PROTOCOL TITLE:

Individualizing Surveillance Mammography for Older Breast Cancer Survivors

PRINCIPAL INVESTIGATOR:

Rachel A Freedman, MD, MPH
Medical Oncology
617-632-3800
Rachel_freedman@dfci.harvard.edu

VERSION NUMBER:

Version 3

NCT03865654

DATE:

07/01/2020

Table of Contents

1.0 Objectives

In this multistep study, we will build on our prior efforts[1] to develop consensus on surveillance mammography and follow-up for breast cancer survivors who are age ≥75 by further developing expert-panel recommendations, examining clinician and patient attitudes towards these recommendations, and testing a strategy for communication of expert recommendations on mammography cessation through direct engagement of specialists, primary care clinicians (PCs), and patients. Specifically, we will work to reduce overscreening of older patients through the following aims:

1.1 Develop a communication tool that summarizes recommendations for clinicians and patients for surveillance mammography and follow-up care for breast cancer survivors age ≥75. This will build off the work of a multidisciplinary expert panel which will come together for a meeting to develop draft recommendations (OHRS exempt protocol #18-526).

- Interview up to 30 patients through telephone-based patient interviews and focus groups and interview oncologists and primary care providers (PCs) through 4-6 focus groups to learn their perceptions and thoughts about when to stop surveillance mammography, how to thoughtfully incorporate life expectancy into decision-making, how to communicate the benefits/risks of surveillance mammography, obtain feedback on the communication tool, and to explore optimal strategies for integrated and unified care between disciplines
- Perform cognitive testing of the communication tool in up to 10 Dana-Farber breast cancer patients and further refine it for Aim 1.2

1.2 Test the surveillance mammography communication tool with older breast cancer survivors and their oncology clinicians

- In a pre-post intervention study, examine the effect of the communication tool among 45 breast cancer survivors age ≥75 years (with low risk of in-breast recurrences) seen by oncologists on women's intentions for and knowledge of the pros and cons of surveillance mammography.

We hypothesize that our communication tool will lead to fewer women intending to receive surveillance mammography in the next year and women having more knowledge of the benefits and risks of surveillance mammography.

2.0 Background

2.1 Increasing burden of breast cancer in older women. Women age ≥75 are among the fastest growing segments of the U.S. population.[2] Meanwhile, breast cancer is the most common non-cutaneous cancer in U.S. women[3] and breast cancer risk increases with age.[4] With an anticipated increase in the number of older breast cancer patients over time[5] and the improving longevity of older breast cancer survivors, more women are living many years after a breast cancer diagnosis and most are dying of non-breast cancer causes[6,7] without more risk for in-breast events than screening populations.[1,8]

2.2 Research and guideline gaps. Despite the growing number of older breast cancer survivors, there are limited data to guide their optimal follow-up care, particularly in the setting of advanced comorbidity.[9] Older women with breast cancer are under-represented in nearly every large, prospective clinical trial to date,[10] with exception of rare therapeutic trials dedicated to older patients.[11,12] Although recommendations for screening mammography in aging populations have recently acknowledged the limitations in applying uniform guidelines to all women,[13,14] many clinicians struggle with discussions around cessation of mammography[15-18] and mammography rates have remained stable over time, regardless of age.[19,20] Similarly and likely as a result of a lack of prospective data, guidelines for older breast cancer survivors regarding surveillance mammography and follow-up care lack consistency or specific attention to the needs of older patients. There are no prospective studies which specifically examine the benefits of surveillance mammography in older patients, let alone those with limited life expectancy, and the use of indefinite mammography in this growing patient population has been questioned by recent National Comprehensive Cancer Network (NCCN) Older Adult Guidelines[21] and in a literature review by our study team.[1] These NCCN guidelines[21] suggest that decisions about mammography in older breast cancer survivors be based on patient preference and life expectancy, with a recommendation to stop surveillance mammography if life expectancy is ≤5 years. However, how to discuss mammography cessation and how to optimally approach follow-up care are not addressed in these guidelines. Further, these NCCN recommendations have not been endorsed in the more widely cited survivorship guidelines from the American Cancer Society and the American Society of Clinical Oncology (ASCO),[22,23] which still recommend annual mammography in all breast cancer survivors with residual breasts, regardless of life expectancy.

2.3 Benefits and Harms of Surveillance Mammography in Older Women. The goal of surveillance mammography is to detect in-breast recurrences and/or new breast cancers that impact survival. Overall, approximately 4-5% of all breast cancer survivors will develop an ipsilateral or contralateral breast cancer in the 5-10 years after initial diagnosis (which is similar to the risk for breast cancer in aging, screening populations),[1,8] but the risk for these events decreases with increasing age, favorable disease biology, and with the use of hormonal therapy in the setting of hormone receptor-positive disease.[24-31]

Among screening populations, it is estimated to take ≥10 years before one breast cancer death is prevented among 1000 women aged 50-74 undergoing mammographic screening.[32] Although the lag-time and degree of benefit from surveillance mammography has not been quantified for older breast cancer survivors, it is likely similar or perhaps even less beneficial, given the lower risk of in-breast events with increasing age,[28,29,33] and the lower-risk tumors that most older patients develop.[34,35] Although some studies suggest ongoing benefit of mammography with increasing age,[36,37] they are limited by the inherent biases of retrospective studies, where healthy, older breast cancer survivors are more likely to undergo surveillance than sicker ones and are thus more likely to survive longer. In a single institution study[38] examining mammography use in women aged ≥80 with a history of early-stage breast cancer during a mean of 50 months, 429 women underwent 1,466 mammograms that detected 13 non-palpable cancers (0.9%), while 9 additional cancers were detected by physical exam. Although the study did not assess long-term breast cancer or survival outcomes, these findings raise questions about the added value of surveillance

mammography in older women. Unlike the potential benefits, the harms of surveillance mammography are immediate and include over-diagnosis, false positive results, unnecessary biopsies, and associated pain and anxiety.[38-47] Further, with comorbidity present in many older patients and very low risk of breast cancer death,[7,34,48] over-diagnosis and the ensuing overtreatment are even more significant risks for older versus younger patients.[39-43]

2.4 Summary. Better strategies are needed for breast cancer surveillance in older survivors, a growing population of women for whom prospective evidence and expert consensus is lacking. Strategies are needed to individualize follow-up care to avoid medical interventions from which patients are unlikely to benefit (or from which they will not benefit for many years) and are likely to inflict immediate harm. We anticipate that our framework for follow-up care for older breast cancer survivors will significantly improve survivorship care, decrease overuse of unnecessary testing, and improve quality of life, with an enhanced understanding of the pros/cons of mammography in the context of having a better understanding of one's life expectancy. Our project will work on how to deliver this information in compassionate, thoughtful, and informative way. Further, we anticipate that clinicians will feel more informed, empowered, and supported to make recommendations for their older breast cancer survivors if they are endorsed by expert consensus. We recognize that conversations on cessation of mammography with breast cancer survivors may be particularly challenging because of their personal experiences with cancer. However, if women understand their individualized risks and benefits, they will at least have the opportunity to make informed decisions rather than have the false security that routine mammograms may indefinitely improve their longevity. Figure 1 below shows the general framework for our approach and some of the considerations in developing guidelines and patient materials.

2.5 Innovation of this Project. How to optimally address surveillance mammography in older patients has never been specifically addressed. We will develop a novel and much needed approach to optimize surveillance mammography use and follow-up care for older women, provide a foundation for discussion about cessation of mammography when appropriate, and better coordinate primary and specialty care. The key innovations of this proposal include: (1) This study focuses on follow-up care for older breast cancer survivors, and will develop expert-based recommendations on mammography use and follow-up care for this population. (2) This is the first study to directly engage patients and clinicians in follow-up care of older breast cancer survivors which will foster consensus and optimize care integration. It will directly engage patients and national experts from complementary specialties around decision-making for mammography and communication of recommended approaches for when mammography cessation should occur. (3) This is the first study to evaluate how to optimally and sensitively incorporate life expectancy into the decision-making process for surveillance mammography in older breast cancer survivors. (4) This study will develop an easy-to-use novel communication tool describing the pros/cons of surveillance mammography for patients and clinicians that we anticipate will lead to more informed decisions on mammography use and less over-utilization.

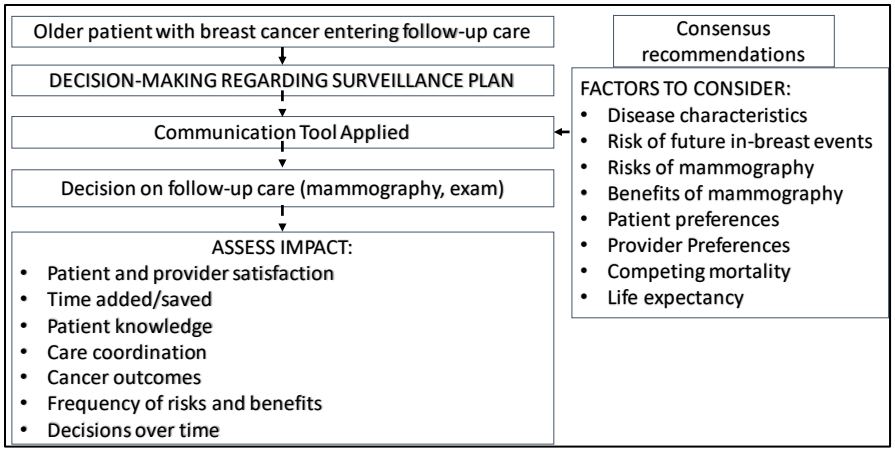
2.6 Preliminary Studies. Our study team has extensive experience in examination of practice patterns for older cancer patients, utilization of mammography, and validation of life expectancy measures. Dr. Freedman is a medical oncologist who has expertise in the care of

older patients with breast cancer[10,49-52] and in addressing the value of surveillance mammography in older breast cancer survivors when life expectancy is limited.[1,53] Dr. Schonberg is a PC physician, and is an expert in optimizing use of mammography screening in older women without a breast cancer history. She has developed widely cited models that predict life expectancy for community-dwelling adults.[6,13,34,44,45,54-66] In addition, she has significant experience recruiting older women to participate in qualitative and survey-based studies. Dr. Keating is a PC physician and health services researcher with wide-ranging expertise in examining patterns of care and outcomes for patients with cancer as well as interpretation of mammography guidelines and patterns of mammography use.[1,19,53,67-70] This proposal builds nicely on our collective, prior work and combined expertise.

Literature review: We recently completed a systematic review of the available literature on surveillance mammography in older populations,[1] concluding that discussions about surveillance and cessation of surveillance should include estimating life expectancy, risk for future in-breast recurrences or new cancers, the anticipated risks/benefits of testing, and preferences. In our review, we suggested specific approaches for follow-up care for older patients and provided talking points for discussing mammography cessation with patients. In Aim 1, we will engage an expert panel of clinician and patient stakeholders to further refine our literature review and recommendations for surveillance mammography and follow-up care.

Utilization of surveillance mammography by life expectancy. We examined use of surveillance mammography by life expectancy (using the Schonberg Index)[55,56,61,71] among 1,040 breast cancer survivors interviewed as part of the National Health Interview Survey (NHIS).[53] We found that nearly 80% of survivors age ≥65 reported having mammography in the last year, similar to other reports of surveillance mammography use.[68] Use of mammography decreased with worsening life expectancy, but 57% of those with estimated ≤5-year life expectancy reported having mammography in the last year. Conversely, 14.1% of those with life expectancy >10 years did not report mammography. These results provide important preliminary work for our proposal and highlight the pressing need to optimize and tailor follow-up care for older patients. We will work to provide information on life expectancy in a compassionate and constructive way.

Figure 1. General framework for impacting decision-making on mammography



2.7 Study Impact. The long-term goals of this work are to optimize mammography use (and decrease overscreening) for older breast cancer survivors, a group in critical need of evidence-based, unified approaches to their follow-up care. Older patients are not adequately represented in any screening or surveillance clinical trials, and the proposed study will address significant knowledge gaps through expert consensus and prospective data collection. In addition, the study will provide a framework for discussions on how/when to stop surveillance mammography in the context of life expectancy framing and how to prioritize follow-up strategies, with the goal to enhance communication between patients and clinicians as well as between PCs and specialists. This study will provide preliminary data for a prospective, randomized study evaluating the use of our expert recommendations among patients and PC and oncology clinicians in a larger, geographically diverse setting, with the ultimate goal to further assess impact, standardize practice, improve coordination of care, and disseminate our novel and urgently needed intervention.

3.0 Inclusion and Exclusion Criteria – the eligibility differ by protocol aim/step and whether it is a patient or provider component of the study. Please see specifics for each aim below.

3.1 Aim 1.1*:* Clinician focus groups. We will recruit a broad, national sample of academic and community clinicians for focus groups. Two groups will include DFCI oncology clinicians, two groups will include Brigham and Women's (BWH) PCs and geriatricians, and two groups will be held virtually via web-ex and will include a broad, national inclusion of physicians.

3.2 Aim 1.1: Patient phone interviews and focus groups. Patients will be eligible if they meet the following criteria:

- Female gender, given that screening guidelines do not exist for men
- Receiving part or all of their care at DFCI
- Ages 75-79 (approximately 10 patients)
- Age ≥80 (approximately 10 patients)

- Age 60-74 (approximately 10 patients, given that some advocacy groups have patients in this age range who will contribute)
- History of stage 0-II breast cancer
- We will try to include patients with ≥1 Charlson comorbidity present[72], defined as one of the following (though this is not mandatory):
    - Diabetes
    - Liver disease
    - History of or other active malignancy other than non-melanoma skin cancers
    - HIV or AIDS
    - Chronic kidney disease
    - History of myocardial infarction and/or congestive heart failure
    - Chronic lung disease (emphysema/chronic bronchitis/chronic obstructive pulmonary disease [COPD], interstitial lung disease)
    - Peripheral vascular disease
    - Cerebrovascular disease (history of TIA or stroke)
    - Dementia
    - Hemiplegia/paralysis
    - Connective tissue disorder
- Underwent treatment of this cancer
- Completed all active breast cancer therapy >3 months prior to enrollment (i.e. any chemotherapy, trastuzumab, radiation). Ongoing hormonal therapy or enrollment in survivorship clinical trials (aspirin, exercise, etc) is allowed.
- English-speaking and reading (for this initial work)

3.3 Aim 1.1. Cognitive testing of the communication tool. The criteria for this are intentionally more flexible than in other aims, as we are simply working to initially test the tool and its readability and understandability. Patients will be eligible to cognitively test the tool if they meet the following criteria:

- Female gender
- Previous diagnosis of breast cancer
- Age ≥75
- Receive some/all care at Dana-Farber Cancer Institute
- English speaking-reading

3.4 Aim 1.2. Pilot testing the communication tool in clinic. These criteria have been updated to assure as much generalizability as possible in study design with ease of screening patients.

