A. Cover Page

1. **Project Title**: Optimizing patient engagement in reporting outcomes among women with metastatic breast cancer.

   **Grant ID number**: 2015ON1

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2. **Abstract**:

   **Goal**: A patient-centered approach to metastatic breast cancer (MBC) requires treatment that is supported by medical evidence, and tailored to patients’ needs and preferences. Unfortunately, patient reported outcomes (PROs), which facilitate decision making and treatment evaluation, are not routinely captured in clinical care, and are usually absent from medical records. Providers cannot optimally manage MBC without access to quality of life and PROs for patients undergoing treatment. To address this critical gap, we propose to develop a new approach to integrating the collection of PROs into clinical care, and creating a new tool for improving patient engagement, called “MY PROfile”.

   **Target population**: Patients with MBC receiving treatment at Smilow Cancer Hospital at Yale New Haven Hospital.

   **Methods**: We propose a mixed methods research study that employs both qualitative and quantitative approaches. In Phase I, we will conduct focus groups and interviews to determine which PROs should be assessed during MBC care, as well as the optimal PRO collection and sharing formats. Phase II will focus on the development of a patient “MY PROfile” tool based on results from Phase I, and then evaluating this tool using a sample of women with MBC.

   **Assessment**: In Phase I we will analyze qualitative data from patients to select appropriate PRO instruments and construct MY PROfile. We will also elicit feedback from medical oncologists to finalize the platform. In Phase II, we will assess the feasibility of incorporating MY PROfile into clinical practice, measure questionnaire completion and patient satisfaction, and conduct a medical record review to assess documentation of PROs.
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C. Reviewer Comments – N/A
D. Main Section of the proposal

1. Overall Goal & Objectives:
   Caring for women with metastatic breast cancer (MBC) requires a tailored approach, in order to address the patient’s social, physical and psychological needs. Assessing and incorporating patient reported outcomes (PROs) into treatment decisions and medical care embodies patient-centered care. Routine capture and review of PROs is essential for providers to have a full knowledge of potential treatment toxicities, and for patients to more effectively evaluate treatment effects on their quality of life. While this is applicable to all clinical practice, this is even more important when cure is not the ultimate goal, as is the case with MBC. However, PROs have not been captured in a standardized manner among women undergoing MBC treatment. This is particularly important for women with MBC; as more therapeutic options become available, there will an increasing need to determine how different treatments impact outcomes of importance to patients.

   This proposal is closely aligned with the needs described in the Metastatic Breast Cancer Request for Proposals. We aim to address a major gap in clinical practice, by enhancing clinician-patient communication to ensure better recognition and management of cancer and treatment-related toxicities. Specifically, the routine, complete collection and use of PROs relevant to patients and caregivers for patients with MBC is a major deficit in the current cancer care delivery system. Many providers, hospitals, payers, and advocates are discussing the collection and use of PROs. However, there is not enough information regarding how to best accomplish this. To address this critical gap, we propose to bring together a diverse team of providers and patients, to create an innovative approach to optimize the care of MBC patients through improving patients’ knowledge of and engagement in their care, and communication between providers and patients. Our proposal focuses on building stakeholder partnerships to facilitate the integration of PRO information into clinical care, in order to assess, manage, and mitigate adverse effects of MBC treatment.

Aim 1: To identify the optimal patient-centered approach to collecting patient reported outcome (PRO) data.
   Aim 1a: To determine PROs (i.e. quality of life, financial and emotional distress) that should be measured during pre-treatment assessment and at follow-up.
   Aim 1b: To determine the preferred interfaces to elicit patient responses to PRO collection instruments.

Aim 2: To ascertain patients’ and providers’ perspectives about the optimal approach to sharing PRO data with patients and their providers.

Aim 3. To develop MY PROfile, a patient-centered report based on the results of qualitative and quantitative analyses in Aims 1 and 2, which is accessible to both patient and providers and can be used enhance communication, and facilitate shared decision making.

Aim 4: To evaluate the feasibility of MY PROfile and its impact of on PRO assessment participation, patient satisfaction, and identification of new symptoms or quality of life concerns in a sample of women undergoing systemic therapy for MBC.
2. Current Assessment of need in target area

2a: Project Need

The Breast Center at Smilow Cancer Hospital within the Yale-New Haven Hospital (YNHH) system, together with the affiliated Smilow Care Centers, constitute the largest network of breast cancer providers in Connecticut. They offer a comprehensive range of services to patients ranging from diagnosis and treatment to recovery and survivorship for women diagnosed with breast cancer. With recent advancements in electronic health records (EHRs), all YNHH facilities use a common and integrated EHR system – EPIC. Patients receiving services through YNHH have access to a patient-portal (MyChart), a feature through which they can access their health records, including appointments, provider notes and laboratory results, as well as securely communicate with their providers. However, the current patient portal does not provide the opportunity for patients and their surrogates to routinely report on health-related quality of life measures. To address this gap in MBC care, we propose an approach to increase patients’ engagement in their care using patient-focused tools and strategies that help support shared decision-making. Our proposal focuses on building a patient portal that will facilitate the integration of PRO information into clinical care. PROs entered by patients will be available in the EHR and a summary report will be provided to the patient in order to enhance the quality and patient-centeredness of MBC care.

