A. Cover Page:

Project Title: *Improving the approach to and management of the older metastatic breast cancer patient via a provider didactic intervention*

Grant ID #: *NCCN and Pfizer Independent Grants for Learning & Change Metastatic Breast Cancer*

Organizations: Fox Chase Cancer Center (FCCC) and members of the NCCN Affiliate Research Consortium and their parent institutions:

	NCCN Member Institution	Affiliated Community Sites
1	Fox Chase Cancer Center	AtlantiCare Cancer Care Institute, Egg Harbor, Township, NJ Pottstown Memorial Medical Center Regional Cancer Center
2	Fred Hutch/Seattle Cancer Care Alliance	Bozeman Deaconess Hospital, Bozeman MT MultiCare Health System, Tacoma WA Confluence Health, Wenatchee, WA

Principal Investigator: Efrat Dotan, MD
Sub investigators: Breast cancer team at Fox Chase Cancer Center: Jennifer Winn, MD, Elias Obeid, MD, Matt Zibelman and Lori Goldstein, MD

Abstract:
Overall goal: Oncologists in the community are challenged with caring for older metastatic breast cancer (MBC) patients who present with a wide variety of concerns that are not directly related to their cancer, yet greatly influence their care. Geriatric patient self-assessment tools have recently been developed to assist the oncologist in carefully evaluating these patients and optimally managing their disease. However, these tools are rarely used in clinical practice. This proposal is aimed at increasing the awareness of the need for careful evaluation of older MBC patients among community oncology practitioners.
Target audience: As older patients are routinely seen community practices, our target audiences will be oncology providers in the community (nurses, physician extenders, and oncologists). We will conduct this study at the community affiliates of the NCCN Affiliate Research Consortium.
Methods: There will be 3 phases to this project: (1) needs assessment – evaluated by a questionnaire; (2) educational session – which will include a didactic session and a pilot study utilizing the geriatric patient self-assessment tool; (3) evaluation of barriers for implementation of geriatric assessment into routine practice – through a practitioners' questionnaire.
Assessment: This study will provide the oncology team at each institution with an educational session, and a hands-on pilot program for implementation of the geriatric assessment into routine management of older MBC patients. This project will allow us to assess the actual needs for these types of programs in the community oncology settings and the feasibility of implementing a geriatric patient self-assessment into a busy oncology practice.

B. Table of Contents:

C. Reviewer Comments

Not applicable.

D. Main Section of the Proposal:

1. Overall Goals and Objectives:

1.1 Project Description - Background: With the aging of the United States (US) population, the number of older patients with cancer continues to rise. The risk of breast cancer increases significantly with age, with 1 in 15 women over the age of 70 diagnosed with this disease [1]. Studies have shown that older patients with breast cancer have lower rates of receiving standard of care therapy such as breast conserving surgery in early stage disease [2, 3]. Under-treatment of older patients has been shown to increase disease-specific mortality and result in poorer outcome [4]. Furthermore, despite the large prevalence of breast cancer among older patients they remain under-represented in clinical trials [5]. Older patients pose a significant treatment challenge due to poor chemotherapy tolerance as a result of underlying co-morbidities, lack of social support, and diminished functional reserve. Oncologists are faced with the challenge of differentiating between patients that can and cannot tolerate chemotherapy, and tailoring therapy to the patient's biologic rather than chronologic age.

Three-quarters of older metastatic breast cancer (MBC) patients present with metastases as a result of hormone positive tumors and are commonly treated with endocrine therapies until evidence of refractory disease [6-8]. Endocrine treatments are considered safe and well tolerated in older patients. Chemotherapy is the treatment of choice for patients with hormone receptor-positive tumors that progressed through endocrine therapies, or hormone-negative tumors. Fit older MBC patients have been shown to have similar responses to chemotherapy and similar survival rates compared to their younger counterparts [9]. Most of the data available regarding the use of chemotherapy in older MBC patients comes from small retrospective studies and sub groups analysis of larger trials. Overall, most of these studies have shown benefit to chemotherapy use in older adults with acceptable tolerance in fit older patients [10-13]. HER-2 expression is seen in about 20% of MBC patients, with lower rates seen in older patients [14]. Trastuzumab has been shown to be safe in older patients, although close cardiac monitoring is necessary [15]. Data is lacking regarding the tolerance and benefit of novel treatments among older MBC patients. The lack of studies targeting older patients with MBC leaves the treating oncologist to make treatment decisions in the setting of limited data.