- Previous diagnosis of stage 0-II breast cancer
- Receive some/all care at Dana-Farber Cancer Institute and affiliated satellite sites (Boston's main campus, South Shore Hospital, or St. Elizabeth's Medical Center)
- Completed any active breast cancer therapy >/=12 months prior to enrollment (i.e. any chemotherapy, trastuzumab, radiation). Ongoing hormonal therapy or enrollment in survivorship clinical trials (aspirin, exercise, etc) is allowed.
- Age ≥75
- Had breast-conserving surgery to treat this cancer
- Provider does not opt out of the patient's enrollment via email notification
- English speaking and reading

For all study aims, we will exclude patients who:

- are unable to consent
- who do not read and write English (for this initial pilot)

4.0 Study-Wide Number of Subjects*

4.1 For Aim 1.1, we will recruit up to 30 patients and up to 48 providers for the qualitative focus group/interview component, and 5-10 patients for the cognitive interviewing of the tool. For Aim 1.2, we will recruit 45 patients and the providers taking care of those patients.

5.0 Study-Wide Recruitment Methods

5.1 Procedures for interview and focus group (and cognitive testing) recruitment- **Patients** (Aim 1.1). Due to due potential challenges in gathering multiple focus groups of older patients who may have issues with mobility and transportation, the potential sensitivity of topics to be discussed (i.e. life expectancy), and because we would like to obtain in-depth, individualized opinions, we will conduct a mixture of one-on-one telephone interviews (30-60 minutes each) by trained DFCI staff. For this aim, we will recruit approximately 10 patients ages 60-74, 10 patients ages 75-79 and 10 patients age ≥80 with a history of stage 0-II breast cancer (thus at low-average risk for in-breast recurrences) and ideally ≥1 Charlson comorbidity[72] (targeting those with shorter life expectancy) who underwent breast surgery and have completed any active breast cancer therapy (i.e. any chemotherapy, radiation >3 months ago) and who are either entering or

are already in the follow-up phase of cancer care. This is an ideal time to recruit patients as they are transitioning to less frequent follow-up and mammography plans are being made and even scheduled. We will purposively recruit a diverse sample based on race/ethnicity and socioeconomic status, including patient advocacy groups in Boston and beyond. In order to identify this focused population of patients, we will use our patient advocacy network (Patient and Family Advisory Council [PFAC] at DFCI, breast cancer advocates in New England, Pink and Black in Boston). We will also reach out to our oncology providers at DFCI for any patients who come to mind that fit our eligibility and the clinical research coordinator (CRC) will also scan DFCI breast oncology clinician schedules for patients who meet these criteria. Appendix G has a flyer/email content for advertising the project. The CRC or study PI will ask each patient's oncologist and/or NP/PA for permission to contact their patient, with providers having the option to opt out if they feel that patient is not appropriate to be approached. We will then mail or email potential patients an invitation to the telephone interview or focus group and a number to call to opt out. The CRC will call patients who do not opt out 2 weeks later to assess their interest in participating. Dr. Freedman, the study PI, will also reach out to patient advocacy groups with an introductory email (Appendix G) to the study to assess for interest though the patient advocates working on this project (on the expert panel). To accommodate scheduling, we will offer flexible interview and focus group times. Once an interview or focus group is scheduled, we will mail or email the patient the communication tool (Draft tool in Appendix B and will be further iterated based on feedback and Aims that precede its use) before the interview with a sensitive introduction to the tool (to minimize any stress associated with receiving it in advance), explaining that the tool will be used during the interview. All patient phone interviews and focus groups will be led by a trained qualitative researcher from the DFCI Survey and Data Management Core ('Core'), Dr. Freedman, or a research assistant trained by the Core. The Core is a very experienced and well-established team that readily organizes and facilitates focus groups, phone interviews, and performs qualitative data analyses. They have a long track record of successful and effective work in this area and their expertise will also be utilized to adapt the communication tool at completion of this qualitative aim. For patients, a waiver of written consent will be requested and verbal consent will be obtained. Patients interviewed by phone only will undergo a brief cognitive function (Blessed Orientation-Memory-Concentration test [BOMC])[73] and capacity evaluation (Appendix A) and will proceed with the interview if they score <10 points on the BOMC and answer ≥4 capacity questions correctly. Upon interview completion, patients will be sent a gift card for $50. Snacks and parking will be provided for any focus group that requires travel.

5.2 Procedures for recruiting focus groups - **Providers** (Aim 1.1)**.** Dr. Freedman will email her colleagues at Brigham and Women's and DFCI to recruit them for a 60- minute focus group discussion, aimed to occur at a regular weekly/monthly meeting for a particular PCP or medical oncology practice. We will provide beverages and snacks for the meeting. We will visit the practice at BWH or DFCI to conduct the focus groups and any virtual focus groups will take place by phone via webex. Dr. Freedman will also reach out to her broad network of physicians outside of DFCI to recruit oncologists from around the country for the virtual focus group (which will occur via

webex/phone). Dr. Freedman (who is experienced in leading clinician-based focus groups) will lead all clinician focus groups. All discussions will be recorded and professionally transcribed. At the start of the clinician focus groups, verbal consent from each participant will be obtained and providers will be provided a written copy of the verbal consent in person or via email. We do not intend to register providers in Oncpro.

5.3 Procedures for recruiting **providers and patients** for the tool intervention (Aim 1.2)
We will then test the communication tool at DFCI, DFCI at South Shore Hospital , and DFCI at St. Elizabeth's breast medical oncology practices. Dr. Freedman will recruit 10-12 medical oncology colleagues who each agree to test the communication tool in ≤5 of their older patients over a 4-6-week period.

Before the visit. To identify mammography-eligible patients with low-to-average risk for in-breast recurrences, the dedicated CRC will scan participating clinician schedules daily over a 4-6-week period at DFCI/St. E's/South Shore Hospital for breast cancer patients with stage 0-II breast cancer who have completed any chemotherapy, surgery, and/or radiation ≥12 months prior and who are aged ≥75 and who had breast-conserving surgery. If a patient meets criteria for possible enrollment, the CRC will email the clinician (Appendix H) to confirm that mammography would typically be discussed at this visit and to ask permission to offer the study to the patient.

If the clinician agrees, the CRC will send information and what will be used for verbal consent (Appendix F) to the patient with an opt-out number and email followed by a phone call (to those who do not opt out) to explain the study's purpose and obtain verbal consent for participation. The CRC will share a blank communication tool to the patient with the 'pre'survey to be filled out before the visit (clinic visit can be virtual or in person), and notify the clinician when a patient enrolls. This can be sent to the patient by mail or email in advance of their virtual/in person clinic visit. If the patient prefers the materials to be given to them in person, the CRC will arrange to meet the patient 30 minutes before their scheduled clinic visit. If the clinic visit is virtual, the CRC can call the patient anytime ahead of the provider visit to review the materials. The study team will be utilizing standard clinical workflows and may involve virtual substitution of office visits such as the use of Zoom Video Communications application. Although in-person office visits are preferred on site, virtual visits via Zoom conferences, which are HIPPA compliant and protected, can provide a safer and efficient alternative for patients.

Visit Day. The day before the clinic visit (virtual or in-person), the CRC will call or email the patient to remind them to fill out the 'pre'-survey and send it to the study team. We will also remind the clinician that the patient is coming/being seen virtually and will email or hand-deliver a blank communication tool before the visit so they are aware it may be discussed. The CRC may meet the patient in the waiting room or communicate by phone/email before their appointment to collect the 'pre' survey (if not already received via email/mail) A copy of the verbal consent can also be given in person or via email/mail if not already done ahead of this visit. Clinicians will be reminded to incorporate the communication tool in a way that feels comfortable to them to facilitate routine practice but without specific instructions. After the visit, the CRC

will ask the patient to complete the paper 'post' surveys in person, by mail, or by email within 7 days of the appointment, concluding the study for that patient. To understand how providers feel about the communication tool, the experience using it, and the comfort with it as a guide for discussions, the clinician will be asked to complete one brief survey per patient enrolled (no provider consent planned but a short introduction to the survey will be provided-see Appendix D), after all of their participating patients have completed their visits. Each patient will be registered to document their participation by DFCI study staff and will receive a $40 gift card for their participation and clinicians will receive a $40 gift card after the all surveys for participating patients have been completed. All data will be entered by the CRC into the secure, REDCap.

5.4 Registration Procedures

The eligibility checklist (Aim 1.2 only) will be filled out and submitted by the DFCI Study Coordinator for registration within 30 days of the patient participant providing verbal consent at the time of the survey. The other qualitative aims will not require study registration. Registered study participants from Aim 1.2 will be entered on study centrally at DFCI by the Study Coordinator after providing verbal consent. All registrations must occur within 30 days of the survey date.

The Study Coordinator will follow DF/HCC policy (REGIST-101) and register eligible participants on the protocol using the Clinical Trials Management System (CTMS) OnCore. Following registration, the Study Coordinator will use the participant study number for identification of all patients.

Participant information, including receipt of verbal consent, will be tracked in a password-protected, secure, on-line, web-based system. We will also secure patient contact information on this portal in addition to a tracking sheets on the number of phone calls made and any contact made with potential participants. Anyone failing screening or declining enrollment will be logged internally (not centrally by ODQ) and confidentially by study staff with the reason for failure or decline.

6.0 Multi-Site Research

All patient research will be conducted on site at DFCI, DFCI at South Shore Hospital, and DFCI at St. Elizabeth's, or by phone. Provider focus groups will take place at DFCI, Brigham and Women's, or virtually/by phone. Although Dr. Schonberg is a collaborator on this study, no research will take place at BIDMC.

7.0 Study Timelines

7.1 Duration of the study:

- The patient and providers are each involved for one time-point.
- We anticipate that all aims will be completed by December 31, 2020.

8.0 Study Endpoints, Statistical Plan, and Sample Size Considerations

8.1 Aim 1.1 (provider focus groups and patient interviews). For each discussion, the transcribed data will be analyzed according to standard comprehensive qualitative analysis methods,[74-76] which consists of a two-stage coding process: level 1 structural coding and level 2 thematic coding. All analyses will be conducting by the DFCI Core. Structural coding will follow the structure of the focus group/interview guide, in which every question receives a code that is applied to the appropriate text. Thematic coding will be based on themes that arise from the structural coding and will be applied in a second pass analysis. Thematic coding allows for a grounded theoretical approach to analysis. These methods will be enhanced by ethnographic data management software (N'Vivo). This state-of-the-art program uses an organizer indexing system for coding, categorizing, searching, retrieving, and attaching analytical memos, creating a conceptual relationship network in textual data that has been taxonomically coded. Quotes that exemplify themes will also be extracted. Once the thematic analysis is complete, Dr. Freedman will lead the preparation of the comprehensive thematic analysis report. Answers to the discrete items at the start of discussions will be tabulated.

8.2 Sample Size Considerations (Aim 1.1). In qualitative research, sampling is recommended until thematic saturation is reached and this typically occurs after including 30 participants or ≥4 focus groups with 6-8 participants per group.[77,78] Therefore, we will recruit 30 patients and ≥24 clinicians (≥4 focus groups). We will begin with 1 DFCI oncology, 1 BWH PC, and 1 oncology virtual focus groups. However, if we do not achieve thematic saturation, we will recruit 3 more groups to reach thematic saturation. The DFCI 'Core' will provide the analytic expertise for the qualitative data analyses an thematic summaries.

8.3 Summary Aim 1.1 At the conclusion of Aim 1.1, we will summarize findings in the thematic analysis report, incorporate suggestions, and revise the recommended guidelines and communication tool to reflect the issues raised by our qualitative analysis.

8.4 Outcomes and Analyses for Aim 1.2. The outcomes of interest are shown in Table 2 below and have been adapted from Dr. Schonberg's prior survey study testing a decision aid for screening mammography for older women.[66] We will focus on a primary outcome of intentions for mammography and will examine how various factors (race, health literacy, numeracy, anxiety, life expectancy) impact intentions. We use the sign rank and exact McNemar's testing to compare the 'pre' vs. 'post' results for the continuous score for intention and proportion who indicate 'yes', respectively. To account for clustering by clinician, we will utilize random effects models if parametric assumptions hold, or alternatively using bootstrap resampling techniques to compute 95% confidence intervals for the change in intention. We anticipate a low number of missed surveys because of the CRC follow-up planned by phone, mail, or email if necessary. If a patient is missed for her 'pre' test survey, we will replace her to ensure enrollment of 45 with 'pre' and 'post' surveys. We will compare characteristics of those with missing surveys and missing questions to those with complete surveys to assess for any notable differences.

