

Empowering Patients to Achieve Individualizing Care for Advanced Breast Cancer

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Abstract (250 words)

The primary goal of this study is to promote individualized care for patients with metastatic breast cancer by empowering patients to identify their preferences and goals of care and to facilitate shared decision regarding care plans in the breast oncology clinic.

Methods: We will conduct focus groups and structured interviews to develop an individualized goals of care discussion guide (IGCDG). We will then recruit 80 patients with metastatic breast cancer at the time of diagnosis or disease progression, assess their goals and preferences for care, provide this information to the patient's physician, and evaluate the impact on decision making, concordance of care and preferences, and patient satisfaction.

Analysis: The primary outcome of interest will be feasibility of the IGCDG based on recruitment, attrition, and measurement of distress. Secondary outcomes will include patient reported satisfaction with the IGCDG and the achievement of individualized care planning as measured by the following validated measures, 1) Medical Decision Making satisfaction scale, 2) The decisional conflict scale, 3) Modified Control Preferences Scale, and 4) The Patient Satisfaction with Cancer Care measure, in addition to study specific questions that will guide further research using the IGCDG.

Deliverables and Impact: This proposal will yield 2 abstracts and 2 manuscripts reporting the feasibility and impact of the IGCDG. The tool we develop will be made publically available through the NCCN and Cancer.Net. This research is intended to yield a pragmatic tool that can empower patients and help translate the vision of individualized care for metastatic breast cancer into reality.

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D. Main Proposal

1. Overall Goal and Objectives

The primary goal of this study is to promote individualized care for patients with metastatic breast cancer by empowering patients to identify their preferences and goals of care and to facilitate shared decision making at critical points in care.

Metastatic breast cancer is incurable but the prognosis is highly variable with many patients surviving for 4 or more years. Just as clinical characteristics and prognosis can vary, so do the values, goals and preferences of individual patients that must be carefully considered and respected in preparing a plan of care at each step in the course of illness. A large body of literature supports the need for improved communication regarding treatment decision making for patients with advanced breast cancer.¹ The American Society of Clinical Oncology has recognized that individualized treatment planning is a critical part of quality cancer care but there are few tools available to promote improvement in this aspect of care or to adapt this framework for metastatic breast cancer. Prior research, reviewed below, has shown that empowering patients to raise questions and address their priorities during office visits can help to engage patients in active decision-making and allows them to provide timely input into their plan of care. There is an opportunity to identify, discuss, and develop individualized care plans both at the time of initial diagnosis of stage IV disease, and at times of disease progression when a switch in treatment is required. **There is an unmet need for tools to promote individualized care in a way that is efficient, supported by patients and physicians and scalable across treatment settings.** This proposal will build upon our groups prior work to identify gaps in communication in treatment planning and seek to improve shared decision-making following a scalable clinic based intervention.

Our Primary Goal is to improve communication and shared-decision making for patient with advanced breast cancer to achieve care consistent with the patients goals and preferences.

Specific Aims:

1. To develop an individualized goals of care decision guide (IGCSG) that will facilitate identifying and prioritizing goals of advanced cancer care consistent with the patient's values and preferences following initial consultation for diagnosis or progression of stage IV disease.
2. To assess the feasibility of providing patient reported goals and preferences for advanced breast cancer care in the form of IGCDG to the patients' oncologist following initial consultation regarding new diagnosis or progression of disease.
3. To explore the impact of the IGCDG on treatment planning, communication, satisfaction with care, and concordance between goals and actual treatment plan.

2. Current Assessment of Need in Target Area

The need for individualized care in advanced breast cancer was articulated in an ASCO policy statement in 2011 by Peppercorn et al.¹ In an era of “personalized medicine” that describes our aspiration to base treatment on the molecular features of the patients disease, we perceived a need to more broadly define care that considered not only disease directed therapy, but the diverse physical, psychological, social, and spiritual impact of cancer and the patients unique goals and preferences in the face of incurable illness, termed “individualized care”. As ASCO noted conversations regarding prognosis, goals of care, and treatment options tend to occur late in course of advanced cancer, or not at all. ASCO called for a change in the paradigm of care to identify and address the patient’s goals early in the course of illness and to tailor therapy appropriately. Key elements of individualized care identified by ASCO are listed in table 1.

