients may experience distress from the questions on the surveys. If a patient experiences distress, she will be referred to our in-clinic Licensed Care Social Worker and she will make appropriate referrals to psychiatric care if necessary. There is also a low risk of loss of privacy and patients will be made aware of this. The benefits of participation are greater patient awareness of their own preferences and decisions.

Please see the study flow diagram on the following page.

Study Flow Diagram

Record decisions made and intentions
to complete therapy

Data Management: All surveys will be administered electronically (tablets will be used for in clinic surveys) and stored on a secure University server. The surveys will be collected both in person (when the patient is in clinic) and electronically.The surveys are will be built into and collected in the Research Subject Registry (RSR) database. Only study personnel will have access to the data and the PI will be responsible for deciding the role and level of access for each person. All digital audio recordings will be stored on a secure, password protected University computer in a locked office at Huntsman Cancer Institute. Again, only study personnel will have access to this data. The digital recordings will be transcribed and de-identified for coding and analysis. The de-identified transcripts will only be available to trained coders, the PI, and study coordinator. The electronic transcriptions will be stored on University based, password protected computers in the secured office area of the PI. Badge access is required to enter the office area during non-business hours. Paper versions will only be used if necessary due to computer outages or significant feasibility issues with the electronic transcripts and will be stored in a locked filing cabinet in the PIs locked office. Again, access will only be given to study personnel.

Statistical Analysis:

We are interested in evaluating whether patients play their desired role in treatment planning, and whether informing providers of patients' preferred roles improves patients' perception of achieving their desired role. Specifically, we will study two groups of patients, a non-intervention control group, where providers are blind to the patient's preferred decision making role and an intervention group where the provider is informed of the patient's preferred role. For this study we plan to enroll 100 patients, where the first 50 will be in the no intervention group and the next 50 will be in the intervention group. We expect the results to provide preliminary data for powering a larger extramural grant.

The primary aim of our study (a) is to evaluate patient perception of whether the patient achieved his/her preferred role in the treatment decision. This aim will be met by estimating perception concordance between baseline and after the clinic visit within the intervention and control groups, and testing for group differences in concordance. A secondary goal (b) will be to similarly estimate concordance of provider's perception of the patient's preferred role versus the patient's perception of the achieved role (where both scales will be measured after the clinic visit). In addition, we also plan to test the following outcomes between groups: c) patient's satisfaction with the decision making process, d) FACT-B assessment of short-term QOL, e) decision regret, f) OPTION assessment of patient involvement and g) completion or intention to complete therapies. Finally, we will compare the patient role concordance estimated in a) with improved short-term and longer-term improvements in: outcomes c)-g). Specific methods corresponding to each analysis objective are described below.

a-b) Concordance measures. The patient and provider perception scales consist of 5 levels ranging from active to passive involvement in treatment decisions. Consistent with other similar studies [5-7], our primary concordance measure will be defined as exact agreement in patient responses between the baseline and post clinic visit. Within each group we will provide concordance rates and the associated 95% confidence interval (CI) using the Wilson Score interval approach. We will also report the weighted Kappa coefficient and its 95% CI. Group differences in concordance will be tested using a chi-squared or Fisher's exact test. As a sensitivity analysis for this assessment, we may adjust for potential confounders in a logistic framework predicting concordance. We will consider the following variables for adjustment if they are associated with the concordance outcome: age, education level, and stage of disease.

c) Patient's satisfaction with the decision making process. Satisfaction with the decision making process will be measured directly after the clinic encounter using a modified version of the Holmes-Rovner Satisfaction with

Decision scale which combines several elements of decisional satisfaction and is designed to measure satisfaction with the decision regardless of prognosis or outcome [5, 8]. It also correlates with decision confidence. It uses a Likert-type ranking of 6 items related to the decision. The modified version will measure the satisfaction with the process of decision making rather than the decision itself. Group satisfaction differences will be assessed using a two-sample two-tailed t-test. We will also use linear regression to consider adjusting for the potential confounders described above (a-b) along with the following treatment related variables: type of surgery received and the sequencing of treatment (chemo first vs. surgery first), surgical complications, recommendation for chemotherapy, and recommendation for radiation treatment in these analyses. We will also compare satisfaction with concordance within groups using t-tests (or regression to adjust for covariates). Finally, we will test whether the relationship between satisfaction and concordance differs across groups using linear regression and testing for significance of a group*concordance interaction.

