JHM IRB - eForm A – Protocol

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1. Abstract

Breast cancer is the most common cancer among survivors in the US and is second only to lung cancer in contributing to cancer death among women. Most patients with breast cancer receive help from family in making complex decisions about treatment, handling logistically demanding care coordination, and managing symptoms and side effects. Although family members (as defined by each patient) play a vital role in cancer care, they are not formally recognized or assessed in care delivery, and their need for information and support is typically unmet. Lack of attention to family in care delivery is an important gap that too often leaves families without adequate information about patient health and treatments. This may prevent families and patients from engaging in open conversations, cause them unnecessary anxiety, and negatively affect the quality of cancer care and delivery.

Communication is particularly important in cancer care, as the optimal course of action is determined through longitudinal discussion of prognosis, treatments, and patient goals, preferences, and concerns. Strategies to improve communication for serious illnesses such as cancer have been developed, but typically target a specific decision, conversation, or setting, most often the inpatient hospital. There is growing agreement that communication among patients, families, and providers should be initiated early and continue throughout the disease trajectory. However, little is known about how to provide ***both*** patients ***and*** families with access to timely information about patient health and mechanisms to communicate directly with health care providers, as proposed in this study.

The goal of this study is to test a multicomponent intervention to strengthen communication and longitudinal partnerships among women with breast cancer and their family members. Recent work by the study team has demonstrated the feasibility, acceptability, and benefit of intervention components which will be combined into a single model of care. Our preliminary studies indicate that clarifying patient and family expectations regarding the role of family and providing family with timely and comprehensive information about patient health (as desired by the patient) leads to more effective family involvement, more frequent patient-familyprovider interactions, more patient-centered communication, and greater preparedness to manage care.

This study will evaluate the feasibility of delivering a multicomponent communication intervention in the outpatient setting comprising: 1.) a patient-family agenda-setting checklist completed immediately before a regularly scheduled medical oncology visit with a participating medical oncologist, 2.) facilitated registration for the patient portal (for patient *and* family member, as desired by the patient), and 3.) education (as relevant) on access to doctor's electronic visit notes. We will enroll up to 70 patients who are in active treatment for breast cancer. We will enroll up to 14 medical oncologists and 70 patient-family members. We will focus on patients who typically attend medical oncology visits with a family member or trusted friend as they are already present and involved in communication. We will compare study outcomes of patients and family members who are in the intervention group and receive the multicomponent communication intervention (n=35 dyads) with patients and family members who are in the control group and receive usual medical oncology care (n=35 dyads). We are asking whether intervention group patients and families have higher quality communication with medical oncology providers, a better understanding of patient's cancer, are more confident in managing patient's care and are more satisfied with cancer care than control group patients and families after 3 months, and 9 months of follow-up. We will also examine symptoms of anxiety.

2. Objectives

We will conduct a two-group randomized pilot trial of a multicomponent communication intervention to strengthen communication and longitudinal partnerships among up to 70 patients being actively treated for

breast cancer (early or advanced stage) and their family "caregiver" in an academic medical oncology clinic at Johns Hopkins. The intervention arm comprises: 1.) a patient-family agenda-setting checklist to be completed immediately before a routinely scheduled medical oncology visit, 2.) facilitated registration for the provider-sponsored patient portal (for the patient *and* family member, as desired by the patient), and 3.) education (as relevant) on access to doctor's electronic visit notes. The control arm comprises usual medical oncology care. We will compare the intervention arm and a control arm of usual care with respect to patient and family-reported outcomes at 3 months and 9 months. We expect that patients and families who receive the intervention will engage in more frequent, higher quality communication with each other and medical oncology providers, and that 3 months and 9 months after enrollment patients and families will have a greater understanding of the patient's illness, higher self-efficacy with respect to their ability to manage the patient's care, and that families will be more highly satisfied with the quality of cancer care as compared with participants who receive a control arm of usual care. We will secondarily assess the effects of the intervention on patient and family symptoms of anxiety at 3 months and 9 months.