Table 1. Key Elements of Individualized Care for Advanced Breast Cancer (adapted from Peppercorn, JCO 2011)

1. Patients should be well informed about their prognosis and treatment options and should have the opportunity to make their preferences and concerns regarding treatment and supportive care known.
2. Evidence based anticancer therapy options should be discussed.
3. Options to prioritize and enhance quality of life should be discussed at the time of diagnosis and throughout the course of illness.
4. Conversations about anticancer interventions should include information on likelihood of response, duration of response, the nature of response (progression, survival, etc), potential adverse effects, risks of therapy, and direct financial costs of treatment.
5. Whenever possible patients should be given the option of participation in clinical trials.
6. When disease directed options are exhausted patients should be encouraged to transition to symptom directed palliative care alone.

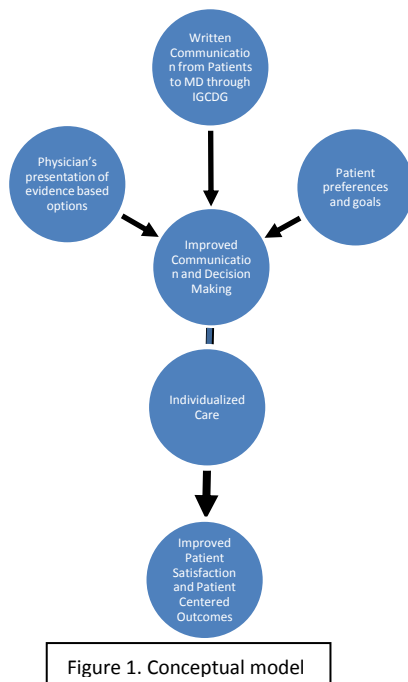
There is a large body of literature documenting preferences for individualized care and shared decision making among patients with breast cancer, but virtually all studies to date focus on patients with early stage disease and the decisions surrounding type of surgery, adherence to endocrine therapy, and the role of adjuvant chemotherapy or radiation therapy.²⁻⁵ When disease is metastatic and incurable, there is no reason to suspect that patients would now want less involvement in decision-making, but there has been little attention to this issue.

Patients with metastatic breast cancer, while incurable, often have survival measured in years. Over the course of disease, they are typically offered multiple lines of therapy, yet whether these decisions are informed by the patient’s understanding of prognosis or her goals and preferences remain unevaluated. This is particularly important because at each decision point at which therapeutic options are addressed, shared decisions should be based on

understanding of tradeoffs in terms of efficacy, toxicity, treatment burden, and financial toxicity. For example, patients with newly diagnosed endocrine receptor positive metastatic breast cancer have options including endocrine therapy alone, or endocrine therapy plus the novel inhibitor of cyclin dependant kinases 4 and 5, palbociclib.

This drug improves progression free survival by close to 1 year, and improves response rate, but with tradeoffs that include a need for more intensive laboratory monitoring and follow-up for neutropenia, and still rare but greater risks of fatigue, alopecia, and stomatitis. In addition, there may be higher out of pocket costs for some patients.⁶ Whether and to what extent such tradeoffs are considered and discussed with patient preferences taken into account is unknown.

Similarly, in the second line setting, patients who are endocrine responsive can be considered for further endocrine therapy alone or endocrine therapy plus an MTOR inhibitor, that improves progression free survival and response rate, but not overall survival, at the expense of greater risk of toxicity and cost.⁷ Options in the second line setting continue to evolve, with recent evidence that palbociclib improves survival in combination with second line endocrine therapy, and again, considerations of the tradeoffs and the patient's individual preferences are indicated.⁸ Patients with her2 positive disease in the first line setting have the option of standard chemotherapy plus trastuzumab, or the same regimen with a second antibody, pertuzumab, that markedly improves survival, but again with potential tradeoffs in terms of toxicity, cost.⁹ Decisions may become more complicated in later lines of therapy, when there are therapeutic options but the expected benefit may decline, and the option to pursue palliative care in combination with disease directed therapy or palliative care alone may be preferred by some patients.