Comprehensive Geriatric Assessment (CGA), a composite of assessment scales evaluating physical, psychological, and social well-being, is the recommended tool for evaluating an older cancer patient and determining appropriateness of therapy [16-18]. The length of time and personnel required for CGA completion hinders its wide implementation into a busy oncology practice. Hence, most oncologists will use the Karnofsky (KPS) or Eastern Cooperative Oncology Group (ECOG) Performance Status tools for assessment of the older patient's fitness for therapy. These generic scales that are not specific to the older population may mislead the treatment decision and have limited ability to predict chemotherapy tolerance [19].

The CGA can provide a comprehensive multidisciplinary assessment of the patient's functional status, co-morbid conditions, nutritional status, sensory deficits, social support, psychiatric well-being and cognitive function [20]. As all of these factors may directly impact the outcomes of

older cancer patients, the CGA is considered the gold standard test for evaluation of these patients [21-24]. A prospective study of over 1,300 frail patients over the age of 65 that were hospitalized at 11 Veterans Affairs medical centers, demonstrated improved functional status and mental health among older patients undergoing geriatric evaluation and management compared to standard care without any increase in cost [25]. In the cancer literature, Chaibi et al. used a variety of scales to assess 161 geriatric oncology patients undergoing treatment. This CGA found severe co-morbidities in 46% of patients, dependence for at least one activity of daily living in 32%, cognitive impairment in 26%, malnutrition in 25%, and depression in 24%[16]. These investigators found that a CGA significantly influenced treatment decisions, including delaying, changing, intensifying or reducing therapy in 82% of study participants. A French study showed modification to the treatment plan in 38% of elderly cancer patients following a CGA [26]. Despite these supportive data, the CGA is rarely used in routine clinical practice due to time and personnel constraints.

Alternative screening scales and chemotherapy toxicity prediction models have been developed to overcome these limitations [19, 27]. One of these is a patient oriented Cancer Specific Geriatric Assessment (CSGA) tool developed by the Cancer and Aging Research Group (CARG) led by Hurria et al. [28, 29]. The patient can complete these assessments independently, with limited input from the treating team. Feasibility studies demonstrated the ability to include this assessment in clinical practice and research setting [17, 29]. Preliminary data evaluating the feasibility of using a computer-based CSGA in clinic resulted in 75% of treating oncologists finding this intervention helpful [17]. The NCCN Senior Adult Oncology Guidelines aim to introduce the oncology practitioner to practical tools that assist in the management and optimization of the care of the older adult with cancer [30]. By using these tools the providers can gain an accurate evaluation of the patient's physical, psychological and social state. Such information is critical for thorough determination of the risks/benefits that are associated with a proposed therapy, especially among older patients who have a different perspective of treatment-related risks. Studies have shown that older patients would decline even curative treatment that would render them with functional or cognitive impairment [31]. Using patient-focused tools can empower the patients and the practitioners to make a shared decision for a treatment that fits the disease, overall health and treatment goals.

In this project we will aim to address this gap in clinical practice with a didactic intervention that will provide the health care professional with hands-on experience of incorporating a thorough geriatric assessment into clinical practice. Our educational intervention will be directly focused on management of older patients with MBC, reviewing the various treatment options and specific consideration in this population. Our hope is that this intervention will incorporate patient-centered values that are not directly related to their disease into a shared decision-making process. By doing so, we will open a better patient-provider communication path, which will result in improved patient care and quality of life. Our goal is to develop a sustainable program that will be implemented at community centers and be used routinely after the completion of this study. Furthermore, the didactic session developed with this project could be used in the future to implement this intervention at other sites.