3. Background: This study will evaluate the feasibility of delivering a multicomponent communication intervention in the outpatient setting comprising: 1.) a patient-family agenda-setting checklist completed immediately before a regularly scheduled medical oncology visit, 2.) facilitated registration for the patient portal (for patient *and* family member, as desired by the patient), and 3.) education (as relevant) on access to doctor's electronic visit notes. In the text that follows we summarize available evidence regarding each of the three intervention components.

3a. Agenda Setting: The study team has designed and established proof-of-concept for a patient-family agenda-setting checklist for older primary care patients. The checklist aims to elicit and align patient and family perspectives regarding issues to discuss with the doctor, and to stimulate discussion about the role of the family member in the visit. The premise for the checklist is that family members are typically motivated to support patients during medical visits, but that they often lack knowledge of the patient's health concerns and visit goals as well as preferences for communication assistance from their family. The checklist involves two activities that are completed by a patient and their family member in the waiting room before a scheduled appointment. The **first** activity involves patients clarifying the help they would like from their family member during the upcoming visit. The **second** activity involves patients and families completing a checklist of common health issues. The instructions ask patient and family to separately identify their concerns for each issue, and decide together what to discuss with the doctor. In a proof of concept randomized study of 32 older patient-family dyads in a primary care setting, the checklist was highly endorsed by patients, families, and doctors. Analyses of audiotaped medical visits indicated that communication was significantly more patient-centered among dyads who completed the checklist (n=17) as compared with those who received usual care (n=15), and did not receive the checklist.[29] In post-visit surveys, doctors were 34% more likely to agree that intervention versus usual care families "helped them provide good care to the patient" (94.1% vs. 60.0%; p=0.02). Intervention patients were more likely than usual care patients to agree that because their family was present they "better understood their doctor's advice and explanations" (82.4% vs. 46.7%; p=0.03). *As the checklist was developed for older primary care patients, we have refined the content to attend to the specific needs of patients with breast cancer (see attachment D1 Checklist).*

3b. Shared Access to the Patient Portal. Health information technology presents new opportunities to rationalize and better support family in delivery processes and communication, as we propose in this study. Through the provider-sponsored patient portal, patients may access information about their health and treatments, exchange electronic messages with providers, and perform health care tasks such as refilling prescriptions and scheduling appointments.[99,100] Many electronic health record vendors, including EPIC MyChart as implemented at Johns Hopkins, afford patients the ability to authorize specific family member to "share access" to their patient portal account using their own identity credentials. Thus, shared access is a strategy that may be used to clarify and respect patient preferences for including family in their care by facilitating access to the patient's electronic health information and a mechanism to communicate directly with providers.[43] Although little empirical evidence exists regarding the effects of shared access, work by our team indicates that shared access is acceptable to patients and families, and that family members who have

been granted their own identity credentials to access the patient's portal account commonly perform health management activities electronically and engage in secure messaging with providers.[31]

3c. Access to Provider's Visit Notes (OpenNotes). Many electronic health records (including EPIC MyChart) have the capacity to allow providers to share their visit notes (OpenNotes) through the patient portal so that patients may read, reflect, and discuss these notes with family or other medical professionals after the visit. In a quasi-experimental pilot study involving more than 100 providers and 18,000 patients at 3 medical institutions, OpenNotes was found to improve patient-provider communication and increase patient engagement in their care.[99] More than 10 million patients across the country are estimated to have access to their provider's visit notes. At some organizations, OpenNotes is standard practice among primary and specialty providers, including medical oncology. Preliminary studies provide evidence of the feasibility and acceptability of sharing doctor's electronic visit notes with *both* patients *and* families through shared access to the patient portal. After 12 months of having access to OpenNotes, the majority of patients and families read doctor's visit notes, reported clinically relevant benefits, and wanted to continue to have access to OpenNotes in the future. Patients and families reported that joint access led to more productive discussions about the patient's care, better agreement about the patients' treatment plan, and improved their ability to formulate questions for the doctor. Families were more likely to access and use the patient portal and reported better communication with doctors, while patients were more confident in their ability to manage clinically important elements of their care.[30] OpenNotes has now been piloted through three stages of physician adoption at Johns Hopkins, including oncology providers, with high acceptability among providers and no reported adverse outcomes. The Johns Hopkins Clinical Practice Association's Board of Governors voted in early June to move toward system-wide standard access to OpenNotes across most lines of business, including ambulatory oncology effective January 1 2018.