Conceptual Model

In our proposed conceptual model, Figure 1, Physicians present a range of evidence based care options, patients bring their preferences and goals to the conversation, and the process of shared decision making is supported by asking patients to specify their goals and preferences across key domains prior to the final care plan decision and this information is then provided to the physician. The result is hypothesized to be improved communication and desired level of involved in decision making by the patient, resulting in individualized care, which in turn will translate into improved patient satisfaction and achievement of patient centered outcomes, as measured in validated decision making and satisfaction scales.

Recent data suggests that achieving individualized care for advanced breast cancer remains an unmet need, but intervention to improve communication and care in this area is feasible. In a multicenter study by Dr. Sepucha and colleagues, patients with metastatic breast cancer were surveyed regarding their preferences for treatment intensity. They were advised of a hypothetical scenario in which they could receive a regimen that was more effective in inducing disease response but also more toxic. Patients demonstrated a diversity of opinion, with 23% preferring the less effective/less toxic approach, and 77% preferring the combination therapy. Patients were then asked their preferences if they had a biomarker that would predict higher benefit and greater toxicity, and again we saw that patient's preferences vary. Fourteen percent changed their treatment preferences based on information about their tumor biology and how they personally would experience tradeoffs in efficacy and toxicity. Of note, roughly half of those patients who changed treatment choices preferred to accept more toxicity in exchange for more benefit, and half were willing to accept less effective treatment in order to avoid greater toxicity.¹⁰ Similarly, in a study of older patients with early stage cancer, Mandelblatt and colleagues found that use of chemotherapy was highly sensitive to patient preferences and satisfaction with communication.¹¹ In a study of patients with metastatic cancer, including many with breast cancer, Meropol and colleagues found that 27% of patients preferred to focus treatment decisions on quality of life, 18% preferred to focus on survival, and 55% wanted equal consideration of both goals.¹²

Bruera demonstrated that patients with breast cancer often want greater involvement in decision making, and oncologists are not good at predicting which patients want greater involvement, suggesting a need to directly assess this and provide the information to the oncologist.¹⁴ There is a high degree of misunderstanding identified among patients with advanced care. In a study of over 1,200 patients with metastatic cancer, Weeks and colleagues found that well over 50% of patients with incurable illness expressed an expectation that they could be cured. Similarly, in a study of patients with metastatic breast cancer, Lux et al. found that patients overestimated benefits of therapy, with most expecting a year or more improvement in survival from every treatment.¹⁵ In this context, patient may make decisions regarding treatment and toxicities they will accept that may not reflect their preferences if they had a better understanding of prognosis.

Patients preferences vary regarding desired information about prognosis and other aspects of care.¹⁶ Understanding and facilitating patient preferences to discuss costs of cancer care is an increasingly important aspect of individualized care given the rising costs that are often shifted to patients, and the highly variable value of available therapeutic options.¹⁷ Dr. Peppercorn and colleagues conducted a survey of evaluating the preferences to discuss costs of cancer care among patients with breast cancer.¹⁸ Among 134 patients, 94% wanted to discuss costs of cancer care with their physician, however only 14% reported ever having such discussions. Most, but not all, patients with metastatic disease wanted to be informed of direct

out of pocket costs, but only 6% wanted to discuss societal costs of care. Other domains, such as the impact of disease and treatment on sexual health, employment, exercise and nutrition, that are the topic of considerable research in early stage breast cancer, have been neglected to date for patients with metastatic disease, despite the fact that many patients will live 5 years or longer with good health.

There is a need to better define the concerns of patients with metastatic breast cancer related to individualized care, and to develop an intervention that will facilitate shared decision making throughout the spectrum of advanced breast cancer.