1.2 Overall Goal: To enhance the care of older MBC patients by increasing awareness among oncology providers to the geriatric assessment tools. This will be achieved through an educational program for community oncology health care professionals (MDs, NPs, PAs, RNs).

Aim 1: Evaluate the gaps that exist in clinical practice in the assessment and management of older MBC patients. <u>Hypothesis:</u> Oncology providers often struggle with the management of older MBC patients. Furthermore, significant gaps exist in the knowledge of available geriatric assessment tools among community oncology practitioners. <u>End point:</u> Defining the gaps to guide the development of a focused educational curriculum.

Aim 2: Develop and implement an educational session for oncology providers consisting of didactic and case-based content focusing on the management of older MBC patients. The educational program will highlight available geriatric assessment tools, their utility and incorporation into clinical practice, as well as specific consideration of the management of older MBC patients. The educational program will include a pilot session at each participating institution that will allow for hands-on experience with these assessment tools. <u>Hypothesis:</u> Educational sessions will improve the practitioner's knowledge of the appropriate approach to an older MBC patient.
<u>End point:</u> Improvement in the provider's knowledge of geriatric assessment tools and approach to the older MBC patient.

Aim 3: Assess the oncology provider's perspective of the geriatric assessment methods, and barriers to their incorporation into clinical practice. <u>Hypothesis:</u> Significant barriers exist that limit the wide incorporation of the geriatric assessment into clinical practice. <u>Endpoint:</u> Increased understanding of existing barriers that will be hypothesis-generating for future studies.

2. Current Assessment of Need in Target Area:
This project is aimed at increasing awareness of community oncology health care providers of the tools available for improving the management of older MBC patients. Older cancer patients will often receive care at community sites, as opposed to large tertiary centers, as a result of challenges with access to care, or limited social support. Despite a significant amount of data, and multiple guideline recommendations by NCCN and other groups, geriatric assessment is rarely used in a busy oncology practice [32, 33]. By educating practitioners of available tools that can be easily incorporated into clinical practice, we hope to increase awareness and improve the care of older MBC patients. Community-based oncology providers would be the ideal target population for the proposed educational intervention. Through a didactic educational session, and a hands-on pilot project, we will aim to provide the practitioner with tools that could be easily incorporated into routine practice and persist beyond the duration of this project. This will ultimately result in better assessment and care of older MBC patients. Furthermore, these NCCN community affiliate community oncology practices will serve as pilot sites for testing this educational initiative. This study would serve as the stepping-stone for development of an educational program that could be implemented to other sites beyond this research network.

3. Target Audience:

We propose conducting this intervention through the NCCN affiliate research consortium members, utilizing their community oncology sites (Table 1). Letters of support for this project from each of the participating sites has been included in this application. The intervention will be targeting oncology providers that routinely care for older MBC patients (MD, PA, NP, RN). Delivery of the educational program to all the members of the care team will facilitate the implementation of the assessment into daily practice. Our ultimate goal is to develop an educational curriculum that could be implemented at other community oncology sites beyond this target audience. The primary institution coordinating the project is Fox Chase Cancer Center (FCCC), a founding member of the NCCN. The team at FCCC has had significant experience working with community affiliates and previously published on quality assurance audits of NCCN guidelines in the community setting [34, 35]. The geriatric oncology team at FCCC, led by Dr. Dotan, has been involved in multiple research initiatives through the Cancer and Aging Research Group (CARG), and has vast experience with incorporation of geriatric assessment into clinical practice and research studies. Thus, FCCC has the tools and the expertise to develop and implement educational and quality improvement programs in the community. A dedicated research coordinator will be identified at each of the member institutions that will coordinate the implementation of the study at the affiliated community sites. There will be routine teleconferences held between the geriatric oncology team at FCCC and the research coordinators at each study site to ensure the appropriate conduct of the study, and timely completion of study goals.