4. Study Procedures

a. **Study design, including the sequence and timing of study procedures** This is a two-group randomized pilot trial of a multi-component communication intervention to more effectively and purposefully engage family members in cancer care. We will enroll up to 70 patients with breast cancer and the family member they identify as most typically attending medical oncology visits with them, for a total of 70 patients and 70 family members. After providing informed consent, each patient-family member dyad will be randomized to the intervention arm or to a control arm of usual care.

We will invite practicing breast cancer medical oncologists at Johns Hopkins to participate in the pilot trial. We expect to enroll up to 14 medical oncologists in this study. As noted in Section 3.c., JHMI is moving toward system-wide use of OpenNotes effective January 1 2018. Participating providers will be invited to turn Open Notes "on" for patients under their care prior to January 2018, and the study team will record the decision made by each provider. Patient/family participants of providers who do not elect to turn "on" OpenNotes prior to January 2018 will receive agenda-setting checklist and facilitated access to MyChart but will not have education about or access to OpenNotes. We will mail letters to established patients of participating doctors who have a scheduled appointment two to four weeks prior to their visit to explain the study, invite them to participate, and invite family members to call us for more information. Patients who do not "opt-out" by mailing back a card to the study team will be contacted by telephone to further describe the trial, answer questions, and complete a screening call. Patients who are eligible and interested in participating will be asked to speak with their family member about the study in cases where the family member has not yet initiated contact with the study team. After the patient has discussed the study with their family member, the patient will ask the family member to call the study team, or given the family member's permission, the patient can call the study team with the family member's contact information. Both the patient and family must consent to participate for the dyad to be enrolled. Patients may identify more than one family member to participate in the intervention processes, but will be asked to identify the person who most typically attends medical oncology visits to participate in this study.

Eligible patient-family dyads will meet a member of the research team in the clinic waiting room 30 minutes in advance of the patient's scheduled appointment. Each dyad will be randomized to the intervention (investigational arm) or the control arm in a 1:1 ratio using stratified, blocked randomization by doctor with alternating block sizes. Participants assigned to the intervention will meet with the

research staff to receive a copy of the patient-family agenda-setting checklist, a clipboard and pen, and instructions describing how to complete the checklist, which they will complete together in the clinic waiting room. Participants who are randomized to the control arm will receive care as usual. Medical oncologists, patients, and families will complete post-visit surveys immediately after the visit. After the visit, patients in the intervention group will meet briefly with research staff to facilitate registration for the EPIC patient portal MyChart, including informational handouts about OpenNotes (as relevant) and MyChart. After the visit, participants in both groups will be offered general breast cancer resource handouts that are available to all breast cancer patients at the Johns Hopkins SKCCC. Patients and families will complete baseline, 3-month and 9-month follow-up telephone interviews by a research assistant who is blind to assignment status. Telephone interviews will be audio recorded for quality control purposes. Patients who decline audio recording will not be excluded from the study. Medical oncologists will complete an exit interview upon completion of patient recruitment.