This proposal builds directly upon pilot work in our center by Sepucha et al. to evaluate a decision aid for patients with metastatic breast cancer.¹³ Patients were recruited at the MGH and Dana-Farber breast cancer clinics and were provided with a 30 minute informational video and accompanying booklet that reviewed the experiences of 4 patients with metastatic breast cancer and the experiences they faced in living with cancer, making decisions, and maintaining hope. Patients considering first through 4th line of therapy were surveyed at baseline and 3 months after the intervention to evaluate feasibility, distress, and impact on shared decision-making. Among 50 patients approached, recruitment rate was 64% and attrition prior to the follow-up survey was only 22%. Most patients (> 70% at each assessment) indicated that they wished to share treatment decisions with their doctor, but only 41 % reported that they had actually shared in decision-making. This research established the feasibility of recruiting patients with metastatic breast cancer to a study of shared decision-making, but also highlights the limitations of a passive process in which patients are merely informed about the decisions they will face. In our proposed study, we advance this research in 2 ways. First, we will ask participants to play an active role in indicating their desired involvement in decisions, informational preferences, and preferences and goals for care. Second, we will provide this information to the physician at the point of care. We hypothesize that this simple but novel approach will enhance shared decision-making and the patient's experience, as per the conceptual model above.

3. Target Audience

There are two target audiences for this research: 1) Patients with metastatic breast cancer, and 2) medical oncologists and other providers treating breast cancer. We are seeking to develop and test a pragmatic tool that can help patients identify and convey their goals and preferences for care to their medical oncologist to enhance shared decision making. At this stage of the research, our goals are to demonstrate both feasibility and potential impact. We will reach the clinician audience through presentation of our work at national meetings and through scientific publication. Our team has a strong record of publication and of highlighting important patient care topics through educational sessions at national meetings and through electronic media. In

addition, we are well poised to disseminate our findings to patients. Dr. Schapira is the editor in chief of Cancer.Net, the patient portal for cancer information supported by the American Society of Clinical Oncology. She is also the section editor for the Journal of Clinical Oncology's "Art of Oncology". Dr. Dizon is highly engaged in patient communication through his blogs for the Oncologist and ASCO connection, and through twitter. We will be able to communicate directly with patients and clinicians both about the importance of individualizing care for advanced breast cancer, and about the tool that we will develop in this study.

We plan to make the IGCDG available for use by clinicians and researchers through the NCCN and ASCO portals, and in our publications related to this work, at no cost. In addition, we plan to further evaluate the IGCD in a subsequent multicenter randomized trial.

4. Project Design and Methods

Phase I: Focus Groups To Develop the Individualized Goals of Care Discussion Guide.

Starting with the experience from our prior metastatic breast cancer decision aid, the domains for discussions of individualized care proposed by ASCO, and based on our expertise and review of the literature, to address Specific Aim 1, we will develop a focus group discussion guide to solicit patient perspectives on important elements of care and communication to include in the IGCDG. Potential domains for the IGCDG are listed in Table 2. We currently conceive this guide as a brief booklet of potential issues to consider and 1 page survey of patient priorities, preferences and goals for discussion and care across domains. We will recruit patients with metastatic breast cancer from the MGH Breast Cancer Clinic to participate in one of four focus groups, involving 6 to 8 patients each. A trained focus group moderator will lead the 90-minute discussion. Among the elements for discussion will be a pilot version of the IGCDG. The focus group will be recorded and transcribed verbatim and an investigator will take field notes to guide analysis. Focus group transcripts will be analyzed and coded to identify major concepts and domains for the IGCDG. The results of the focus groups will be independently analyzed and submitted for a publication describing shared decision-making preferences among patients with metastatic breast cancer.

Table 2. Potential Individualized Goals of Care Discussion Guide Domains

1. Preferences for disease directed therapy and supportive care
2. Priorities for goals of therapy <ul style="list-style-type: none">• Tumor response• Progression free survival• Overall survival• Symptom management
3. Toxicity concerns
4. Quality of life priorities <ul style="list-style-type: none">• Pain control• Emotional distress• Fatigue• Physical function• Sexual health
5. Spirituality
6. Financial considerations and concerns
7. Decision making preferences
8. Prognostic information preferences
9. Interest in research participation
10. Preferences for discussion of end of life care
11. Preferences regarding drug administration (oral, IV, frequency of visits).

Phase II. Structured Interviews

Following completion of the focus groups we will develop a 1 page IGCDG that will assess patients treatment priorities, information preferences, and desire to discuss available elements of care and any other issues identified in Phase I of the research. We will pilot test this guide among 10 patients with metastatic breast cancer and 5 oncologists to identify issues related to comprehension and acceptability, and to be sure that we have achieved saturation for major domains of care addressed with the guide. Following this pilot study, we will develop the final version of the IGCDG.