Table 2. Outcomes of Interest for Aim 1.2	
Outcome(s) of Interest	**Outcome definitions, planned analyses**

***Primary Outcomes**:* Patients: Frequency of change in intentions for mammography in the next year	15 point validated scale to assess 'pre' vs 'post' survey responses where scores 1-5 = yes to having mammography, 6-10 = unsure, 11-15 = no for mammography. We will use a continuous outcome of 1-15.[66,79]
Patients & Clinicians: Acceptability & Feasibility	Length, clarity; tabulate responses[80]; 75% report the tool is useful
Secondary Outcomes:	
Clinicians: satisfaction, time added/removed	Tabulate responses, prepare descriptive analyses
Patients: preferred decision-making role	'Pre' survey: Examine preferences for active, shared, passive decision-making [81]
Patients: Decisional conflict	'Pre' vs. 'Post' survey: 16 item scale, Calculate total and sub-scale responses. Scores range 1-100, lower scores indicating higher quality decision-making[82,83]
Patients: Knowledge about mammography	Number of correct (10) knowledge questions on 'pre' vs. 'post' surveys. [66,84,85]
Patients: intentions vs. actual decisions for mammography	'Post': Examine whether patient intentions for mammography agree with whether mammography is scheduled or not (using chart abstraction)
Patients & Clinicians: Agreement in intentions	'Post' for patients and providers: degree of agreement on scores 1-15
Patients & Clinicians: life expectancy wishes	'post' for patients and providers: tabulate responses for willingness to discuss

8.5 Primary Outcomes for Aim 1.2: We will focus on the primary outcomes of intentions for mammography and acceptability/ feasibility. We use the sign rank and exact McNemar's testing to compare the 'pre' vs. 'post' results for the score for intention and proportion who indicate 'yes', respectively. To account for clustering by clinician, we will utilize random effects models if parametric assumptions hold, or alternatively using bootstrap resampling techniques to compute 95% confidence intervals for the change in intention. We anticipate a low number of missed surveys because of the CRC follow-up planned by phone if necessary. If a patient is missed for her 'pre' test survey, we will replace her to ensure enrollment of 45 with 'pre' and 'post' surveys. We will compare characteristics of those with missing surveys and missing questions to those with complete surveys to assess for any notable differences. For feasibility, we will declare the tool feasible if ≥75% of patients and physicians report usefulness of the tool.

At the conclusion of this am, we will have preliminary data on how the communication tool impacted care, its feasibility, and about multiple exploratory, secondary endpoints. If we have difficulties with recruitment of patients or clinicians for this project, we will contact additional clinicians and patients to reach our desired accrual goals. Given the high volume of breast cancer patients and clinicians in our system, we anticipate that accrual will occur with ease.

9.0 Procedures Involved

9.1 Procedures for provider focus groups/ patient interviews. Dr. Freedman (who is experienced in leading clinician-based focus groups) will lead all

clinician focus groups. All patient focus group and phone interviews will be led by a trained qualitative researcher, Dr. Freedman, or a trained CRC from the DFCI Survey and Data Management Core ('Core'). All discussions will be recorded and professionally transcribed. The Core is a very experienced and well-established team that readily organizes and facilitates focus groups and performs qualitative data analyses. They have a long track record of successful and effective work in this area and their expertise will also be utilized to adapt the communication tool at completion of this qualitative aim. At the start of the clinician focus groups, verbal consent from each participant will be obtained. For patients (who are interviewed by phone), a waiver of written consent will be requested and verbal consent will be obtained. Patients will undergo a brief cognitive function (Blessed Orientation-Memory-Concentration test [BOMC])[73] and capacity evaluation (Appendix A) and will proceed with the interview if they score <10 points on the BOMC and answer ≥4 capacity questions correctly.

9.2 Discussion Content. Clinicians will be asked to comment on (a) the panel recommendations from DFCI OHRS exempt protocol *18-526*, (b) how they currently talk with patients about surveillance and whether and how they might incorporate risk or life expectancy in conversations, (c) the draft communication tool (including exploring whether electronic tools appeal to clinicians), and (d) ideal communication strategies for PCs and oncologists to coordinate follow-up care. Patients will first be asked a short series of discrete questions which will be followed by discussion of topics focused on the patient experience and comfort in hearing information about life expectancy, whether they have ever discussed cessation of mammography, and their preferences for receiving the information presented on the communication tool (mailed to them ahead of time). We will also inquire about whether electronic versions of the tool might appeal to patients and clinicians or whether they prefer paper versions. Draft scripts for clinician and patient focus group and phone interviews are provided in Appendix C. These will be amended as appropriate before initiation of this component of the study.

9.3 Survey Instruments. The draft 'pre'/'post' patient surveys and a post-visit clinician survey (all three draft surveys) are in Appendix D. Surveys contain closed-ended questions (except for solicited comments at the end) and are adapted from Dr. Schonberg's prior, validated surveys conducted before and after the use of a decision aid for screening mammography in older women.[66] We will ask about demographics, health literacy and numeracy ('pre' patient), mammography intentions ('pre' and 'post' patient), mammography knowledge ('pre' and 'post' patient), anxiety about recurrence ('pre' patient), acceptability of the communication tool ('pre' patient and clinician), comfort level and interest in discussions about life expectancy ('pre' and 'post' patient and clinician), decisional

conflict ('pre' and 'post' patient), preferences for a paper/online tool ('post' patient and clinician), and time added to appointments ('post' clinician).

10.0 Data and Specimen Banking – there is no specimen banking as part of this protocol

11.0 Data Management and Confidentiality

11.1 The data analysis plan and procedures are described in Section 8.

11.2 Data Management Plan: We will use a secure, password-protected REDCap database to capture information for the intervention part of this study (Aim 1.2). Data elements to be included in the centralized study data repository will include baseline demographics, comorbidity, medications, date of diagnosis, disease characteristics, and survey information. All survey data will be specifically entered and maintained securely in password protected systems.

All study components will be run from Dana-Farber Cancer Institute. Study staff will computerize the data from the patient questionnaires in this observational study. In addition, study staff will computerize medical information on each of the study participants into the centralized, secure database. For patients invited into the study but who choose not to participate, there will be no retention of patient identifiers. Study staff will record the age, race, date of diagnosis and surgery for all patients who decline participation to allow for demographic comparison of participants and nonparticipants. All original copies of data will be kept in file cabinet locked in study staff offices. Computerized databases will be password protected. Data will be collected, coded, and managed by study staff only. The name and address file will be stored on a separate computer with password protection from the data files to protect the identity of respondents. Data and software will be backed up on a nightly basis as per our institutional norm.

11.3 Data Security. All data files will be stored on password-protected, secure servers. Access to the data will be limited to members of the research team. All patient names and contact information will be kept strictly confidential in a password-protected file stored separately at each study site, separate from the survey and medical record data. The survey/medical record data files will contain the CASE ID only, a unique study identification number, and only that number will be included in analytic databases shared by team members. Patient contact information will be stored in a separate password-protected database, for use by the study team only. This list will be used only for tracking potential participants, specifically for documenting attempts to reach patients. A separate password-protected file containing the crosswalk between the patient name and unique ID will be maintained

separately. Upon enrolling a patient, the study staff will use the unique study ID and will enter survey responses directly into the database from the computer interface. All answers to survey questions will be linked with the case ID only and no identifying information.

11.4 The study protocol will strictly adhere to all HIPAA and Dana-Farber regulations. Confidentiality of the subjects will be maintained. The study team will be utilizing standard clinical workflows and may involve virtual substitution of office visits such as the use of Zoom Video Communications application. Although in-person office visits are preferred on site, virtual visits via Zoom conferences, which are HIPPA compliant and protected, can provide a safer and efficient alternative for patients. No data will be linked to a particular name or personal identifiers. The individual results will not be disclosed. The de-identified dataset will be provided to the investigators for analysis. The composite results will be analyzed and summarized for presentation and publication. We will minimize risks regarding confidentiality by strictly following the practices described above.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This is not a therapeutic intervention study. If a patient notes distress or physical concerns, we will immediately notify her treatment team.

13.0 Withdrawal of Subjects

Patients may withdraw at any time if they wish to end their involvement of the study.

14.0 Risks to Subjects

We anticipate that this study will entail minimal physical and psychological risk on the part of the subjects. In the letter of introduction and in verbal consent, patients will be advised to contact their physicians or a study representative with any questions or concerns. Individual patient results will be kept confidential. As with any collection of individually identifiable health information, there is a risk of breach of confidentiality. However, adequate safeguards will be in place to ensure that these risks are minimized, including the following measures described below.

15.0 Potential Benefits to Subjects

There are no direct benefits to study participants, but the study team will show our appreciation for study enrollment with gift cards as described. We hope that patients will be satisfied with having participated in and contributed to a study where there is great need for prospective data.

16.0 Vulnerable Populations

We aim to include older patients, a vulnerable patient group who is in urgent need of more prospective evidence to guide their care. We also aim to have a diverse sample by socioeconomic and race/ethnicity factors.

17.0 Community-Based Participatory Research

For optimal generalizability, we are working with DFCI, DFCI at South Shore Hospital, DFCI at St. Elizabeth's,and Brigham and Womens Hospital primary care physicians and geriatricians on this project. We will also have a virtual component for providers so that we get input from providers outside of Boston. We aim to be very inclusive of providers caring for patients in our study including primary care providers and oncologists.

18.0 Sharing of Results with Subjects

We will not directly share results with patients but they will be widely available once published and disseminated..

19.0 Setting

See sections above- this study will take place at DFCI main campus/St. Elizabeth's/South Shore Hospital, Brigham and Women's Hospital,, and on the phone/virtually, depending on the study component.

20.0 Resources Available

Dr. Freedman (along with her collaborators) is well poised to execute the proposed research focusing on older breast cancer patients because of her training, expertise, and experiences as a clinician-researcher focused in this area of study. The work planned in this study logically builds on her prior work and on the prior work of her study collaborators. Dr. Freedman will have all of the recourses available to her at DFCI for the duration of this study, including statistical, research, and nursing support in addition to grants support and the support of the collaborating institutions participating in this work (DFCI satellites and affiliates).

21.0 Prior Approvals – N/A

22.0 Recruitment Methods – See Section 5

23.0 Local Number of Subjects- See Section 4

24.0 Provisions to Protect the Privacy Interests of Subjects

Study staff will obtain permission from the primary medical oncologist before contacting potential subjects. Only study staff who have completed institutional training and are familiar with the protocol will contact patients for an informed verbal consent. Only staff who have completed training can access Epic or other patient medical record databases. Study staff may conduct a limited review of a patient's medical record in order to confirm eligibility; they may continue to access their records.

25.0 Compensation for Research-Related Injury

This study involves Minimal Risk to subjects. Therefore, there is no compensation available to subjects in the event of research-related injury.

26.0 Economic Burden to Subjects

We plan to approach patients when they are already at their provider visits and will call them if time point is missed in person. We do not anticipate any additional costs to patients while participating in this study. Participants are given gift cards for their time.

27.0 Consent Process

All participating patients (interviews) and providers (focus groups) will provide informed verbal informed consent at the start of their interview/focus group (Appendix E). All participating patients for Aim 1.2 (pilot intervention) will provide verbal informed consent (Appendix F) before any study procedures are performed. Patients and providers will receive a copy of their verbal consent. Ethical standards for human subjects will be strictly followed. We will not obtain written consent as it is practically prohibitive for this short survey-based intervention. The consent script will include all required information commonly included on signed consent forms. Moreover, the participant will explicitly be asked if he or she consents to participate prior to commencing the survey.

All investigators and research assistants will have undergone full training in Human Subjects Protection Certification. In addition, all research team members will undergo formal training regarding the research procedures, including the informed consent process. The purpose, procedures, duration, risks, and alternatives of the study will be explained to potential subjects. It will be emphasized in the verbal consent that participation is completely voluntary and that patients may choose to withdraw at any time without adverse consequence to their medical care or loss of benefits to which they are otherwise entitled. Patients will be informed of the research nature of this project. Extent of confidentiality provided and procedures for protecting confidentiality will be discussed in specifics, such as the need to review medical records to confirm cancer treatments. Informed verbal consent will be contingent upon the patient's full awareness and affirmation of these ethical standards. Once all questions have been addressed and the individual indicates she would like to participate, informed consent will be obtained. Individuals who are unable to provide informed consent will be excluded from participation in the study.

28.0 Process to Document Consent in Writing

28.1 Because this research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, we waive the requirement to obtain written documentation of consent as noted above.

29.0 Drugs or Devices -N/A

REFERENCES

1. Freedman RA, Keating NL, Partridge AH, et al: Surveillance Mammography in Older Patients With Breast Cancer-Can We Ever Stop?: A Review. JAMA Oncol, 2016
2. United States Census Bureau. www.census.gov/. Accessed March 8, 2017.
3. Amercian Cancer Society. Cancer Facts & Figures 2017. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/cancer-facts-and-figures-2017.pdf. Accessed March 8, 2017.
4. American Cancer Society. Breast Cancer Facts and Figures 2015-2016. http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-046381.pdf. Accessed November 18, 2016.
5. Smith BD, Smith GL, Hurria A, et al: Future of cancer incidence in the United States: burdens upon an aging, changing nation. J Clin Oncol 27:2758-65, 2009
6. Schonberg MA, Marcantonio ER, Ngo L, et al: Causes of death and relative survival of older women after a breast cancer diagnosis. J Clin Oncol 29:1570-7, 2011
7. Yancik R, Wesley MN, Ries LA, et al: Effect of age and comorbidity in postmenopausal breast cancer patients aged 55 years and older. Jama 285:885-92, 2001
8. American Cancer Society. Breast Cancer Facts and Figures 2015-2016. http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-046381.pdf
9. Jacobsen PB, Rowland JH, Paskett ED, et al: Identification of Key Gaps in Cancer Survivorship Research: Findings From the American Society of Clinical Oncology Survey. J Oncol Pract 12:190-3, 2016
10. Freedman RA, Foster JC, Seisler DK, et al: Accrual of Older Patients With Breast Cancer to Alliance Systemic Therapy Trials Over Time: Protocol A151527. J Clin Oncol 35:421-431, 2017
11. Muss HB, Berry DA, Cirrincione CT, et al: Adjuvant chemotherapy in older women with early-stage breast cancer. N Engl J Med 360:2055-65, 2009
12. Hughes KS, Schnaper LA, Berry D, et al: Lumpectomy plus tamoxifen with or without irradiation in women 70 years of age or older with early breast cancer. N Engl J Med 351:971-7, 2004
13. Schonberg MA: Decision-Making Regarding Mammography Screening for Older Women. J Am Geriatr Soc, 2016
14. Oeffinger KC, Fontham ET, Etzioni R, et al: Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. JAMA 314:1599-614, 2015
15. Schonberg MA, Ramanan RA, McCarthy EP, et al: Decision making and counseling around mammography screening for women aged 80 or older. J Gen Intern Med 21:979-85, 2006
16. Torke AM, Schwartz PH, Holtz LR, et al: Older adults and forgoing cancer screening: "I think it would be strange". JAMA Intern Med 173:526-31, 2013
17. Hoffman RM, Elmore JG, Pignone MP, et al: Knowledge and values for cancer screening decisions: Results from a national survey. Patient Educ Couns 99:624-30, 2016
18. Fairfield KM, Gerstein BS, Levin CA, et al: Decisions about medication use and cancer screening across age groups in the United States. Patient Educ Couns 98:338-43, 2015

19. Pace LE, He Y, Keating NL: Trends in mammography screening rates after publication of the 2009 US Preventive Services Task Force recommendations. Cancer 119:2518-23, 2013

20. Breen N, Gentleman JF, Schiller JS: Update on mammography trends: comparisons of rates in 2000, 2005, and 2008. Cancer 117:2209-18, 2011

21. National Comprehensive Care Network (NCCN) Guidelines: Older Adult Oncology http://www.nccn.org/professionals/physician_gls/pdf/senior.pdf. Assessed April 1, 2016. .