b. **Study duration and number of study visits required of research participants.**
Medical oncologist participation in the study will occur throughout the duration of recruitment. Immediately after providing informed consent, medical oncologists will be asked to complete a one-page survey of socio-demographic characteristics, training, and experiences in the care of persons with breast cancer. Medical oncologists will subsequently complete a brief one-page survey immediately after the visit of participating patients, and a one-page exit survey upon completion of patient recruitment for the study. Patient and family participation in this study will transpire over no longer than 26 weeks, and will involve a screening telephone call to determine eligibility, one in-person encounter at the time of a regularly scheduled physician office visit, and two follow-up telephone calls of approximately 30 minutes duration at 1 weeks (range: 0-3 weeks), 3 months (range: 10-20 weeks) and 9 months (range: 3555 weeks). The in-person encounter is not expected to require more than 45 minutes time beyond the regularly scheduled physician visit. Participants will provide written consent to participate in the study (10 minutes) complete a pre-visit communication tool (10 minutes), and complete a brief post-visit survey (10-15 minutes). The expected duration of the study from the perspective of patient and family participants will proceed over the course of about 16 weeks (but may transpire over a longer period for some participants who are unavailable to complete the follow-up calls at the scheduled 16 week interview); the duration of the study for medical oncologist participants will proceed throughout the course of patient/companion enrollment. The overall study duration is expected to be about 12 months.

c. **Blinding, including justification for blinding or not blinding the trial, if applicable.** This is a single blind, two group randomized trial where the study team will be blinded to group assignment. Outcome measures will be assessed by interviewers masked to treatment assignment and without interventionist contact. Patient/family dyads will not be blinded to group assignment.

d. **Justification of why participants will not receive routine care or will have current therapy stopped.**
Not applicable. This is a study of a behavioral intervention to improve communication.

e. **Justification for inclusion of a placebo or non-treatment group.**
We will undertake a single blind, two group randomized trial to estimate the potential effects of the intervention on outcomes for patients with breast cancer and their family caregivers. The strategies that are being proposed are low cost, already exist, have been designed to minimize impact on clinical workflow, and are readily transferrable to other provider systems. The study will examine the effects of the intervention protocol on communication outcomes, as well as provide evidence of its acceptability in mainstream medical oncology practice that would support broader diffusion. For these reasons, the control group protocol will comprise usual care which is in this case existing clinical practice.

f. **Definition of treatment failure or participant removal criteria.**
Not applicable. This is a study of a behavioral intervention to improve communication.

g. **Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.**
Not applicable/relevant. Participation in the study is voluntary. This is a study of a behavioral intervention to improve communication.

5. Inclusion/Exclusion Criteria

Participants of this study will include three groups: (1) medical oncology patients, (2) family members (broadly defined), and (3) medical oncologists. Inclusion/exclusion criteria for each of these groups are as follows:

A. Medical oncology patients. Inclusion criteria: established patient of participating medical oncologist greater than 18 years of age, have a diagnosis of early stage or advanced breast cancer, are receiving active systemic therapy (in the form of IV adjuvant systemic therapy if early stage), are English speaking, able to provide informed consent themselves, and identify a family member who they would like to include in their care. Exclusion criteria: younger than 18 years, pregnant, not being treated for breast cancer, do not attend medical visits with family member or unpaid friend or unwilling for their family member or unpaid friend to be contacted.

B. Family. Inclusion criteria: Family member (spouse, adult child, parent, adult sibling) or unpaid friend who accompanies patient to medical visits. Exclusion criteria: paid non-family member.

C. Medical oncologist. Inclusion criteria: practicing medical oncologist at a participating clinic who provides care to patients with breast cancer.

6. Drugs/ Substances/ Devices

a. **The rationale for choosing the drug and dose or for choosing the device to be used.**
Not applicable

b. **Justification and safety information if FDA approved drugs will be administered for nonFDA approved indications or if doses or routes of administration or participant populations are changed.**
Not applicable

c. **Justification and safety information if non-FDA approved drugs without an IND will be administered.**
Not applicable