Table 1: List of NCCN affiliate research consortium (ARC) members and their community oncology sites:

	NCCN member institution	Affiliated community sites
1	Fox Chase Cancer Center	AtlantiCare Cancer Care Institute, Egg Harbor Township, NJ Pottstown Memorial Medical Center Regional Cancer Center, Pottstown, PA
2	Fred Hutch/Seattle Cancer Care Alliance	Bozeman Deaconess Hospital, Bozeman, MT MultiCare Health System, Tacoma WA Confluence Health, Wenatchee, WA

4. Project Design and Methods:
4.1. Overall Study Design:

The overall study strategy is outlined in Figure 1. The study will have 3 Phases: (1) Needs assessment; (2) Educational intervention; (3) Final assessment. Each phase of the study is directly linked to our study aims (Figure 1). We are confident that through the 3 phases of this study practitioners will gain the necessary experience and understanding of the recommended approach to the older MBC patient. At the completion of this project, our goal would be to have an educational intervention that could be further disseminated to community practices that care for older cancer patients. The patient oriented CSGA is freely available online for use (www.mycarg.org). We believe that the educational intervention developed during the timeline of this project will prove to be useful and become publically available at no cost as a supplement to the assessment tools. The educational session will be developed by Dr. Dotan (a geriatric

oncology expert) and breast cancer medical oncology group at FCCC. This collaboration will ensure that the didactic session will provide the practitioners with an extensive overview of geriatric assessment and management of older MBC patients.

4.2 Aim 1 (Needs Assessment):

Evaluate the gaps that exist in clinical practice in assessment and management of older MBC patients.
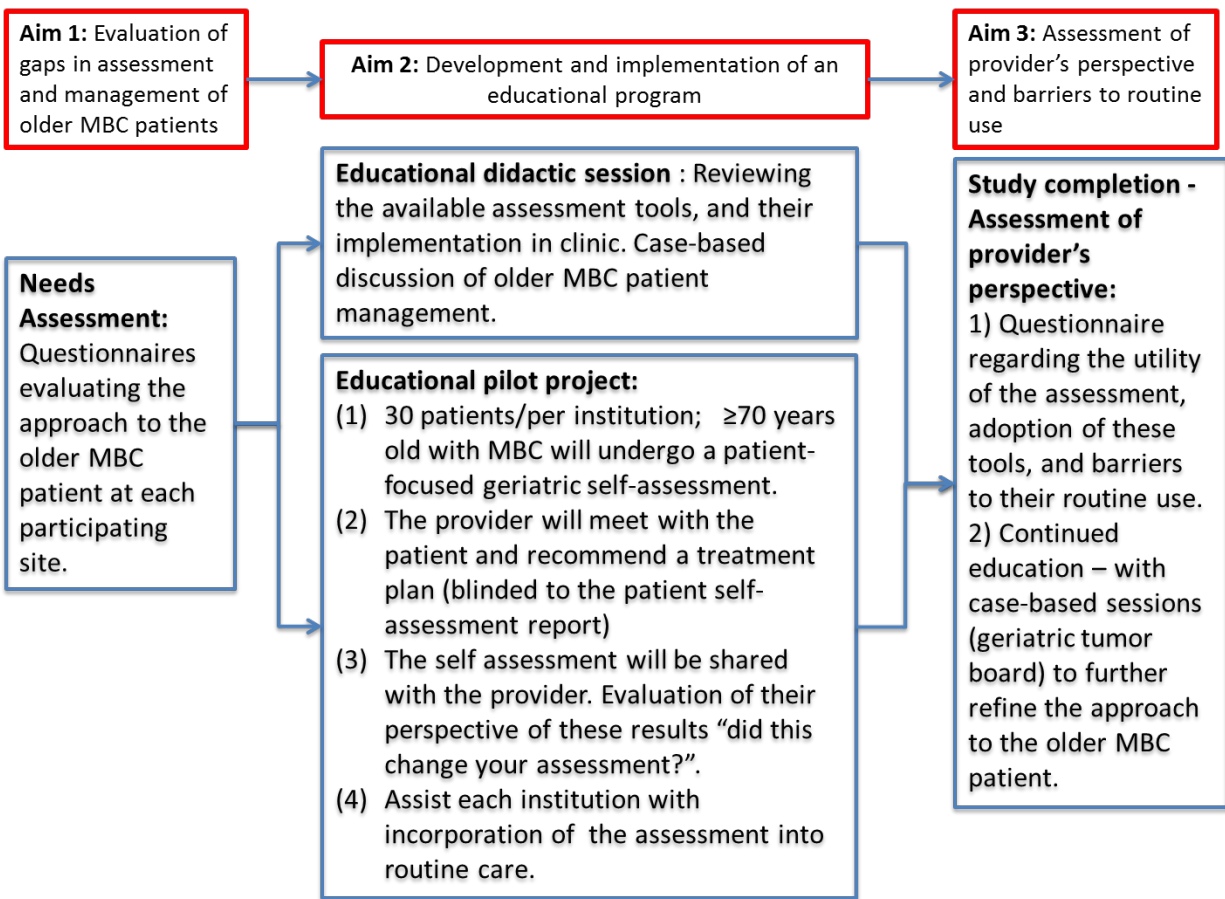
We hypothesize that a large number of older MBC patients are seen in community oncology practices and that providers struggle with management of these patients. We further hypothesize that providers have limited knowledge of available geriatric assessment tools. This phase of the study we will obtain information about each practice that will guide our educational intervention to fit the specific needs of that practice.