22. Runowicz CD, Leach CR, Henry NL, et al: American Cancer Society/American Society of Clinical Oncology Breast Cancer Survivorship Care Guideline. J Clin Oncol 34:611-35, 2016

23. Runowicz CD, Leach CR, Henry NL, et al: American Cancer Society/American Society of Clinical Oncology Breast Cancer Survivorship Care Guideline. CA Cancer J Clin 66:43-73, 2016

24. Nguyen PL, Taghian AG, Katz MS, et al: Breast cancer subtype approximated by estrogen receptor, progesterone receptor, and HER-2 is associated with local and distant recurrence after breast-conserving therapy. J Clin Oncol 26:2373-8, 2008

25. Liu FF, Shi W, Done SJ, et al: Identification of a Low-Risk Luminal A Breast Cancer Cohort That May Not Benefit From Breast Radiotherapy. J Clin Oncol 33:2035-40, 2015

26. Arvold ND, Taghian AG, Niemierko A, et al: Age, breast cancer subtype approximation, and local recurrence after breast-conserving therapy. J Clin Oncol 29:3885-91, 2011

27. Kunkler IH, Williams LJ, Jack WJ, et al: Breast-conserving surgery with or without irradiation in women aged 65 years or older with early breast cancer (PRIME II): a randomised controlled trial. Lancet Oncol 16:266-73, 2015

28. Chen Y, Thompson W, Semenciw R, et al: Epidemiology of contralateral breast cancer. Cancer Epidemiol Biomarkers Prev 8:855-61, 1999

29. Nichols HB, Berrington de Gonzalez A, Lacey JV, Jr., et al: Declining incidence of contralateral breast cancer in the United States from 1975 to 2006. J Clin Oncol 29:1564-9, 2011

30. Rasmussen CB, Kjaer SK, Ejlertsen B, et al: Incidence of metachronous contralateral breast cancer in Denmark 1978-2009. Int J Epidemiol 43:1855-64, 2014

31. Cuzick J, Sestak I, Baum M, et al: Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 10-year analysis of the ATAC trial. Lancet Oncol 11:1135-41, 2010

32. Lee SJ, Boscardin WJ, Stijacic-Cenzer I, et al: Time lag to benefit after screening for breast and colorectal cancer: meta-analysis of survival data from the United States, Sweden, United Kingdom, and Denmark. BMJ 346:e8441, 2013

33. Early Breast Cancer Trialists' Collaborative G, Darby S, McGale P, et al: Effect of radiotherapy after breast-conserving surgery on 10-year recurrence and 15-year breast cancer death: meta-analysis of individual patient data for 10,801 women in 17 randomised trials. Lancet 378:1707-16, 2011

34. Schonberg MA, Marcantonio ER, Li D, et al: Breast cancer among the oldest old: tumor characteristics, treatment choices, and survival. J Clin Oncol 28:2038-45, 2010

35. Howlader N, Altekruse SF, Li CI, et al: US incidence of breast cancer subtypes defined by joint hormone receptor and HER2 status. J Natl Cancer Inst 106, 2014

36. Lash TL, Fox MP, Buist DS, et al: Mammography surveillance and mortality in older breast cancer survivors. J Clin Oncol 25:3001-6, 2007

37. Buist DS, Bosco JL, Silliman RA, et al: Long-term surveillance mammography and mortality in older women with a history of early stage invasive breast cancer. Breast Cancer Res Treat 142:153-63, 2013

38. Massimino KP, Jochelson MS, Burgan IE, et al: How Beneficial is Follow-Up Mammography in Elderly Breast Cancer Survivors? Ann Surg Oncol, 2016

39. Hubbard RA, Kerlikowske K, Flowers CI, et al: Cumulative probability of false-positive recall or biopsy recommendation after 10 years of screening mammography: a cohort study. Ann Intern Med 155:481-92, 2011

40. Braithwaite D, Zhu W, Hubbard RA, et al: Screening outcomes in older US women undergoing multiple mammograms in community practice: does interval, age, or comorbidity score affect tumor characteristics or false positive rates? J Natl Cancer Inst 105:334-41, 2013

41. Marmot MG, Altman DG, Cameron DA, et al: The benefits and harms of breast cancer screening: an independent review. Br J Cancer 108:2205-40, 2013

42. Harding C, Pompei F, Burmistrov D, et al: Breast Cancer Screening, Incidence, and Mortality Across US Counties. JAMA Intern Med 175:1483-9, 2015

43. Welch HG, Schwartz L, Woloshin S: Over-diagnosed. Making People Sick in the Pursuit of Health. , Beacon Press, 2012

44. Walter LC, Schonberg MA: Screening mammography in older women: a review. JAMA 311:1336-47, 2014

45. Schonberg MA, Silliman RA, Ngo LH, et al: Older women's experience with a benign breast biopsy-a mixed methods study. J Gen Intern Med 29:1631-40, 2014

46. Houssami N, Abraham LA, Miglioretti DL, et al: Accuracy and outcomes of screening mammography in women with a personal history of early-stage breast cancer. JAMA 305:790-9, 2011

47. Sinclair N, Littenberg B, Geller B, et al: Accuracy of screening mammography in older women. AJR Am J Roentgenol 197:1268-73, 2011

48. Satariano WA, Ragland DR: The effect of comorbidity on 3-year survival of women with primary breast cancer. Ann Intern Med 120:104-10, 1994

49. Freedman RA, Vaz-Luis I, Barry WT, et al: Patterns of chemotherapy, toxicity, and short-term outcomes for older women receiving adjuvant trastuzumab-based therapy. Breast Cancer Res Treat 145:491-501, 2014

50. Freedman RA, Muss HB: Managing metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer in the older patient. J Geriatr Oncol 5:2-7, 2014

51. Vaz-Luis I, Keating NL, Lin NU, et al: Duration and toxicity of adjuvant trastuzumab in older patients with early-stage breast cancer: a population-based study. J Clin Oncol 32:927-34, 2014

52. Freedman RA, Pitcher B, Keating NL, et al: Cognitive function in older women with breast cancer treated with standard chemotherapy and capecitabine on Cancer and Leukemia Group B 49907. Breast Cancer Res Treat 139:607-16, 2013

53. Freedman RA, Keating NL, Pace LE, et al: Use of Surveillance Mammography among Older Breast Cancer Survivors by Life Expectancy. J Clin Oncol, in press, 2017.

54. Schonberg MA, Silliman RA, Marcantonio ER: Weighing the benefits and burdens of mammography screening among women age 80 years or older. J Clin Oncol 27:1774-80, 2009

55. Schonberg MA, Breslau ES, McCarthy EP: Targeting of mammography screening according to life expectancy in women aged 75 and older. J Am Geriatr Soc 61:388-95, 2013

56. Schonberg MA, Li V, Marcantonio ER, et al: Predicting Mortality up to 14 Years among Community-Dwelling Adults Aged 65 and Older, in press. J Am Geriatr Soc, 2016

57. Schonberg MA, Birdwell RL, Bychkovsky BL, et al: Older women's experience with breast cancer treatment decisions. Breast Cancer Res Treat 145:211-23, 2014

58. Schonberg MA, Breslau ES: Mammography screening for women aged 70 and older: at a crossroads. J Am Geriatr Soc 63:170-2, 2015

59. Schonberg MA, McCarthy EP: Mammography screening among women age 80 years and older: consider the risks. J Clin Oncol 27:640-1; author reply 641-2, 2009

60. Breslau ES, Gorin SS, Edwards HM, et al: An Individualized Approach to Cancer Screening Decisions in Older Adults: A Multilevel Framework. J Gen Intern Med 31:539-47, 2016

61. Schonberg MA, Davis RB, McCarthy EP, et al: Index to predict 5-year mortality of community-dwelling adults aged 65 and older using data from the National Health Interview Survey. J Gen Intern Med 24:1115-22, 2009

62. Schonberg MA, McCarthy EP, York M, et al: Factors influencing elderly women's mammography screening decisions: implications for counseling. BMC Geriatr 7:26, 2007

63. Schonberg MA, Davis RB, McCarthy EP, et al: External validation of an index to predict up to 9-year mortality of community-dwelling adults aged 65 and older. J Am Geriatr Soc 59:1444-51, 2011

64. Schonberg MA, Kistler CE, Nekhlyudov L, et al: Evaluation of a Mammography Screening Decision Aid for Women Aged 75 and Older: Protocol for a Cluster-randomized Controlled Trial. J Clin Trials 4:191, 2014

65. Schonberg MA, Smith AK: Discussing Long-term Prognosis in Primary Care: Hard but Necessary. JAMA Intern Med 176:678-80, 2016

66. Schonberg MA, Hamel MB, Davis RB, et al: Development and evaluation of a decision aid on mammography screening for women 75 years and older. JAMA Intern Med 174:417-24, 2014

67. Pace LE, Keating NL: Risk and benefits of screening mammography--reply. JAMA 312:649-50, 2014

68. Keating NL, Landrum MB, Guadagnoli E, et al: Factors related to underuse of surveillance mammography among breast cancer survivors. J Clin Oncol 24:85-94, 2006

69. Keating NL, Pace LE: New Guidelines for Breast Cancer Screening in US Women. JAMA 314:1569-71, 2015

70. Pace LE, Keating NL: A systematic assessment of benefits and risks to guide breast cancer screening decisions. JAMA 311:1327-35, 2014

71. Schonberg MA, Breslau ES, Hamel MB, et al: Colon cancer screening in U.S. adults aged 65 and older according to life expectancy and age. J Am Geriatr Soc 63:750-6, 2015

72. Charlson ME, Pompei P, Ales KL, et al: A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 40:373-83, 1987

73. Katzman R, Brown T, Fuld P, et al: Validation of a short Orientation-Memory-Concentration Test of cognitive impairment. Am J Psychiatry 140:734-9, 1983

74. Pope C, Ziebland S, Mays N: Qualitative research in health care. Analysing qualitative data. BMJ 320:114-6, 2000

75. Richie JP, Spencer L. Qualitative Data Analysis for Applied Policy Research in The Qualitative Researchers Companion. Huberman, A.M and M.B. Miles eds. London: Sage Publications. 2002.

76. Creswell. J.W. 2013 Qualitative Inquiry & Research Design: Choosing among Five Approached. 3rd edition. Sage Publications.

77. Krueger RA & Casey MA (2000) Focus Groups: A Practical Guide for Applied Research, 3rd edn. Sage Publications Inc., Thousand Oaks, CA.

78. Morgan DL (1998) Focus Group Kit Volume 1: Focus Group Guidebook. Sage Publications Inc., Thousand Oaks, CA.

79. O'Connor, A.M. User Manual-Measures of Decision/Choice Predisposition. Ottawa: Ottawa Hospital Research Institute. 1996:5. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_ChoicePredisposition_Decision.pdf.

80. O'Connor, A.M. User Manual- Accectability. Ottawa: Ottawa Hospital Research Institute; copyright 1996:5. https://decisionaid.ohri.ca/docs/develop/Tools/Acceptability_osteoporosis.pdf.

81. Degner LF, Kristjanson LJ, Bowman D, et al: Information needs and decisional preferences in women with breast cancer. JAMA 277:1485-92, 1997

82. O'Connor AM: Validation of a decisional conflict scale. Med Decis Making 15:25-30, 1995

83. O'connor, A.M. User Manual- Decisional Conflict Scale. https://decisionaid.ohri.ca/docs/develop/Tools/DCS_English.pdf.

84. Mathieu E, Barratt A, Davey HM, et al: Informed choice in mammography screening: a randomized trial of a decision aid for 70-year-old women. Arch Intern Med 167:2039-46, 2007

85. van Agt H, Fracheboud J, van der Steen A, et al: Do women make an informed choice about participating in breast cancer screening? A survey among women invited for a first mammography screening examination. Patient Educ Couns 89:353-9, 2012

APPENDIX A
Blessed Orientation-Memory Concentration Test

Cognition: Orientation-Memory-Concentration Test[73]

IV) Cognition: Orientation-Memory-Concentration Test

	Patient's response	Maximum errors	Score	Weight	Final Score
1. What year is it now? [without looking at a calendar]	☐☐☐☐	1	☐	x 4 =	☐
2. What month is it now? [without looking at a calendar]	☐☐	1	☐	x 3 =	☐
Memory phrase Repeat this phrase after me: 'John Brown, 42 Market Street, Chicago .'					
3. About what time is it?[within 1 hour - without looking at your watch]	☐☐:☐☐	1	☐	x 3 =	☐
4. Count backwards from 20 to 1.		2	☐	x 2 =	☐
5. Say the months in reverse order.		2	☐	x 2 =	☐
6. Repeat the memory phrase.		5	☐	x 2 =	☐☐
				Total Score =	☐☐

Scoring: For items 1 to 3, the response is either correct (score 0) or incorrect (score 1). For items 4 to 6, subtract one point for each error (item 4 and 5 maximum error is 2; for item 6, maximum error is 5); total all scores in "Final Score" column. Total score of 11 or greater indicates cognitive impairment; please notify MD and assist patient in completing questionnaires. Maximum score = 28

APPENDIX B

Updated (May 2020) Communication Tool
(adapted and revised from Dr. Schonberg's prior and ongoing decision aid work)
[Schonberg, M.A. et al JAMA Intern Med, 2014. 174(3):417-424]

MAMMOGRAPHY FOR BREAST CANCER SURVIVORS AGE 75+

Dana-Farber Cancer Institute

Are mammograms still right for me?