7. Study Statistics

a. **Primary outcome variable.**
We will assess a comprehensive set of process measures and outcomes that correspond to the efficacy and implementation potential of the intervention. We will assess clinical efficacy of the intervention by examining communication processes and outcomes. Implementation measures will be assessed from practice-based metrics relating to infrastructure, resources, and clinician and staff time and effort for intervention start-up and delivery. Clinical efficacy measures have been selected based on the following criteria: 1.) known reliability and validity, 2.) sensitivity to change, 3.) clinical relevance to quality of life, 4.) reflection of objective indicators of the domains we seek to impact, and 5.) psychometric properties of instruments balanced with practical considerations relating to respondent burden. Efficacy measures will be derived from survey responses provided by patients, families, primary care providers, health and service utilization from the patient's electronic medical record, and date and time-stamped records of MyChart interactions. Our four primary outcomes will be assessed at 3 months and 9 months on the basis of patient and family caregiver surveys. These outcomes include: patient and family illness understanding, family satisfaction with cancer care, patient and family self-efficacy in managing patient care, and symptoms of anxiety.

Patient and family illness understanding will be measured from four items that assess knowledge that is considered to be essential to making informed treatment decisions in serious illness, including: 1.) understanding of illness, 2.) knowledge of disease status, 3.) awareness of disease state, and 4.) expectation of duration of life (months, years, or decades).(1) Each item will be coded 1 or 0 to reflect the presence or absence of each element of illness understanding. We will use scoring that is adapted to reflect patient stage of disease. These four items will be

summed to construct a summary score (range: 0-4) that reflects illness understanding. This measure has been found to be responsive to communication with oncologists.(1)

Family satisfaction with cancer care will be measured with the short-form 10-item version of the FAMCARE, a validated instrument that was developed to assess family perspective on cancer care.(2, 3) Respondents are asked to rate 10 items that relate to emotional support, personalization of care, support of decision-making, accessibility, and coordination. Response categories include "very satisfied" (2 points), "satisfied" (1 point), or "not satisfied" (0 points), and the 10-items may be summed to yield a total score (range: 0 to 20) with higher scores reflecting greater satisfaction. The internal reliability coefficient of the 10-item FAMCARE is 0.94 across varied age, gender, education, ethnic, and relationship groups. The FAMCARE is responsive to change and has been widely used to support findings of the benefit of interventions to improve the quality of cancer care.

Self-efficacy refers to the extent that patients(4, 5) and families(6-9) are equipped to manage their experiences with care and enact the patient's care plan. Following measurement conventions(5) questions will begin with the phrase "how certain are you right now that you can ..." and respondents will be asked to place themselves on a 10-point scale ranging from 1 (not at all certain) to 10 (very certain). We will ask patients and families to report their self-efficacy for engaging in tasks related to managing patient care that include managing health information and communicating with patients' health care providers. The scale is scored by calculating the mean of all items; higher scores reflect greater confidence. Prior work finds self-efficacy is inversely associated with anxiety and stress, positively associated with behavioral outcomes including physical and mental health, and responsive to change.(10)

Anxiety will be measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale, a well-established 7-item instrument that asks about symptoms of anxiety in a two-week recall period from 0 ("not at all") to 3 ("nearly every day").

b. Secondary outcome variables.
Secondary outcomes involve the following process measures: patient and doctor reports of family effectiveness in visit communication, patient and family satisfaction with the doctor, and reported quality of communication.