Evaluation Design: This assessment will be conducted using a questionnaire that will be disseminated to the healthcare providers who care for older MBC patients at each center. This questionnaire will evaluate the number of older patients with MBC seen in the practice, the usual treatment choices for these patients (with specific consideration to hormonal and HER-2 status), the provider's knowledge of the available geriatric assessment tools, and the degree to which these tools are used in clinical practice. For confirmation, information regarding the number of patients will also be obtained from institutional administrative data. The questionnaire will be completed in an electronic format, and the results will automatically be saved in our database to allow for rapid analysis of the data.

End Points: This assessment will provide a better understanding of the gaps that exist in the practice with regards to the care of older MBC patients. This will enable us to tailor the didactic intervention to fit the needs of the practice. Furthermore, we will be able to collect valuable data regarding the patterns of care of older MBC patients and the gaps that exist in the community. These data are quite limited in the literature and would be of high interest towards the development of a larger scale intervention program.

Statistical Analysis: Providers' needs and knowledge gaps will be assessed using descriptive statistics. We will stratify the results of the questionnaire based on the type of the provider (physician, nurse or physician extender) and based on the location of the practice. As the purpose of this aim is to gather information to inform an educational intervention, formal hypothesis testing will not be conducted.

Figure 1

| Aim 1: Evaluation of gaps in assessment and management of older MBC patients | → | Aim 2: Development and implementation of an educational program | → | Aim 3: Assessment of provider's perspective and barriers to routine use |

Needs Assessment: Questionnaires evaluating the approach to the older MBC patient at each participating site.

Educational didactic session : Reviewing the available assessment tools, and their implementation in clinic. Case-based discussion of older MBC patient management.

Educational pilot project:
(1) 30 patients/per institution; ≥70 years old with MBC will undergo a patient-focused geriatric self-assessment.
(2) The provider will meet with the patient and recommend a treatment plan (blinded to the patient self-assessment report)
(3) The self assessment will be shared with the provider. Evaluation of their perspective of these results "did this change your assessment?".
(4) Assist each institution with incorporation of the assessment into routine care.

Study completion - Assessment of provider's perspective:
1) Questionnaire regarding the utility of the assessment, adoption of these tools, and barriers to their routine use.
2) Continued education – with case-based sessions (geriatric tumor board) to further refine the approach to the older MBC patient.

4.3 Aim 2 (Educational Intervention):

Develop and implement an educational session for oncology providers consisting of didactic and case-based workshop focusing on the management of older MBC patients.