The benefits and risks of mammograms change as women grow older.

For breast cancer survivors who are 75 years of age or older, mammograms may be less useful than before, and often women can safely stop getting them. Our risk of breast cancer and other health conditions changes as we age.

Many women are glad to stop mammograms, which can be stressful, painful, or result in more tests like ultrasound or biopsy that, in the end, do not find cancer.

Others do not feel comfortable stopping, especially if they have been told for most of their lives that they should have a mammogram every year.

Whether mammograms will continue to be helpful for you depends on your breast cancer risk, your health in general, and what's important to you.

Accurate, expert infomation

Many breast cancer survivors fear that their risk of another breast cancer is higher than other women, but this is often not the case. It's important to make your decision with information that is accurate and trustworthy.

This guide was developed by national cancer experts and is based on review of hundreds of available clinical trials and studies.

Talk to your health care provider

This guide can help you understand:

- Your breast cancer risk
- Your health in general
- What's important to you

Your health care provider can answer your questions and help decide what's right for you.

1. Understanding your breast cancer risk

Understanding your breast cancer risk can help you make the best decision about future mammograms.

Most older breast cancer survivors have a similar risk of future breast cancer as other older women who did not have breast cancer. Many women are surprised to learn this.

If you received hormone therapy for your breast cancer, your risk is much lower risk than other women.

If your risk is the same as or lower than other older women who did not have breast cancer, you may want to consider stopping mammograms.

For women whose risk is higher than average because of their tumor type, treatment, or family history, mammograms may continue to be useful.

The charts on the next page show show the average risk of future breast cancer among breast cancer survivors.

If you want to compare your risk to that of older women who did not have breast cancer:

Women age 70-80 who did not have breast cancer,

4 out of **100 women,**

4 will develop breast cancer

Risk in the unaffected (noncancerous) breast

These charts show the average risk of breast cancer developing in the unaffected breast in the 10 years after diagnosis.

Women with a history of breast cancer

out of
100 women,
4 will develop breast cancer in the unaffected breast

This risk is the same as women age 70-80 years with no history of breast cancer.

Women treated with pills that lower estrogen (hormone therapy)

out of
100 women,
1.5 will develop breast cancer in the unaffected breast

This risk is much lower than women age 70-80 years with no history of breast cancer, because hormone therapy reduces cancer risk.

Risk in the breast that was treated for cancer (recurrence)

If you have had a mastectomy, you can skip this section and go to the next page.

If you did not have your breast removed, your cancer sub-type and treatment may increase or decrease the risk of cancer coming back in the treated breast. These charts show the average risk of cancer coming back in the treated breast during the 10 years after diagnosis.

Women who had ER+ breast cancer (sensitive to estrogen) breast cancer and their treatment

Surgery + pills + radiation

out of
100 women,
1.5 will develop a new cancer in the treated breast

This risk is much lower than that of women age 70-80 who did not have breast cancer.

Surgery + radiation

out of
100 women,
5 will develop a new cancer in the treated breast

This risk is slightly higher than that of women age 70-80 who did not have breast cancer.

Surgery + pills

out of
100 women,
7 will develop a new cancer in the treated breast

This risk is higher than that of women age 70-80 who did not have breast cancer.

Women who had HER2+ or triple negative breast cancer and their treatment

Surgery + radiation + chemotherapy

out of
100 women,
4 will develop a new cancer in the treated breast

This risk is the same as that of women age 70-80 who did not have breast cancer.

Surgery + radiation

out of
100 women,
13 will develop a new cancer in the treated breast

This risk is about three times higher than that of women age 70-80 who did not have breast cancer.

Talk to your health care provider about how your type of breast cancer, treatment, and family history affect your personal risk.

2. Your general health

A woman's general health can affect whether having a mammogram may be useful for her.
Circle your answers to each question and add up your points at the end.

					Points
How old are you?	75 – 79 **0**	80 – 84 **2**	85 or older **4**		
How much do you weigh?	More than 130 pounds **0**	130 pounds or less **2**			
How would you describe your health?	Excellent **0**	Very good **0**	Good **1**	Fair **2**	Poor **2**
Have you ever been told by a doctor that you had emphysema or chronic bronchitis?	No **0**	Yes **2**			
Have you ever been told by a doctor that you had cancer other than breast or non/melanoma skin cancer?	No **0**	Yes **2**			
Have you ever been told by a doctor that you had diabetes (including borderline diabetes or "pre-diabetes")	No **0**	Yes **2**			
Because of physical mental, or emotional problem, do you need help from other people with routine needs? These include everyday household chores, shopping, or getting around for other purposes?	No **0**	Yes **2**			
By yourself and without using any special equipment, how difficult is it for you to walk a ¼ mile or 3 city blocks?	Not at all difficult **0**	A little to very difficult, can't do it, don't do it, or can only do it with cane or walker **2**			
What is your cigarette use?	Never smoked or smoked less than 100 cigarettes in your life **0**	Former smoker **2**	Current smoker **4**		
How many times did you stay in the hospital overnight during the past year?	None **0**	Once **1**	Twice or more **3**		

Add up your points for questions 1-10 →

Based on your answers about your general health:

If your score was between 0-6, a mammogram may still be useful.

If your score was 7 or more, other health issues may be of more concern than your breast cancer risk, and **a mammogram may not be useful.**

3. What's important to you?

There's no right or wrong decision about mammograms—just the decision that's right for you. Here are some of the key reasons to have mammograms (benefits) or stop them (harms). Please check the reasons that feel important to you.

Reasons to have mammograms

- ☐ I'm more at risk than other women because of my cancer sub-type, treatment, or family history.
- ☐ I believe that continuing to have mammograms will help me stay healthy.
- ☐ Having mammograms helps me feel I am taking care of myself.
- ☐ I am worried about cancer returning to my affected breast.
- ☐ I'm worried about breast cancer in my unaffected breast.

Reasons to stop having mammograms

- ☐ My risk is low because of my cancer sub-type, treatment, and family history.
- ☐ I am more worried about other health issues.
- ☐ I'd rather rely on clinical breast exams by my health care provider.
- ☐ I do not want to find breast cancer that won't cause a problems in my lifetime.
- ☐ If I found a new breast cancer, I don't think I would want to have treatment for it.
- ☐ It is stressful when a mammogram requires more tests that then do not find cancer.
- ☐ Mammograms are sometimes painful.
- ☐ I would like to avoid the small amount of radiation from mammograms over time

4. Discuss and decide with your doctor

Talk with your health care team to help decide whether continuing to have mammograms is right for you. Important things to discuss are:

- The possible benefits or harms of mammograms based on your cancer sub-type, treatment, and family history
- Your risk for a new breast cancer or a cancer coming back in your breast
- Your general health
- What's important to you

To make sure you're still making the decision that's right for you, talk about this again with your doctor about once a year or when anything about your health changes.

APPENDIX C DRAFT FOCUS GROUP SCRIPTS

**Draft Focus Group Script Outline – Provider Discussions

****Scripts will vary slightly with regard to focus surveillance vs. screening, depending on whether the group is comprised of primary care providers, oncologists, or both)****

Total time = 60 mins

Part A

INTRODUCTION, CONSENT, GRAB BREAKFAST/LUNCH (during the first 10 minutes)

Good morning/good afternoon. My name is Rachel Freedman and I am a medical oncologist who works at Dana-Farber. This is [insert note taker], she/he also works at Dana-Farber and will be helping by taking notes today. First, we would like to thank you for taking the time to participate in today's discussion about follow-up care and mammography.

There are no right or wrong answers in our discussion today, and your honest feedback and insight are the best way for us to better understand your opinions. We want to welcome all perspectives, so while it is OK to disagree with each other, please be respectful towards your fellow group members, even if you have a different point of view. We also want to make sure that we provide a welcoming space for everyone to participate. I encourage you to speak to each other, and I will be here to listen and ask some specific questions. In order to be respectful of your time and the task at hand, I may need to interrupt at times in order to move us on. Thank you for your cooperation if those circumstances arise.

Your ideas and perspective are tremendously important and we don't want to miss anything. With your permission, I would like to audio record this interview to make sure that we capture your comments and accurately represent your perspectives. Our conversation will be kept strictly confidential and you will not be identified in any reports or write-ups. Today's discussion will last about 1 hour, and you will receive $50 in appreciation for your time today.

To begin I would like to go around the room and do introductions. Please tell us your first name and tell us where you are from (purpose is to make people feel comfortable and encourage participation). Thank you all for sharing, I really look forward to learning more about your experiences.

PART B (to be discussed during the next 35-45 minutes)

I will first provide an overview of this project, the intent, and will briefly review the current screening and surveillance guidelines for mammography in older patients. We will also briefly look at the data for recurrence with regard to the subtype and past treatments a woman has received and risk factors for local recurrences. (Dr. Freedman will present a short slide presentation on these topics for background.)

DISCUSSION OUTLINE

*****START RECORDING*****

Topic 1: Cessation of testing. We are interested in how you approach an older patient with a history of breast cancer with regard to her surveillance mammography (or secondary screening) [for primary care clinicians can add that we realize they may do more screening discussions than surveillance- we are interested in their opinions on all of this]

- In general, how would you describe your approaches/standards pertaining to mammography for patients (with a history of breast cancer) as they get older?
- Who typically orders surveillance mammography for your breast cancer survivors?
    - In general, how comfortable do you feel having conversations about surveillance with older patients?
- Thinking about women who have a history of breast cancer, what role does age, particularly advanced age, play in their mammogram recommendations from you?
    - When, if at all, do you think women should stop having routine screening mammography?
    - When do you think breast cancer survivors should stop having regular surveillance mammography?
- Have you discussed cessation of mammography with your patients?
    - If so, how did you approach this topic? How did it go?
    - Does your approach differ in the screening vs. surveillance setting?
- For those who discuss stopping surveillance mammography, are there any tools you use to help with these conversations? Decision aids? Life expectancy tools? Other graphics?

Topic 2: Life expectancy discussions

- What role does life expectancy play in your conversations about screening and or surveillance mammography?Do you routinely incorporate life expectancy into conversations about screening/surveillance?
    - If yes, how? And how does it go with patients?
    - If no, why not? (Have you done it in the past and it went poorly, anxious to have conversations, etc)
- Do you feel comfortable incorporating life expectancy into conversations with patients? What has worked or not worked? What are you concerns about this? How do you think this can be done well? Do you think it is important?
- Do you think if you had more guidance on using life expectancy in conversations with patients, it would be easier?
- How do you estimate your older patients' life expectancy? (website, took, personal estimation)

Topic 3: Communicating risks and benefits of surveillance mammography?

- When discussing surveillance mammography, which topics do you emphasize the most in these discussions?
    - Do you typically discuss the potential risks and benefits of testing?
    - How do you discuss this?
    - If you don't typically discuss surveillance mammography with patients, how do you typically discuss the risks and benefits of screening mammography?
- Do you use any tools to help such as aids, graphics, etc. to help discuss mammography?

Topic 4: Communication tool review (pass out the tool [draft in Appendix 1] for review to the group) This tool is meant to provide breast cancer survivors and their clinicians a framework for discussions on cessation of mammography, incorporating risks and benefits of surveillance mammography, information on life expectancy, and to help with decisions about mammography.

- What are your initial impressions of this tool?
- What do you think about the *amount* of information this tool contains?
- What do you think about the *content/information* found in this tool?
    - How about the way risks and benefits are displayed?
    - How do you feel about how the information regarding life expectancy is displayed?
- What do you think of the tool design? (layout, photos, colors, fonts, etc.)
- Are you comfortable with the language used in the tool?
- Could you envision using this tool in your discussions with patients? Why/why not?
- Do you anticipate any barriers to incorporating this into your work?
- How do you think the patients would react to receiving this handout?
- How do you think the life expectancy component looks and will go with patients?
- How would you like to access this tool? (*Probe*: embedded in an electronic medical record or web-based rather than paper)

Topic 5: Communication between primary care and oncology clinicians
We also are exploring ways that follow up care can be better coordinated between oncology and primary care clinicians.

- From your perspective, what issues are most important to consider when trying to improve communication around patient care and cessation of mammography between these patients?
- Do you think this tool could help communication between disciplines?
- What other ideas do you have about how to improve care coordination to promote unified messaging about use of surveillance mammography and other follow up care?

Topic 6: Any additional comments or feedback on improving older women's decision making around surveillance mammography?

PART C (5 minutes)
CLOSING:
We thank you for participating in this focus groups. Here is a $50 in appreciation of your time and opinions.

****Draft Patient Phone Interview and Focus Script****

– TOTAL IS 30-60 MINS and may vary slightly depending on setting of group or one-on-one interview

Part A (To be discussed during the first 5 minutes)
INTRODUCTION AND VERBAL CONSENT – SEE APPENDIX E

*****START RECORDING*****

We are working on strategies to better tailor follow up care for women aged 75 and older who have a history of breast cancer. We are a deeply interested in understanding patients' perspectives about how doctors and patients can work together to make decisions about follow up care. In the mail, you should have received a packet. Please keep this packet with you during our conversation. We will have you open the seal on it during our interview, a bit later on.

PART B
BACKGROUND QUESTIONNAIRE (10 minutes)
We will first ask you a series of questions that help us learn about you and your cancer history.

1. **Orientation-Memory-Concentration Test Short Blessed Test (SDT) – Scores filled in by interviewer (**http://geriatrictoolkit.missouri.edu/cog/bomc.pdf)- ***Entire Part B is for patient one-on-one interviews only***

Question	Maximum Error	Score X	Weight
What year is it now?	1	____ x 4	= ____
What month is it now? Repeat this phrase and I will ask you to remember it and tell it to me later: John Brown, 42 Market Street, Chicago	1	____ x 3	= ____
About what time is it? (within one hour)	1	____ x 3	= ____
Count backwards 20 to 1	2	____ x 2	= ____
Say the months in reverse order	2	____ x 2	= ____
Repeat the phrase just given	5	____ x 2	= ____
Total error score = _____			

(If patient scores ≥10, she is ineligible. Thank her for her time, let her know she is not eligible)

We will next ask you about your breast cancer and current follow up plan.