c. Statistical plan including sample size justification and interim data analysis. In this two-group randomized pilot trial, we will compare the effects of the intervention in the investigational arm on communication and outcomes for up to 70 patients (35 per group) with (a) advanced (stage IV) or (b) early (stage I-III) breast cancer (if receiving IV adjuvant systemic therapy) and their family member. As a Stage 1 developmental study of a complex behavioral intervention, the sample size is based on pragmatic considerations related to available resources, project duration, and study objectives. Analyses will be performed in SAS statistical software, with each patient-family dyad as the unit of analysis. We will rely on established cut-points and approaches to constructing outcome measures, as well as measures of patient and family attributes that will serve as control variables (sociodemographic characteristics, health status, aspects of the patient and family relationship, family role appraisal). We will stratify the study sample based on AJCC TNM staging (stage I-III or stage IV). We will primarily evaluate the consistency, direction, and magnitude of differences in study outcomes by undertaking analyses that are stratified by treatment group (intervention versus control arm) and for subgroups of patients by cancer stage (early or advanced stage). We will evaluate recruitment, retention, and the timeliness and completeness of collected data, as well as intervention acceptability (utility, burden, helpfulness) using questions from our formative work. We recognize the need for caution in interpreting pilot trial results. Therefore, inferential statistical testing is not planned in analyses of the pilot trial. However, we will evaluate recruitment and dropout rate as well as effect size of primary and secondary

outcomes to help inform the design and sample size calculations for a larger trial. **d. Early stopping rules.** None.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency. The risks of participating in this study involve inconvenience, personal time, the potential for becoming upset, psychologically stressed or fatigued, and potential loss of confidentiality. There may be some inconvenience to patients and families associated with arriving to a scheduled oncology visit earlier than otherwise necessary and staying later to complete a survey. There are risks associated with a breach of confidentiality. Subjects may experience discomfort discussing health or worries. Family members who screen positive for depressive symptoms (on the basis of PHQ-2 scores >=3 at follow-up) or anxiety (on the basis of Generalized Anxiety Disorder scores of>= 10) will receive oral notification of this finding and will be asked if they would like to be mailed an educational brochure about depression or anxiety (as appropriate) and options for treatment. Companions will be encouraged to follow-up with their health care provider.

b. Steps taken to minimize the risks.

Participants will be instructed that participation in the study is completely voluntary and that they may decide to stop at any time. They will be informed of the length and nature of participation. Protection of participant information and audio recordings of telephone interviews will be a key responsibility of study staff. Information from participants will be reported anonymously. All participant surveys, consent forms, and other records containing participant identifiers will be kept in a locked file cabinet. Data will be password protected; only study personnel will have access to identifying information. Redacted (deidentified) versions of the data collection sheets will be used for coding and analysis. No personal identifiers will be included in the analytic database.

c. Plan for reporting unanticipated problems or study deviations.

This is a study of communication in breast cancer care. The study will evaluate a multicomponent intervention for patients with breast cancer and their family caregivers – each of the intervention components has been successfully tested and found to be acceptable. Adverse events that result from this study are unlikely. Unanticipated problems or adverse events will be reported promptly to the IRB by the PI. Study deviations will be documented and monitored in keeping with Good Clinical Practice in Social and Behavioral Research.

d. Legal risks such as the risks that would be associated with breach of confidentiality. Participant privacy will be ensured by asking sensitive questions by telephone so that others who are present at the time of the survey are unable to hear the questions that are being asked. Research staff will assist patient participants in completing study surveys and questions that are asked in person will not involve sensitive topics. Pre-consultation consent and post-visit surveys for patients and family participants will typically be completed in a private room proximal to the clinic waiting room for additional privacy. Information collected from patients and families will not be shared with one another. e. **Financial risks to the participants**. None

9. Benefits

a. Description of the probable benefits for the participant and for society.

Benefits accrued by individual study participants will be minimal for the control group. Benefits accrued by treatment group participants may include greater clarity regarding patient treatment goals, family roles in medical care, and more effective communication with the medical oncologist. We hypothesize that the intervention might improve satisfaction with medical care, as well as outcomes that pertain to information recall and treatment adherence. Information to be gained may improve care processes and benefit people in the future.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

All patient and family participants will receive a $20 gift card at the conclusion of the post-visit survey and they will have the potential to receive $20 gift cards if they complete baseline, 3-month and 9-month follow-up telephone calls ($80 in total) that will be mailed to their place of residence. There are no consequences for participants who do not complete both phases of the research.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Not applicable/relevant. This is a study of a behavioral intervention to improve communication and does not involve the administration of a drug or treatments.