The second phase of the study is divided into two educational interventions:

(1) Didactic Session**:** This session will include an overview of the approach and management of older MBC patients through a case-based presentation. This one-hour long session will cover specific clinical issues associated with care of these patients (i.e. appropriate therapy for various types of MBC; use of routine drugs in older patients; special consideration when treating older MBC patients). In addition, we will review the recommended evaluation of older cancer patients through a geriatric assessment. Providers will be educated on the various geriatric assessment tools available. We will specifically review the patient-focused cancer specific self-assessment tool that was developed by CARG and the recommended evaluation of older patients suggested by the NCCN adult oncology guidelines [19, 32]. This tool is being used in multiple clinical trials and geriatric clinics across the country with good patient satisfaction and completion rates [29]. Summary of the domains tested and tools used by this assessment is outlined in table 2. Dr. Dotan and a member of the FCCC breast cancer team will deliver the sessions as web-based presentations to each institution individually.

Table 2: Patient focused cancer-specific geriatric self-assessment:

Scale/assessment tool	Administered by	Assessment
ECOG Performance Status	Treating physician	Functional Status
Activities of Daily Living subscale [36]	Patient	Functional Status
Instrumental Activities of Daily Living (IADL) [37]	Patient	Functional Status
Timed Up and Go test [38]	Clinical Research Coordinator	Functional Status
Number of falls in the past 6 months	Patient	Functional Status
Evidence of weight loss in the past 6 months	Patient	Functional Status
MOS Social Support Scale [39]	Patient	Social Support
Geriatric Depression Scale [40]	Patient	Depression
Montreal Cognitive Assessment (MoCA)	Clinical Research Coordinator	Cognition
Charlson Comorbidity Scale [41]	Clinical Research Coordinator	Co-morbidity
Pre-treatment BMI	Clinical Research Coordinator	Nutrition

(2) Pilot Project: The second part of the educational initiative will include hands-on experience with geriatric assessment tools in the clinic. Each institution will enroll 30 MBC patients over the age of 70. There will be no specific requirements regarding the type of therapy the patient is receiving or the length of time they have been treated. The patient will be asked to complete a patient-focused cancer-specific geriatric self-assessment. Studies have shown the feasibility of completion of this assessment in a clinic setting with mean time for completion of 27 minutes [28]. At FCCC we have developed an electronic version of this assessment on a tablet that is routinely used in our clinical trials [19, 42]. Studies have demonstrated the feasibility of delivering this patient self-assessment through an electronic medium [17]. We will give the patient the option of completing this assessment on paper or electronic format. Each site will be provided with a tablet that will have an electronic version of the assessment connected online to a central database. Once the assessment is entered into the tablet by the patient or study personnel (for those patients that completed the paper assessment) the data will automatically be saved in our central database. This will ensure maximal capturing of the data and allow for rapid analysis of the data at study completion. The web site containing this information will be a secured password protected web site, maintained by the FCCC team.

Evaluation Design: The provider, who will be blinded to the results of the patient's self-assessment, will determine the treatment plan. They will be asked to determine the oncologic therapy, as well as identify any other specific geriatric issues that require attention (i.e.: functional status, cognition, nutrition, psychosocial status, and social support). If such concerns are raised, the provider will be asked to recommend a treatment plan. Following the patient's encounter, the study team will review and summarize the patient's completed geriatric assessment. A report summarizing the full assessment will be shared with the provider. The provider will then be questioned about the utility of this information and its effect on the treatment plans (i.e. would you change anything in the patient's treatment plan? Would you refer the patient to other services?).

End Point: We will evaluate the effect of the geriatric assessment on the management of the older MBC patient. We will specifically evaluate the number of geriatric abnormalities detected by the geriatric assessment versus the standard oncologic evaluation and the percent of cases that the geriatric assessment prompted a change in the treatment plan.