2. When was your breast cancer diagnosed?
    - Less than one year ago
    - More than one but less than 2 years ago
    - Between 2 and 5 years ago
    - More than 5 years ago
    - Not sure

3. Do you still see a medical oncologist or a nurse practitioner/physician assistant in the medical oncologist's office regularly?
    - Yes → If yes, how often?
    - No → If no, when was the last time you had follow up with your medical oncologist?
    - Not sure

4. Do you still see a surgical oncologist or an NP/PA in their office?
    - Yes → If yes, how often?
    - No → If no, when was the last time you had follow up in your surgeon's office?

5. Do you see anyone else for follow up of your cancer?
    - Yes→ who?
    - No
    - Not sure

6. Does your primary care provider discuss your breast cancer history with your regularly?
    - Yes
    - No
    - Not sure
    - Other _____

7. Do you still get mammograms?
    - Yes → If yes, when was your last mammogram? → Who typically orders your mammograms? (Oncologist, PCP, someone else?)
    - No → If no, when was your last mammogram?

8. Have you ever had a biopsy of your breast since your cancer was diagnosed that wasn't cancer?
    - Yes
    - No
    - Not sure

Next, I want to ask you some questions about you and your health.

9. How old are you? *(points are for interviewer calculation only and will not be read aloud to patient)*
    - 75-79 (0 points)
    - 80-84 (2 points)
    - 85 and older (4 points)

10. How much do you weigh?
    - More than 130 lbs.? (0 points)
    - 130 lbs. or less? (2 points)

11. Would you say your health is…
    - excellent (0 points)
    - very good (0 points)

- good (1 point)
- fair (2 points)
- poor (2 points)

12. Have you ever been told by a doctor/health professional that you had…

    Emphysema or chronic bronchitis or COPD?
    - No (0 points)
    - Yes (2 points)

    Cancer other than breast cancer (do not include skin cancer unless it was melanoma)?
    - No (0 points)
    - Yes (2 points)

    Diabetes?
    - No (0 points)
    - Yes (2 points)

13. Because of physical mental, or emotional problem, do you need help from other people with routine needs? These include everyday household chores, shopping, or getting around for other purposes?
    - No (0 points)
    - Yes (2 points)

14. By yourself and without using any special equipment, how difficult is it for you to walk a ¼ mile or 3 city blocks?
    - Not at all difficult (0 points)
    - A little to very difficult (3 points)
    - Can't do/do not do/can only do with cane or walker (3 points)

15. Which best describes your cigarette use?
    - Never smoked or smoked less than 100 cigarettes in your life (0 points)
    - Former smoker (1 point)
    - current smoker (3 points)

16. During the past 12 months, how many times were you hospitalized overnight?
    - None (0 points)
    - Once (1 point)
    - Twice or more (3 points)

Interviewer quickly calculates life expectancy based on the Schonberg Index by adding up all of the points for responses to questions 9-16. If points 15 or higher, that patient has a >50% 5-year mortality risk (or life expectancy <5 years). If points are 10 or higher, a patient has >50% 10-year mortality risk (≥10 points) or a life expectancy ≤10 years

PART C. OPEN-ENDED QUESTIONS: FURTHER DISCUSSION (20-30 mins)
We will next ask you some questions about your feelings and perspectives around mammograms. Please know that there are no right or wrong answers, and your insight and experience are very valuable.

- How do you feel about having mammograms?
- How do you decide about whether or not to have a mammogram?
    - What influences your decision?
- What do you think are the advantages of having regular mammograms?
- What do you think these downsides are?
    - *Could probe with*: Have you ever had discomfort or anxiety or other symptoms related to having mammograms?
    - Have you ever had a mammogram that required you to come back for additional testing? [describe] How did it turn out? Did you have another cancer? Was it benign?
- Do you think mammograms are worthwhile for everyone?
- Do you think that there are any women who might not benefit from mammograms?
- How do you feel about seeing your oncologist or primary care physician for regular follow up visits?
- Has a healthcare professional ever discussed with you the downsides of getting mammograms?
- If you are still having mammograms, have you ever thought about stopping them?
- What if a doctor told you that you no longer needed mammograms? How would you feel about that? Have you ever thought about this before?

Using the answers to the questions about your health I asked you earlier, there are ways to help estimate your life expectancy, which is an estimate of how long you may have to live.

- Is this something your doctors have ever discussed with you? If so, how did it go?
- If not, would you be interested in hearing this information? (If no, why not?)
- If yes, how would do you think it might be discussed in a way you were comfortable with?
- Do you think this information might help you make decisions about screening tests?
- If a provider were to want to discuss your life expectancy, how might you like to hear or discuss this information? [can prompt about graphics, comparisons to other individuals, how it might help them with decisions, etc]

Now I'd like you to take out and reference the communication tool we sent you in the mail or over email. If you don't have it with you, I have provided additional copies here. Please break the seal on the envelope and open up the communication too. We want to review it with you now and get your thoughts about how it may or may not help you make decisions about getting mammograms. We would like you to be as honest as possible.

Please read it and let me know what you think as you are reading it. You may need to read it more than once.

1. Can you take a look at the benefits of mammography listed there? Let's review them (*interviewer reviews the list)* Please explain in your own words what this means or how would you explain to a friend what you read?

2. Is anything unclear?
3. *[if participant stated they would be interested in hearing their life expectancy above, ask the following:]* Based on your health from the questions you answered above…you have _[*to be filled in by interviewer*]____ chance of benefiting from mammography. How does it make you feel to hear that?
    a. How does this information affect your thoughts about getting a mammogram?
    b. How do you feel about seeing this information about life expectancy here? Helpful? Does it make you feel anxious? Does it make you uncomfortable?
4. How clear was the information in the breast cancer risk communication aid?
    a. Anything you would change?
5. Would you prefer this to be electronic and visible on your phone or computer? Or do you prefer the paper version?
6. Was the length of the aid too short, just right, or too long?
7. Would you find this useful to bring to your doctor's office visit when discussing mammography?
8. Do you find that your primary care doctor or nurse is aware of your follow up plan for your breast cancer?
9. How would you describe communication between your primary care doctor and oncology team?
10. Could this communication be better or does it work well (in your opinion)?
11. Do you think having this communication aid could help with communication between your oncology and primary care doctors?
12. Would you be willing take it with you to your provider visits to show the discussions you had?
13. Any other suggestions on the communication tool?
14. Any other comments or suggestions about anything else we have discussed today?

PART D (5 minutes)
BRIEF DEMOGRAPHIC QUESTIONNAIRE –provided on paper for focus group at the end of the discussion and on the phone for one-on-one interviews
We would like to ask some questions about your background so that we have an idea of the characteristics of the women we interview. All of these answers will be confidential and will not be recorded along with any identifiable information (such as your name, etc.). Please answer the following questions to the best of your ability. While this information will be helpful to us, you do not have to answer any questions if you do not wish to.

- What is the highest grade you finished in school?
    - < 6th grade
    - 6th grade
    - 7th grade
    - 8th grade
    - 9th grade
    - 10th grade
    - 11th grade
    - 12th grade
    - 1 year of college
    - 2 years of college or an Associate's degree
    - 3 years of college
    - 4 years of college or a Bachelor's degree

  - Master's degree
  - Doctoral degree or a law degree
  - Trade, vocational, or technical school
  - GED

- How confident are you filling out medical forms by yourself?
  - Extremely confident
  - Quite a bit confident
  - Somewhat confident
  - A little confident
  - Not at all confident

- How often do you have someone like a family member, friend, hospital, or clinic worker or caregiver, help you read hospital materials?
  - Always
  - Often
  - Sometimes
  - Rarely
  - Never

- How often do you have problems learning about your medical condition because of difficulty understanding written information?
  - Always
  - Often
  - Sometimes
  - Rarely
  - Never

- We would like to know how you prefer to receive health educational materials in general. Do you prefer health education materials on:
  - Paper
  - Computer/internet
  - Web-based or mobile application
  - No preference
  - Other

- Do you have a computer at home?
  - No
  - Yes

- How would you describe your knowledge of computers?
  - Excellent
  - Very Good
  - Good
  - Fair

- Poor

- Do you have internet access at home?
  - No
  - Yes

- If so, which statement below best describes how comfortable you are using the internet?
  - I use the internet very comfortably
  - I use the internet somewhat comfortably
  - I use the internet but not comfortably
  - other

- How frequently do you use the internet?
  - Daily
  - Once a week or less
  - Less than once a week but greater than once in a month
  - Once a month
  - Less than once a month

- How would you describe your household's financial situation right now? (please select one answer)
  - o After paying the bills, you still have enough money for special things that you want.
  - o You have enough money to pay the bills, but little spare money to buy extra or special things.
  - o You have money to pay the bills, but only because you have cut back on things.
  - o You are having difficulty paying the bills, no matter what you do.

- Which of the following best describes your current marital situation?
  - o Married
  - o Living as married or domestic partner
  - o Divorced or separated
  - o Widowed
  - o Never married

- What race do you consider yourself to be? You may select one or more of the following.
  - o *American Indian or Alaskan Native (Native Person/Aboriginal).* A person having origins in any of the original peoples of North, Central, or South America, who maintains tribal affiliation or community attachment.
  - o *Asian.* A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
  - o *Black, Haitian, or African American.* A person having origins in any of the black racial groups of Africa.
  - o *Native Hawaiian or other Pacific Islander.* A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
  - o *White.* A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

o You prefer not to provide this information

- Do you consider yourself to be Hispanic or Latina? *(Spanish, Hispanic, or Latina* is a person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture of origin, regardless of race.)
  o Yes
  o No
  o Other_____

PART E (2 minutes)
CLOSING
We thank you so much for participating in this interview. We will be mailing you a $50 gift card in appreciation of your time and opinions. Where shall we mail this or email this?

APPENDIX D- SURVEYS FOR AIM 1.2

References for survey questions from patient and provider are at the end of this appendix. Validated surveys were used whenever possible.
All surveys will be provided to patients on REDCap but can be done on paper when patient requests and then later submitted to REDCap by the study team.

Baseline ('Pre') Patient Questionnaire

Thank you for agreeing to participate in this study.

Study ID _____ (to be filled out by study team)

Date:_____

1. If your doctor or nurse asked you right now to make a choice about whether or not to get a mammogram, on a scale from 1-15 how certain are you about whether or not you would choose to get a mammogram in the next year? (1 means you are sure you would get a mammogram while 15 means you are sure you would not get a mammogram, if you are unsure please give a number between 1 to 15, 8 is the middle).

(**If interview is being done over the phone because the in-person visit was missed, then ask patient: From 1-15, how likely are you to get a mammogram, 1 means you are certain I will get a mammogram and 15 means you are certain you will not get a mammogram. If you are not sure, please give a number between 1 and 15 that best describes how likely you are to get a mammogram)**

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

Will Get a Mammogram — **Unsure** — **Will Not Get** Mammogram

As women age, the benefits of routine (when no symptoms are present) mammography may get smaller. As we try to learn from you, we would appreciate your honest answers to the questions below. These questions are about how you feel about whether or not to get a mammogram. Please say whether you Strongly Agree, Agree, are not sure, Disagree, or Strongly Disagree with the statements below.

2. I know which options are available to me for getting tested for breast cancer.

☐ Strongly Agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly Disagree

3. I know the benefits of getting a mammogram.

☐ Strongly Agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly Disagree

4. I know the downsides or risks of getting a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

5. I am clear about which benefits of getting a mammogram matter most to me.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

6. I am clear about which downsides or risks of getting a mammogram matter most to me.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

7. I am clear about whether the benefits of getting a mammogram are more important to me than the downsides or risks.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

8. I have enough support from others to make a choice whether or not to get a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

9. I am choosing without pressure from others about whether or not to get a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

10. I have enough advice to make a choice about whether or not to get a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

11. I am clear about the best choice for me when it comes to getting a mammogram

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

12. I feel sure about what to choose in terms of whether or not to get a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

13. The decision whether or not to get a mammogram is easy for me to make.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

14. I feel I have made an informed choice whether or not to get a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

15. My decision about whether or not to get a mammogram shows what is important to me

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

16. I expect to stick with my decision whether or not to get a mammogram

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

17. I am satisfied with my decision whether or not to get a mammogram.

☐	☐	☐	☐	☐
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

The next set of questions are questions about mammograms in general. Your best guess is fine.

18. Among women aged 75 or older, who is more likely to die from breast cancer?

- ☐ Women who get mammograms
- ☐ Women who do NOT get mammograms
- ☐ There is almost no difference
- ☐ I don't know

19. The benefit of getting a mammogram is finding and treating a breast cancer when it is small and can be treated with only minor surgery.

☐ True ☐ False

20. Getting a mammogram will prevent me from getting breast cancer.

☐ True ☐ False

21. Most women who have an abnormal mammogram have breast cancer.

□ True □ False

22. Women aged 75 or older have a higher chance of getting breast cancer than younger women.
□ True □ False

23. More women aged 75 or older die of heart disease than breast cancer.
□ True □ False

24. Your other health problems should affect whether or not you get a mammogram.
□ True □ False

25.Some breast cancers found by a mammogram would never have shown up or caused problems in a woman's lifetime. .
□ True □ False

26. Most women aged 75 or older with breast cancer are treated with chemotherapy.
□ True □ False

27. Some breast cancers are not detected by mammograms.
□ True □ False

28. What is your preferred role in decision-making around mammography?
- □ I prefer to make the final decision about whether or not to get a mammogram.
- □ I prefer to make the final decision about whether or not to get a mammogram after seriously considering my health care provider's opinion.
- □ I prefer that my health care provider and I share responsibility for deciding whether or not to get a mammogram is best for me.
- □ I prefer that my health care provider make the final decision about whether or not I should get a mammogram, but seriously considers my opinion.
- □ I would prefer to leave all decisions regarding mammography to my health care provider.
- □ Don't know

We would like to get a sense of how much you worry about your cancer coming back. Please answer the next set of questions as honestly as possible.