Phase III. Evaluation of the Individualized Goals of Care Discussion Guide in Clinical Practice

Design overview: This is an interventional study involving patient self-administration of the IGCDG at the time of treatment decisions, provision of the information to the patient's oncologist prior to the next visit, and a follow-up survey to evaluate impact on patient satisfaction, communication, and concordance of care.

Intervention: To address Aims 2 and 3 of this proposal, we will recruit 80 patients with metastatic breast cancer to evaluate the feasibility and impact of the IGCDG.

1. We will recruit patients following a medical oncology clinic visit for newly diagnosed metastatic breast cancer or progression of disease, when treatment decisions are considered.
2. Patients will be provided with the IGCDG as well as an explanatory booklet (as used in our prior research). They will be asked to complete and return the IGCDG questionnaire to the study team.
3. At baseline we will also evaluate baseline distress with the NCCN distress thermometer.
4. The study team will provide the patient's responses to the IGCDG to the medical oncologist prior to the patients return visit to further discuss or start therapy.
5. We will then conduct a follow-up survey with the patient 2 months after administration of the IGCDG to evaluate the impact on patient satisfaction with care and communication, care received, and concordance between the patient's care and preferences. The survey will be mailed to patients with a return envelope and postage provided. If the survey is not received within 2 weeks of mailing, we will call the participant and administer the survey by phone. Participants will receive token \$10 incentive with the mailed survey.

This is designed to be a pragmatic trial with a simple intervention that could be easily scalable to community oncology practices if a positive impact on patient outcomes is identified.

Patient Population:

Patients will be recruited from the MGH Breast Cancer Clinic. The 12 medical oncologists specializing in breast cancer and affiliated nurse practitioners will refer patients to the study team. Study contact details will be posted in all physician work rooms and study accrual will be reviewed regularly at breast oncology team research meetings. The program coordinator will periodically send email reminders and update the breast medical oncology providers regarding study goals, eligibility, and accrual.

Eligibility: Eligible patients will be English speaking adults with breast cancer who are presenting to clinic for a discussion of treatment options regarding A) a new diagnosis of stage IV disease or B) progression of known stage IV disease. Patients considering any line of therapy will be eligible. Patients who have already started a new line of disease directed therapy will be excluded. Patients who have recently begun a new medication for symptom control alone are eligible to participate.

Outcome Measures

The primary outcome of interest will be feasibility of the IGCDG using the definition established previously by Sepucha et al of recruitment 60% or greater, less than 32% attrition

rate, and no significant increase in distress between baseline and the follow-up survey as indicated by the NCCN distress thermometer.¹³

Secondary outcomes will include patient reported satisfaction with the IGCDG and the achievement of individualized care planning as measured by the following validated measures:

1) The Satisfaction with Decision Making Scale: This is a six item validated scale designed to measure patient satisfaction with medical decision making. Participants rate their level of agreement on a 5-point scale with statements regarding medical decision-making. Higher satisfaction with medical decision making on this scale has been shown to correlate with less decisional conflict.¹⁹

2) The Decisional Conflict Scale: This is a 16-item likert scale with proven validity and reliability. Scores range from 1 to 5, with higher scores suggesting increased difficulty and conflict over decision making.²⁰

3) Modified Control Preferences Scale: This 2 question scale is used to measure a participant's desired and actual participation in decision-making using examples that involve pictures and statements. As in prior work by Sepucha et al, we have collapsed participation into 3 categories, decisions made mainly by the patient, decisions made equally, and decisions made mainly by the clinician.^{13,21}

4) Patient Satisfaction with Cancer Care: The Patient Satisfaction with Cancer Care measure is a validated 18 item tool with responses on a 5 point likert scale designed specifically to assess satisfaction among patients from diverse sociodemographic backgrounds. We have modified the scale to remove 3 questions that were not relevant for this study population.²² Total score for this scale is calculated by adding all component scores, with lower scores indicating higher satisfaction with care.

In addition, we will include 6 study specific questions that will guide further research using the IGCDG. The combined follow-up survey will include up to 50 questions and take 20 minutes to administer.