Statistical Analysis: We will compare the number of geriatric abnormalities detected with the patient self-assessment to the number detected by the provider during standard oncologic evaluation. Based on the prior studies we anticipate that about 50% of the patients evaluated will have at least one geriatric abnormality detected by the CSGA [16, 43]. We further hypothesize that about 20-30% of patients will have abnormalities that are unlikely to be detected in a standard clinical evaluation (i.e. mild cognitive impairments, nutritional abnormalities, functional difficulties or psychosocial issues). We will test the proportions of patients having at least one abnormality detected by the CSGA that was missed in the standard clinical assessment compared to a null-hypothesis rate of 5%. With 30 patients at each site and 5 participating sites we will have a total of 150 patients. If within-site correlation is negligible, we will have 80% power to detect a rate of at least 11%, assuming a two-sided test with 5% type-I error. To account for clustering, we will estimate and test the proportion using an intercept-only logistic regression model with Generalized Estimating Equations (GEE) with robust standard errors. Data will be captured using descriptive statistics regarding the geriatric abnormalities noted within this population. We will also use logistic regression models, controlling for the effects of tumor type, stage, and type of provider. To account for the possibility of increased provider's awareness over time, we will also adjust for the number of prior assessments reviewed by each practitioner. In all models, we will account for within-site effects using GEE with robust standard errors.

We will further assess the percentage of cases in which disclosure of the patient oriented CSGA resulted in a change to the treatment plan. A change will be considered as any alteration to the treatment including: change of dose, treatment regimen, addition of supportive care measures or referral to supportive services. Reports from the literature are conflicting regarding the effect the geriatric assessment has on the treatment plan of oncology patients. A European study reported a change to the treatment in over 80% of patients based on the geriatric assessment[16]. Alternatively, a small study from the US found no change to the treatment plan based on geriatric assessment results [17]. We view a change in at least 20% of the cases as clinically meaningful, and thus elected to use this as our cut off. We will consider the geriatric assessment to be clinically useful if ≥20% (i.e. at least 30 out of 150) of patients' treatment plans are changed based on the results. There will be a 93% chance of seeing at least 30 treatment plans change if the true rate is high (25% or more). If the true rate is low (15% or less), the probability of seeing ≥30 treatment plans change is ≤16%. Descriptive statistics will be used to evaluate the type of treatment alterations that were documented (supportive care measures vs. change to the treatment plan), and we will compare rates of change across different age groups, tumor types (hormone positive versus HER-2 positive), and type of treatment planned (hormonal therapy, chemotherapy or radiation) using exact tests. We will also analyze this outcome using logistic regression models similar to those described for the primary objective.

4.4. Aim 3 – Provider's Perspective:

<u>Assess the oncology provider's perspective of the geriatric assessment methods and barriers to their incorporation into clinical practice.</u>

At the completion of the educational intervention, we will conduct a final assessment of the provider's view with regards to this educational intervention. We will further evaluate their plans for future use of the geriatric assessment and any barriers they can identify for incorporation of this assessment into routine patient care. We will complete the study with a "geriatric tumor board". This will be a session in which 1-2 cases identified during the pilot study will be reviewed in a webinar, and the recommended management of the MBC patient as well as any geriatric syndromes identified, will be discussed.

<u>Evaluation Design:</u> The assessment of the provider's perspective will be evaluated through a questionnaire that will be completed at the conclusion of the pilot phase of the study.

<u>End Point:</u> Defining the barriers that exist for routine incorporation of patient self-assessment CSGA into clinical practice. These data will be hypothesis-generating and will inform future studies aimed at improving the awareness of providers to the special needs of older MBC patients.

<u>Statistical Analysis:</u> The second physician questionnaire at study completion will inquire about the physician's perception of the patient oriented CSGA, and any barriers to routine utilization of this tool. Similar to aim 1 data from the questionnaires will be summarized using descriptive statistics, with stratification by tumor type and practice location.

4.5 Feasibility, Anticipated Challenges, and Solutions:

The incidence of breast cancer increases with age, and the majority of older patients with cancer are cared for in community centers rather than tertiary centers. Therefore, we believe that our goal for enrolling 30 older patients with MBC at each community site is quite feasible. One possible challenge is related to our target audience of healthcare providers (MD, PA, NP, RN) who may have time constraints that can impact their willingness to participate in our educational intervention and complete the questionnaires. Our goal will be to increase the provider's awareness to the utility of this intervention in improving patients' care and outcome and efficiency of caring for older patients. As this is expected to be an increasing number the patients seen in community practices, we hope to motivated practitioners to participate in this project. The questionnaires will be succinct and will not burden the provider or the patient. Each provider taking part in this study will be asked to complete 2 questionnaires over 2 years. The educational session will be scheduled with each site individually to maximize attendance. The session will be recorded and shared with the site electronically for those who were not able to attend. The study personnel will enter all assessments completed by the patient electronically to our database. During our pilot study, we anticipate that the 30 patients enrolled in each site will be distributed between 3-4- providers within that practice, which will limit the burden on the providers. Finally, each site will receive a financial incentive for participation in this program as detailed in the budget.