29. On a scale of 1 – 6, with 6 being the most worried and 1 being the least worried, how much do you worry about your cancer coming back?

□	□	□	□	□	□
1	2	3	4	5	6
Not at all worried					very worried

30. On a scale of 1 – 6, with 6 being the most worried and 1 being the least worried, how much do you worry about needing more tests after you have a mammogram?

□ □ □ □ □ □

1	2	3	4	5	6
Not at all worried					very worried

31. On a scale of 1 – 6, with 6 being the most worried and 1 being the least worried, how much do you worry about getting another cancer besides breast cancer?

□	□	□	□	□	□
1	2	3	4	5	6
Not at all worried					very worried

We would like to know how you feel about hearing information regarding your life expectancy (or how many more years someone like you is expected to live).

32. Have any your health care providers ever talked with you about how much time you have left to live?

- □ Yes
- □ No
- □ Don't know

33. If your health care provider could estimate how long you may have to live based on your current health status, would you want him or her to tell you?

- □ Yes
- □ No
- □ Don't know

34. We have no idea how long you will live. We would like to give you a made up example. Let's say your health care provider thinks you have less than 5 years to live. Would you want to know this information?

- □ Yes
- □ No
- □ Don't know

35. We would like to give you another made up example. Let's say your health care provider thinks you have less than 1 year to live. Would you want to know this information?

- □ Yes
- □ No
- □ Don't know

36. Would having this information help you make decisions about your health care?

- □ Yes
- □ No
- □ Don't know

We will now ask you some questions about you.

37. How would you define your marital status?
- □ Single (never married)
- □ Currently married or living as married
- □ Divorced
- □ Separated
- □ Widowed
- □ Don't know

38. Do you live alone or with others?
- □ I live alone
- □ I live with others

39. What is the highest level of school you have completed or the highest degree you have received?
- □ less than or equivalent to 8th grade
- □ GED or equivalent
- □ High school or less, no diploma
- □ High school graduate
- □ Some college or an Associate's degree
- □ Bachelor's degree (i.e., BA, AB, BS, BBA)
- □ Master's degree (i.e., MA, MS, MEngineering, MEducation, MBA)
- □ Professional School degree (MD, DDS, DVM, JD)
- □ Nursing degree
- □ Doctoral degree (PhD, EdD, ScD)
- □ Don't know
- □ Other

40. Do you consider yourself to be Hispanic or Latino?
- □ No, I am not Hispanic or Latino
- □ Yes, I am Hispanic or Latino
- □ Don't know

41. Which of the following racial groups do you most identify with?
- □ White or Caucasian
- □ Black or African American
- □ Asian
- □ American Indian or Alaska Native
- □ Native Hawaiian or other Pacific Islander
- □ Other
- □ Don't know

- 42. How would you describe your household's financial situation right now? (please select one answer)
  - □ After paying the bills, you still have enough money for special things that you want.
  - □ You have enough money to pay the bills, but little spare money to buy extra or special things.
  - □ You have money to pay the bills, but only because you have cut back on things.

- □ You are having difficulty paying the bills, no matter what you do

43. What type of health insurance do you have?
- □ Private health insurance plan
- □ Medicare A and B
- □ Medicare Advantage/Medicare Choice/Medicare HMO
- □ Medicaid
- □ Medicare +Federal
- □ Medicare +Private health insurance plan
- □ No Coverage
- □ Other

44. How confident are you filling out medical forms by yourself?
- □ Extremely confident
- □ Quite a bit confident
- □ Somewhat confident
- □ A little confident
- □ Not at all confident

45. How often do you have someone like a family member, friend, hospital, or clinic worker or caregiver, help you read hospital materials?
- □ Always
- □ Often
- □ Sometimes
- □ Rarely
- □ Never

46. How often do you have problems learning about your medical condition because of difficulty understanding written information?
- □ Always
- □ Often
- □ Sometimes
- □ Rarely
- □ Never

47. We would like to know how you prefer to receive health educational materials in general. Do you prefer health education materials on:
- □ Paper
- □ Computer/internet
- □ Web-based or mobile application
- □ No preference
- □ Other _____

48. Do you have a computer at home?
- □ No

□ Yes

49. How would you describe your knowledge of computers?
    - □ Excellent
    - □ Very Good
    - □ Good
    - □ Fair
    - □ Poor

50. Do you use the internet?
    - □ No
    - □ Yes

51. If yes, which statement below best describes how comfortable you are using the internet?
    - □ I use the internet very comfortably
    - □ I use the internet somewhat comfortably
    - □ I use the internet but not comfortably
    - □ Other _____

52. How frequently do you use the internet?
    - □ Daily
    - □ Once a week or less
    - □ Less than once a week but greater than once in a month
    - □ Once a month
    - □ Less than once a month

53. How good are you at working with fractions?

□	□	□	□	□	□
Extremely Good	Very Good	Good	Somewhat Good	A little bit Good	Not at all Good

54. How good are you at working with percentages?

□	□	□	□	□	□
Extremely Good	Very Good	Good	Somewhat Good	A little bit Good	Not at all Good

55. How good are you at calculating a 15% tip?

□	□	□	□	□	□
Extremely Good	Very Good	Good	Somewhat Good	A little bit Good	Not at all Good

56. How good are you at figuring out how much a shirt will cost if it is 25% off?

□ □ □ □ □ □

Extremely Good	Very Good	Good	Somewhat Good	A little bit Good	Not at all

57. When reading the newspaper, how helpful do you find tables and graphs that are part of a story?

□ Extremely Helpful	□ Very Helpful	□ Quite Helpful	□ Somewhat Helpful	□ A little Helpful	□ Not at all Helpful

58. When people tell you the chance of something happening, do you prefer that they use <u>words</u> ("it rarely happens") or <u>numbers</u> ("there's a 1% chance")?

□ Always prefer words	□ Most of the time prefer words	□ Sometimes prefer words	□ Sometimes prefer numbers	□ Most of the time prefer numbers	□ Always prefer numbers

59. When you hear a weather forecast, do you prefer predictions using <u>percentages</u> ("there will be a 20% chance of rain today") or predictions using only <u>words</u> ("there is a small chance of rain today")?

□ Always prefer percentages	□ Most of the time prefer percentages	□ Sometimes prefer percentages	□ Sometimes prefer words	□ Most of the time prefer words	□ Always prefer words

60. How often do you find numerical information to be useful?

□ Extremely Often	□ Very Often	□ Quite Often	□ Somewhat Often	□ A little	□ Never

Thank you for completing the baseline questionnaire.
We will find you after your appointment to complete the second survey. If we miss you, we will call you or email you in the next 1-7 days to complete the survey by phone, email, or mail. You will receive $40 after completing the next survey.

<u>Post-visit Patient Questionnaire**</u>**

Study ID: _____

Date:_____

Thank you for agreeing to participate in this study. Now that you have had your visit with your provider, there are a few more questions that we would like you to answer.

If your health care provider asked you right now to make a choice about whether or not to get a mammogram, on a scale from 1-15 how certain are you about whether or not you would choose to get a mammogram in the next

year? (1 means you are sure you would get a mammogram while 15 means you are sure you would not get a mammogram, if you are unsure please give a number between 1 to 15, 8 is the middle).

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

Will Get a Mammogram **Unsure** **Will Not Get** Mammogram

(**If interview is being done over the phone because the in-person visit was missed, then ask patient: From 1-15, how likely are you to get a mammogram, 1 means you are certain I will get a mammogram and 15 means you are certain you will not get a mammogram. If you are not sure, please give a number between 1 and 15 that best describes how likely you are to get a mammogram)**

2. When do you plan to get your next mammogram?

- □ Never
- □ In the next year
- □ More than 1 year from now but less than 2 years from now
- □ More than 2 years from now
- □ Other:_____

The next set of questions are about how you feel about whether or not to get a mammogram and are the same questions we asked you before your visit today. Please say whether you Strongly Agree, Agree, Neither, Disagree, or Strongly Disagree with the statements below.

3. I know which options are available to me for getting tested for breast cancer.

□ Strongly Agree □ Agree □ Not sure □ Disagree □ Strongly Disagree

4. I know the benefits of getting a mammogram.

□ Strongly Agree □ Agree □ Not sure □ Disagree □ Strongly Disagree

5. I know the downsides or risks of getting a mammogram.

□ Strongly Agree □ Agree □ Not sure □ Disagree □ Strongly Disagree

6. I am clear about which benefits of getting a mammogram matter most to me.

□ Strongly Agree □ Agree □ Not sure □ Disagree □ Strongly Disagree

7. I am clear about which downsides or risks of getting a mammogram matter

most to me.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

8. I am clear about whether the benefits of getting a mammogram are more important to me than the downsides or risks.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

9. I have enough support from others to make a choice whether or not to get a mammogram.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

10. I am choosing without pressure from others about whether or not to get a mammogram.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

11. I have enough advice to make a choice about whether or not to get a mammogram.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

12. I am clear about the best choice for me when it comes to getting mammograms

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

13. I feel sure about what to choose in terms of whether or not to get a mammogram.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

14. The decision whether or not to get a mammogram is easy for me to make.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

15. I feel I have made an informed choice whether or not to get a mammogram.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

16. My decision about whether or not to get a mammogram shows what is important to me

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

17. I expect to stick with my decision whether or not to get a mammogram

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

18. I am satisfied with my decision whether or not to get a mammogram.

□	□	□	□	□
Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree

19. Did your health care provider discuss your life expectancy with you today?

- □ Yes
- □ No
- □ Don't know

20. If yes, how did this make you feel? You can check as many answers as you think apply:

- □ Comfortable
- □ Uncomfortable
- □ Informed
- □ Sad
- □ Content/Happy
- □ Scared
- □ Anxious
- □ Calm
- □ Interested
- □ Uninterested
- □ Other _____

The next questions are questions and are the same questions we asked you on your baseline survey. Please state whether each of the following statements is true or false (your best guess is fine).

21. Among women aged 75 or older, who is more likely to die from breast cancer?

- □ Women who get mammograms
- □ Women who do NOT get mammograms
- □ There is almost no difference
- □ Don't know

22. The benefit of getting a mammogram is finding and treating a breast cancer when it is small and can be treated with only minor surgery.

□ True □ False

23. Getting a mammogram will prevent me from getting breast cancer.
□ True □ False

24. Most women who have an abnormal mammogram have breast cancer.
□ True □ False

25. Women aged 75 or older have a higher chance of getting breast cancer than younger women.
□ True □ False

26. More women aged 75 or older die of heart disease than breast cancer.
□ True □ False

27. Your other health problems should affect whether or not you get a mammogram.
□ True □ False

28. Some breast cancers found by a mammogram would never have shown up or caused problems in a woman's lifetime.
□ True □ False

29. Most women aged 75 or older with breast cancer are treated with chemotherapy.
□ True □ False

30. Some breast cancers are not detected by mammograms.
□ True □ False

The next questions are about the communication tool that we provided you before your clinic visit

Did it…

31. Help you recognize that a decision needs to be made about whether or not to get a mammogram?
□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

32. Prepare you to make a better decision about whether or not to get a mammogram?
□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

33. Help you think about the pros and cons of getting a mammogram?
□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

34. Help you think about which pros and cons about getting a mammogram are most important to you?
□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

35. Help you know that the decision whether or not to get a mammogram depends on what matters most to you?

□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

36. Help you organize your own thoughts about the decision whether or not to get a mammogram?

□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

37. Help you think about how involved you want to be in this decision?

□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

38. Help you identify questions you want to ask your health care provider about mammography?

□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

39. Prepare you to talk to your health care provider about what matters most to you about whether or not to get a mammogram?

□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

40. Prepare you for a follow-up visit with your doctor?

□ A great deal □ Quite a bit □ Somewhat □ A little □ Not at all

41. At your follow-up visit, did you talk to your health care provider about getting a mammogram?

□ YES □ NO

42. Did your provider talk to you about the benefits of getting a mammogram?

□ YES □ NO

43. Did your provider talk to you about any downsides of getting a mammogram?

□ YES □ NO

44. What did your provider recommend in terms of mammograms?

□ Continue having mammograms
□ Get another mammogram but consider stopping after that
□ It is my choice
□ To not get a mammogram now but reconsider later
□ To stop getting mammograms
□ Other:_____

45. The length of the communication sheet was

□ □ □ □ □

Much too Long	A little too long	Just right	A little too short	Much too short

46. The amount of information was

□ Much less than needed	□ A little less than needed	□ Just right	□ A little more than needed	□ Much more than needed

47. How clear was the information?

□ Everything was clear	□ Most things were clear	□ Some things were clear	□ Many things were unclear

48. I found the information

□ Clearly slanted towards getting a mammogram	□ A little slanted towards getting a mammogram	□ Completely balanced	□ A little slanted towards NOT getting a mammogram	□ Clearly slanted towards NOT getting mammogram

49. Reading the information made me feel:

□ Not anxious at all	□ A little anxious	□ Very anxious	□ As anxious as could be

50. Please check the most accurate statement below:

- □ I understood none of the information
- □ I understood a little of the information
- □ I understood most of the information
- □ I fully understood all of the information

Any other Comments for us??

_____
_____

51. How helpful was the communication tool in making a decision about mammography?

□ Very helpful	□ Somewhat helpful	□ A little helpful	□ Not helpful

52. Would you recommend the use of this communication tool?

□ Definitely Recommend	□ Probably Recommend	□ Probably not Recommend	□ Definitely not Recommend

It would be helpful to learn how you prefer to receive health educational materials such as the one you read today.

53. What is your preferred format for health education materials:
- □ A pamphlet like the one you read for this study
- □ The computer/internet
- □ No preference
- □ Other

54. Which would you prefer:
- □ To be mailed health educational materials that relate to me before a visit
- □ To be emailed health educational materials that relate to me before a visit
- □ To receive health educational materials in the waiting room before a visit
- □ To have your doctor or nurse give you health educational materials during the visit
- □ To have your doctor's staff give you health educational materials after a visit to read at home.
- □ No preference
- □ Other

Thank you so much for your help. You will receive $40 for participating in this study.