d) Comparing FACT-B assessment of short-term QOL between the groups. Quality of life will be assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B) questionnaire. This scale will be used prior to the first consultation to establish a baseline for each patient and will subsequently be used at 2 to 6 weeks and 6 months after initial clinic visit. This questionnaire is a well validated tool for assessing quality of life in breast cancer patients. It measures 27 items in five different areas: physical well-being, social/family well-being, emotional well-being, functional well-being, and additional concerns specific to this patient population. It has been shown to have significant sensitivity for changes in performance status and quality of life [9]. We will compare the FACT-B assessment between the intervention and control groups using a linear mixed effects model framework with an unstructured covariance, adjusting for baseline FACT-B levels. The final time point (6 months) is our main time point of interest, but we will also estimate differences at 2 to 6 weeks. We will consider controlling for the covariates described in c). We will also compare FACT-B with concordance within groups using separate linear mixed effects models for each group. Finally, we will test whether the relationship between satisfaction and concordance differs across groups using linear mixed effects regression and testing for significance of a group*concordance interaction.

e) Decision regret. The decision regret outcome will be measured using the Decision Regret Scale which will also be administered at 2 to 6 weeks and 6 months after initial clinic visit. This scale has been used in modified version to assess for elements specific to breast cancer surgery and was found to have high internal consistency [4]. It is a 5 item scale with items ranked on a 5-point Likert-type scale and added together with higher score indicating more regret. The analysis framework for comparing groups will be similar to d), except that there is no baseline level to control for in the models.

f) OPTION assessment of patient involvement. The outcome of patient involvement at the clinic encounter will be measured using the OPTION scale. This scale was developed to measure the extent to which providers involve patients in decisions. A description of the measures used and timeline is illustrated in Table 2. With this scale, 2 independent raters will use a 12 item list to code and score a clinical consultation. It provides a reliable method for detecting differences between the extent of patient involvement with good inter-rater reliability and inter-rater agreement [10, 11]. Raters will be hired graduate students who will be trained in this method, with each rater coding and scoring the first 10 transcripts followed by comparison of the results using the intraclass correlation coefficient (ICC) and its 95% CI before switching to a single rater per transcript method. These scores will be compared between the intervention and control groups for differences in patient involvement using a two-sample t-test and linear regression to adjust for the covariates described in c). We will also compare patient involvement with concordance within groups using t-tests (or regression to adjust for covariates). Finally, we will test whether the relationship between involvement and concordance differs across groups using linear regression and testing for significance of a group*concordance interaction.

g) Completion or intention to complete therapies. Group differences in completion or intention to complete recommended therapies will be assessed at 6 months after the clinic visit through chart review of all participants' charts. Intent will be defined as initiation or scheduled initiation of a recommended treatment. The variables of decision made (i.e. type of surgery or sequence of therapy) and completion or intention to complete recommended therapies will be compared between groups using a chi-squared or Fisher's exact test. We will also use a logistic regression framework to test whether the relationship between concordance with completion differs by group. We will consider adjusting for a few covariates described in c), keeping in mind a minimum of 5-10 events per predictor in our models. [12]

Table 2.

Measure Name	Assesses	Prior to Clinic Visit	Immediately After Clinic Visit	2 to 6 Weeks After Clinic Visit	6 Months After Clinic Visit
Patient Preference Scale	*Patient's preferred role in decision making process*	**X**			
Patient Perception Scale	*Role the patient perceives they played in decision making process*		**X**		
Provider Perception Scale	*Role the provider perceives the patient played in the decision making process*		**X**		
FACT-B	*Breast cancer specific health related quality of life*	**X**		**X**	**X**
Decision Process Satisfaction Scale	*Level of satisfaction patient had with the decision making process*		**X**		
Decision Regret Scale	*Regret about decision made*			**X**	**X**
OPTION Scale	*3rd party assessment of patient involvement in decision making (from recorded encounter)*		**X**		

Sample Size Justification

Concordance estimates. A similar study conducted by Bilodeau and Degner estimated 50% agreement between a patient's initial decision-role preference and the role that was achieved [13].Within each group (n=50), we expect to achieve a confidence interval (CI) width of 29% for an expected concordance of 50%, corresponding to a 95% CI of 36%-64%.

Comparison of intervention versus control concordance. With 50 subjects per group we would have 80% power to detect an absolute increase in concordance of 28% in the intervention versus the control group using a two-sided Fisher's exact test at a 0.05 significance level.

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