The main challenge of our study is related to the fact that it will be conducted in a remote fashion. Utilizing a local representative at each institution will facilitate conducting the study and will be

helpful in bridging logistic differences amongst institutions. In order for the study to run smoothly, a study manager will be employed by the FCCC team to work directly with the research coordinators at each site and ensure the timely conduct of the study. We will conduct teleconferences every 2 weeks with each site to review the study progress and coordinate each step of the project. We will leverage the IT department (population sciences department) to ensure good electronic connectivity to the participating sites. The study will require IRB approval for each participating site. For this reason we will allow 6 months to obtain IRB approval. The study will start at the time of IRB approval at each site. The NCCN affiliate research consortium has been developed specifically for conducting studies such as this one. In case one of the sites will not be able to participate in the project, we will contact one of the other NCCN designated cancer centers with affiliated community sites for opening the study. Alternatively, we will allow other FCCC partner community sites to take part in this initiative.

5.0 Evaluation Design: Dissemination plan:
This study will be conducted through the NCCN affiliate research consortium that will allow for testing of this pilot program in various community practices around the country. Through the 3 phases of our study, we will be able to obtain valuable information in the following areas:
1. Gaps that exists in practice with regards to the management of older MBC patients.
2. Our ability to increase awareness of oncology providers regarding the utility and benefit of geriatric assessment.
3. Barriers identified by healthcare professionals that would limit the incorporation of routine geriatric assessment into practice.

During the study period we will identify the specific gaps that exist in each practice and develop an educational intervention to match these gaps. The final questionnaire at the end of the study will allow us to analyze our success in addressing these gaps and identify barriers that remain. Our expectation is that all involved practices will benefit from incorporating a geriatric assessment into their practice and will find it feasible to use the tools provided. These data are of high importance to the oncologic community and would be hypothesis-generating for future clinical trials. We will publish our findings in national conferences and journals to further disseminate this approach. We are confident that with the approach outlined in this proposal, we will be able to disseminate the patient-focused geriatric self-assessment tool to the participating institutions and facilitate implementation of geriatric assessments into community oncology practices. Furthermore, the educational modules could be further disseminated into community practices outside the scope of this consortium.

6.0 Detailed Work Plan and Deliverables Schedule:
The project will span 24 months during which all 3 phases of the study will be completed. The initial 6 months will be used for protocol development, IRB approval, and development of the educational intervention and questionnaires that will be used in the study. The needs assessment phase will last 3 months, followed by 9 months in which each center will undergo the didactic session and the pilot hands-on intervention. The final 6 months of the study will be used for collecting the end of study questionnaire, conducting the final educational session, summarizing the results, and analyzing the data.

Table 3: Study Timeline:

0-6 months	6-9 months	9-18 months	18-24 months
1. Protocol development +IRB approval. **2.** Questionnaire and educational program development. **3.** Study initiation at participating sites.	**1.** Needs assessment at each site. **2.** Pre-study questionnaires regarding the management of older MBC patients.	**1.** Educational didactic session of geriatric assessment and management of older MBC patients. **2.** Pilot interventions with 30 older MBC patients at each site.	**1.** End of study questionnaires. **2.** Study completion, data analysis, and summary of the results. **3.** Continued educational session with geriatric tumor board.

The study will be conducted with robust support from our technology department at FCCC. We will aim to have all the providers and patients' assessments and questionnaires completed in an electronic form and directly saved on to our database. This will allow rapid data collection and timely analysis of the results.

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