****Post-visit Clinician Questionnaire****

Thank you for agreeing to participate in this study. We are going to ask you some questions relating to this particular visit with the patient. All of your answers will be kept confidential, will not be linked to your name for future use, and are for informational purposes only as we try to understand how helpful this tool was in your discussions with patients. Please answer openly and honestly and you can skip any question you prefer not to answer

Study ID _____

Date:_____

Intentions for mammography

1. What did you recommend in terms of mammograms for this patient?
   - □ Continue having mammograms
   - □ Get another mammogram but consider stopping after that
   - □ It is the patient's choice
   - □ To not get a mammogram now but reconsider later
   - □ To stop getting mammograms
   - □ Did not discuss mammograms
   - □ Other:_____

2. Before the visit, what did you think you would recommend?
   - □ Continue having mammograms
   - □ Get another mammogram but consider stopping after that
   - □ It is the patient's choice
   - □ To not get a mammogram now but reconsider later
   - □ To stop getting mammograms
   - □ I did not think I would discuss mammograms
   - □ Other:_____

3. During the visit today, did you discuss any of the following (circle each answer):

- Pros of mammograms? Yes No Not sure
- Cons of mammograms? Yes No Not sure
- The patients individual risk of in-breast, pre-cancer or invasive cancer events? Yes No Not sure
- Family history? Yes No Not sure
- Life expectancy? Yes No Not sure

- Any other relevant discussion points you discussed?

_____

3A. If yes to discussing life expectancy, how did this go? Check any that apply:

- ☐ Helpful to patient
- ☐ Helpful to me
- ☐ It was uncomfortable
- ☐ It was comfortable
- ☐ Made decision-making easier for mammogram
- ☐ Made decision-making harder for mammogram
- ☐ Neutral effect on decision-making
- ☐ Other _____

3B. If no to discussing life expectancy above, why not? Check any that apply

- ☐ It didn't come up
- ☐ I was uncomfortable talking about it
- ☐ Patient did not want to discuss it
- ☐ Patient was anxious
- ☐ Patient healthy so I didn't think it was important
- ☐ I didn't have time
- ☐ I didn't think it was important for this discussion

Questions about the Communication Sheet (with regard to its use during this visit with the patient)

4. The length of the communication sheet was

☐	☐	☐	☐	☐	☐
Much too Long	A little too long	Just right	A little too short	Much too short	I didn't use it

5. The amount of information was

☐	☐	☐	☐	☐	☐
Much less than needed	A little less than needed	Just right	A little more than needed	Much more than needed	I didn't use it

6. How clear was the information?

☐	☐	☐	☐	☐ I didn't use it
Everything was clear	Most things were clear	Some things were clear	Many things were unclear	

7. I found the information

□	□	□	□	□	□
Clearly slanted towards getting a mammogram	A little slanted towards getting a mammogram	Completely balanced	A little slanted towards NOT getting a mammogram	Clearly slanted towards NOT getting mammogram	I didn't use it

8. How helpful was the communication tool in making a decision about mammography?

□	□	□	□	□
Very helpful	Somewhat helpful	A little helpful	Not helpful	I didn't use it

9. Would you recommend the use of this communication tool?

□	□	□	□
Definitely Recommend	Probably Recommend	Probably not Recommend	Definitely not Recommend

It would be helpful to learn how you prefer to use health educational materials such as the one you used today.

10. What is your preferred format for health education materials:

- □ A pamphlet like the one you used for this study
- □ The computer/internet
- □ No preference
- □ Other _____

11. How did using this tool affect the length of the visit with your patient today?

- □ Made visit a lot longer
- □ Made visit a little longer
- □ No effect on visit time
- □ Made visit a little shorter
- □ Made visit a lot shorter
- □ Not sure
- □ Other
- □ I didn't use it

12. Please let us know about any other thoughts you have about using the tool in practice. Please be as honest as possible.

_____

Thank you so much for your help. You will receive a one-time $40 at the end of this study for participating in these surveys.

CITATIONS

***All questionnaires are adapted and revised from validated surveys used in the following publications :*
Decision Aid evaluation for screening by Schonberg M.A. et al JAMA Intern Med 2014; 174(416-424),
https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_ChoicePredisposition_Decision.pdf,
https://decisionaid.ohri.ca/docs/develop/Tools/DCS_English.pdf,
https://decisionaid.ohri.ca/docs/develop/Tools/Acceptability_osteoporosis.pdf)
Gotay CC and Pagano. Assessment of Survivor Concerns: A newly proposed brief questionnaire. Health Qual Life Outcomes 2007; 5: 15.
Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. J Gen Intern Med 2008; 23:561-566
Enzinger AC, Zhang B, Schrag D, et al. Outcomes of prognostic disclosure: associations with prognostic understanding, distress, and relationship with physician among patients with advanced cancer. J Clin Oncol 2015; 33:3809-3816.
Ahalt C, Walter LC, Yourman L, et al: "Knowing is better": preferences of diverse older adults for discussing prognosis. J Gen Intern Med 27:568-75, 2012

APPENDIX E: VERBAL CONSENT FOR THE PATIENT PHONE INTERVIEWS AND FOCUS GROUPS

Hi and thanks for participating in this interview today. I'm from Dana-Farber Cancer Institute and we're doing a study on how we can better approach mammography in older breast cancer survivors. We've asked you to participate in this discussion because we'd like to hear your perspectives on your experiences and how you feel about this topic. This project is funded by a grant from the National Cancer Institute.

I'd like to start off by introducing myself. I'm [name of interviewer]. I'll be conducting this interview and will be recording our discussion. As was mentioned to you when you were invited to participate, we will audiotape this session. We are doing this to make sure that we remember everything that you say. Your comments are really important to us. The tapes are confidential information. Your name or any other information that could identify you will not be linked to the tape recordings. The tapes will be listened to only by the research staff or by the professional transcriptionist (the person who will type what is on the tape). Once the recordings have been typed and the data analyzed, we will erase the tapes. All records of the discussions will be kept in a locked file. Only the researchers will have access to these records. Any results of your interview and those of other women (including the views of you and other women) will be reported or published as a group and will not be associated with any identifiers.

Everything that you say is confidential and will not be shared with anyone other than the research staff. Therefore, I want to encourage you to speak openly about your ideas. There are no right or wrong answers. The goal is to hear your views and experiences to fully understand how you feel on the topics we will discuss. We expect that you will find the questions generally easy to answer, but if you find that any parts of the discussion are upsetting, you can ask the interviewers to move on. If you experience any distress during or after the discussion, please let us know and we will refer you to your doctor or nurse for follow-up care.

This is a voluntary activity. Today's discussion will last about 30-45 minutes. You may choose not to take part in this study. If you do decide to participate, you can stop at any time or choose not to answer any of the questions. Choosing not to take part or leaving the study will not affect any current or future medical care in any way. We will mail you a $50 gift card after you complete the interview. Thank you so much for agreeing to participate. .

Are you ready to begin? [Then start recording and begin interview]

APPENDIX F: INFORMATION FOR MAILING AND VERBAL CONSENT FOR AIM 1.2 (PILOT INTERVENTION)

Dear potential participant:

I'm from Dana-Farber Cancer Institute and we're working on a research study that looks to improve how we follow patients with breast cancer who are 75 and older. We've asked you to participate because we'd like to hear your perspectives on your experiences on this topic. This project is funded by a grant from the National Cancer Institute. We will be calling you in the next week or so to review the information provided here to see if you are interested in participating. Your participation is completely voluntary. We have also enclosed a phone number and email address in case you want to let us know ahead of time that you are interested *or* not interested in participating. If we do not hear back from you, we will call you to introduce you to this study and review this form again.

Purpose: Our goal is to develop a communication tool that will provide recommendations for clinicians and patients for surveillance mammography and follow-up care for breast cancer survivors over the age of 75. Specifically, this tool will help prevent over screening breast cancer survivors by reducing unnecessary mammograms in follow-up care. With your permission, we will provide you with an information sheet about mammograms. We will then ask you to answer some questions about your breast cancer, your intentions for mammography before and after your next follow-up visit at Dana-Farber, and your decision-making and your experiences.

Procedures: This is a two-time survey that will occur before and after your upcoming Dana-Farber follow-up appointment and will take approximately 20-30 minutes in total. You can take these surveys by email (through a link), by paper (in person or through mail), or by phone. You are free to skip any questions you do not wish to answer or end the survey at any time. At this time, we are also asking for your consent to review your medical record. The medical record review is an important part of this study because we can confirm information about your cancer, the treatments you may or may not have received, as well demographic data such as your age. Only members of the study team will have access to the information in medical records. When we finish the surveys, we will arrange for a $40 gift card to be sent to you.

Benefits: There are no direct benefits to you. However, the information you provide us with will provide important information on follow-up care for survivors of breast cancer.

Risks: The risks of participating in this interview are minimal. We expect that you will find the questions generally easy to answer, but if you find that any questions are upsetting, you can ask the interviewer to move on. If you experience any distress during our discussion, please let us know and we will refer you to your doctor or nurse for follow-up care. Another potential risk is a loss of confidentiality. We will take measures to protect the

privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Confidentiality: All the information you give us will be kept confidential. Your name and address will not be linked directly to your interview responses. We will keep all our study notes in locked files and secured computers. To protect your confidentiality, your signature will not be required in this or other documents. Your verbal agreement to participate in the survey will serve as your consent. We will destroy the file containing your name and address information as soon as we have completed the study.

Future Research: Your personal information collected during this study may be retained and used for future research. Any personal identifiers will be removed, before the information is shared, so that the information cannot be linked back to you. As a result, we will no longer be able to identify and destroy them. Investigators, including investigators from collaborating institutions, can request these data for new research. Your information may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate. You will not be asked to provide additional informed consent for the use of your de-identified information in future research.

It is YOUR choice! Your participation is important but voluntary. You may choose not to take part at all, or to stop at any time after you begin. You can refuse or quit at any time without penalties of any kind or loss of any benefits you are otherwise entitled. Also, if you experience distress during the surveys and would like to speak to the Principal Investigator of this study, you are welcome to do so and Dr. Freedman's information is below.

If you would like to opt in or out of this study, feel free to let us know by calling the study coordinator, Haley Gagnon, at 617-632-6257 or email: haleyc_gagnon@dfci.harvard.edu. If we don't hear from you, we will try to contact you soon and look forward to chatting with you.

Questions? If you have any questions or comments about this study, or to report a study-related problem or injury, you are also welcome to contact Dr. Rachel Freedman from Dana-Farber Cancer Institute at 617-632-3800 or by mail at Dana-Farber Cancer Institute, 450 Brookline Avenue, Boston, MA. If you have any questions or comments about your rights as a research participant; or to report problems, concerns, or complaints, please contact the Office of Human Research Services at 617-632-3029, extension #6.

If you decide to participate in the study: This document will be reviewed with you and considered verbal consent. Our team will be sure you have a copy of this paper.

APPENDIX G – INFORMATIONAL EMAIL/FLYER FOR POTENTIAL PATIENTS FOR FOCUS GROUPS AND INTERVIEWS (Aim 1.1)

Are mammograms still right for me?

Goal of the Project

Breast cancer is a disease of aging. With our aging U.S. population, we will see more breast cancers in older patients. However, older patients are often not included in clinical trials that guide our care. This is part of the reason why there are still many unanswered questions about how we should follow older breast cancer survivors over time. The goal of this study is to better understand when it may be the right time to stop mammograms in breast cancer survivors over time –as patients age–and how to have these conversations with them. The benefits of mammograms become less as people age, while the risks of the test, such as false alarms, may increase.

What We are Asking from You

We have created an information tool to help women decide on whether having a mammogram is still right for them. We have also crafted a set of recommendations regarding getting a mammogram test. Now we would like to share this information with you to get your opinion.
Would you be available to discuss the tool and our recommendations with us? This would take about 45 minutes over the phone, for a one-on-one interview. You could also attend one of our focus group sessions in which a group of 6 to 8 people would get together to review all the information and tell us what they think.
In appreciation of your time, we would provide a $50 gift card at the end of the interview.
If you are interested, please let us know. We hope to hear from you!

Rachel Freedman, MD, MPH
Dana-Farber Cancer Institute
Boston, MA
617-632-xxxx or rafreedman@partners.org

Appendix H: Draft email to providers for patients potentially eligible for the pilot intervention (Aim 1.2)

From: Freedman, Rachel A., M.D., M.P.H. [or appropriate site PI]
Sent: Tuesday, August 07, 2020 3:29 PM
To: xx
Subject: potential patient for protocol 19-001, Individualizing Mammography in the Older Breast Cancer Survivor

Dear MD/NP/PA team:

I am writing about your patient, *(insert name)*, regarding Protocol 19-001, **which is study evaluating an information sheet for older breast cancer surivovors on the pros and cons for surveillance mammography** (PI: Rachel Freedman, MD, MPH [Dana-Farber]; co-investigators Meredith Faggen, MD [South Shore], and Philip Poorvu, MD [St. Elizabeth's]).

Per our medical record review, it seems that *Ms. XX is aged 75 or older, had breast conservation, and is in long-term follow-up care for her breast cancer. She is likely eligible for protocol 19-001.* As you may know, this is survey-based study where patients will be given an information tool to discuss mammography with you that can be used as you like and per your discretion. Patients will be surveyed before and after your visit on their mammography decisions and how the information tool may have helped/not helped them make decisions. Participants will receive $40 for their time. ***This cohort is purely survey-based and there is no therapeutic component to the study.***

If we do not hear from you within 2 business days, we will assume permission to initiate contact with the patient. We will mail your patient an introduction to the study and then call them a week later to assess their interest. If this patient is interested in participating, we will be responsible for consenting her and for all study procedures. **We will survey you at the end of the patient encounter via email and at the end of the study, you will receive a $40 amazon gift card in appreciation of your time.**

Thank you for your assistance and support of this study. Please feel free to contact us if you have any questions.

Sincerely,

Rachel Freedman, MD, MPH