5. Evaluation Design

Analytic Plan: All data will be transcribed from paper surveys that include the tools described above and entered into REDCap, a web-based, password protected electronic database maintained by Partners Healthcare. Data entry will be double-checked for accuracy.

We will evaluate the primary hypothesis, that administration of the IGCDG in breast oncology clinic is feasible, by evaluating the recruitment rate, attrition rate, and change in distress as measured by the NCCN distress thermometer between baseline administration and the 2-month follow-up survey. Recruitment will be calculated as the number of patients who choose to participate divided by the number approached to enroll. Attrition will be calculated as the number of participants who do not complete the follow-up survey divided by the number enrolled. A recruitment rate of greater than 60%, attrition rate of less than 32% and no

significant difference between baseline and follow-up distress scores among the participants will be deemed feasible. Distress levels at baseline and at two month follow-up will be compared using paired t-tests.

We will present descriptive data reporting patient preferences for care and information, care received, patient satisfaction with care, decisional conflict, and participation in shared decision making. Evaluation of the impact of the IGCDG is an exploratory aim (Aim 3) and the effect size of the IGCDG on the validated scales described above is unknown. The effect size identified in this study will be used to guide future randomized testing of this intervention in a multicenter trial. We will evaluate sociodemographic and clinical correlates of response on the basis of breast cancer subtype, line of therapy, age, race/ethnicity, gender, educational level, and household income. Frequency distributions will be used to summarize data and we will evaluate bivariate and multivariate predictors of responses. The 5% level of significance will be used to assess predictive power of each individual term.

Sample Size Calculation: This is a single arm interventional study, and we have selected our sample size based on our prior work with breast cancer decision aids and based on the primary objective to evaluate the feasibility of administering the IGCDG.¹³ To address Aims 2 and 3, the feasibility and impact of the IGCDG, we will recruit a convenience sample of 80 patients with metastatic breast cancer from the MGH Breast Oncology Clinic. We treat over 350 patients per year with metastatic breast cancer in the MGH Breast Oncology Clinic and enrolled over 80 patients with estrogen receptor positive metastatic disease (a subset of all patients with metastatic breast cancer at GH) to therapeutic trials in 2014. Patients with any subtype of breast cancer are potentially eligible for this study; therefore we anticipate recruitment of 80 patients within 12 months.

Anticipated challenges and solutions: 1) Recruitment: From prior work we anticipate recruitment of 100 patients in a 12-month time frame. If after 3 months accrual is not consistent with this goal we will consider a) opening the study at other NCCN sites, and b) broadening eligibility to enroll patients with stage IV disease at any point in their care. 2) Differences in preferences based on line of therapy: We are anticipating that there will be differences in goals and preferences by line of therapy. We will conduct a preplanned stratified analysis of patients considering 1st line, 2nd and 3rd line, and 4th and subsequent lines of therapy.

Timeline, Deliverables and dissemination strategies: We anticipate at least one manuscript reporting prevalence and predictors of preferences and goals of care among patients with metastatic breast cancer and a second manuscript reporting the impact of the IGCDG on shared decision-making and achievement of individualized cancer care. The IGCDG will be formatted so that it can be uploaded into the patient's electronic health record. In addition, the IGCDG will be made publically available through the NCCN and through Cancer.net. It is anticipated that

this research will require 24 months and will proceed according to the detailed timeline in **Figure 2** below.

Deliverables: This research will produce 2 abstracts and 2 manuscripts. The first will describe the results of focus groups and the structured interviews with patients regarding preferences for individualized care. The second will present the results of our intervention and follow-up surveys.

Figure 2. Research Timeline

	Year 1				Year 2			
	1 st Qtr	2 nd Qtr	3 rd Qtr	4 th Qtr	1 st Qtr	2 nd Qtr	3 rd Qtr	4 th Qtr
Protocol Develop and IRB Submission								
Conduct Focus Groups								
Transcribe Data								
Qualitative Analysis								
Conduct Structured Interviews								
Analysis and presentation of initial results, 1 st paper submission.								
Development of Final Discussion Guide								
Intervention with Individualized Goals of Care Discussion Guide in Breast Cancer Clinic								
Conduct of Follow-up Survey								
Analysis								
Presentation of intervention data, manuscript writing and 2 nd paper submission								

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