To date, patient EHRs have largely focused on the collection of clinical, demographic, and outcomes (treatment and survival) information. While patient health records provide an invaluable resource for clinical care, the “patient’s voice”, a very important consideration in the context of incurable disease such as MBC is most often absent. PROs represent this missing patient voice in EHRs. PROs capture patients’ self-reported health-related quality of life, provide short and long-term information about treatment and disease burden, and can only be obtained from patients and/or their families. Quality of life (QOL), including emotional distress, physical and financial burden, and other social support concerns are essential to comprehensively assessing MBC care, but are not routinely captured during a regular medical encounter. Patient health status in physician notes is often ambiguous and non-standardized, such as “patient is doing well”. It has also been shown that clinicians miss or underreport on symptomatic adverse events experienced by patients, and that both physical and financial toxicity may go unrecognized by providers. Most often physicians do not inquire about a patient’s financial stress as a result of cancer care. In the absence of this information, providers cannot adequately address the patient’s social, physical and psychological needs related to MBC. To emphasize the importance of QOL in the context of incurable disease, the American Society of Clinical Oncology (ASCO) introduce the notion of ‘quality adjusted survival’ in its 1995 recommendations. Yet QOL is not routinely captured in a standardized manner.

With the emphasis on patient-centeredness in cancer care, there has been increasing interest to collect and include PROs in EHRs and patient registries. PROs in clinical practice can improve symptom identification and patient satisfaction, make clinic visits more efficient and improve accuracy of symptom assessment. A very small number of large academic care
centers in the U.S. have introduced PROs into their Oncology clinical practice using electronic interfaces that feed the patient information into the EHR. Some of these electronic PRO systems include patientviewpoint, patient care monitor (PCM) and TELL US™. However, these PRO systems rarely provide information to the patient and to our knowledge, none of these reports was created in partnership with patients. Further, little is known about how these systems potentially impact patient satisfaction or quality of life. We propose an approach to engage patients in an effort to address an important gaps in MBC care at Yale/Smilow. By improving PRO collection and results sharing in a patient-friendly report (MyPROfile), we hypothesize that a patient-driven approach to designing the content, ascertainment strategy, and sharing of PRO data is not only feasible, but can increase patients’ ability to understand and influence their healthcare and their well-being.

Our overarching aim is to develop a new approach to collecting PRO information from patients and ensure that it is being used at the point of care to guide treatment decisions. The requested funding would enable the collaborators at the Yale Breast Center to devise a new approach, including a “MY PROfile” tool that can subsequently be used across Yale and disseminated to other care delivery systems. We view this initial funding as a critical step in yielding meaningful change in the delivery of MBC care.

*MY PROfile* will be developed using intense patient and provider engagement, and will be designed to specifically address issues of optimal patient/family participation in clinical decision when collecting PROs in a clinical setting (Figure 1), poor completion rates and follow-up, and to improve overall patient-centeredness in MBC care. Specifically, rather than the physician’s perception of the patient’s health status and quality of life being documented in the electronic record, where it resides in a form of a “black box” that patients never see (left side of Figure 1), the *MY PROfile* tool aims to ensure these PROs are a central part of interactions between physician and patient (right side of Figure 1). An individualized *MY PROfile* report will be generated each time patients completes their PROs. The specifics of *MY PROfile* such as formatting and information to be included will be determined in the initial phases of this project. Nevertheless, *MY PROfile* is designed to operationalize relevance, self-efficacy, choice and impact, all of which—together with health literacy— are crucial for patient empowerment and improved communication.

It is important to note that the proposed intervention aligns well with the areas of interest highlighted in the NCCN/Pfizer RFP. Specifically, we aim to develop and evaluate a new approach for: improving timely and effective communication with patients, supporting health care professionals in their efforts to address and overcome barriers to treatment (through recognition of physical of financial toxicity), and improving patient’s knowledge of and engagement in their care.
2b: Environmental Scan of Current Approaches

A major challenge to integrating PRO data into registries is that patients may frequently be unwilling, uninterested, or unable to complete the PRO data collection instruments. Initial efforts to collect PRO data, as part of clinical care, have found very low rates of patient adherence. For instance, the electronic Self-Assessment and Management (SAM) system piloted at Memorial Sloan Kettering Cancer Center and UCSF experienced 1-year response as low as 41%, despite relatively high (>70%) baseline response rates. In a large survivorship study in the UK, only 57.6% of individuals submitted complete PROs for all 3 time points requested, even though over 95% were still enrolled by the third time point. Novel approaches are needed to optimize patient willingness and ability to provide data, in order to ensure that important symptoms are relayed to their clinician and documented in the medical record. Despite general consensus recommending the measurement of key PROs, many practices lack the resources, infrastructure, and knowledge to be able to support this need. Patient engagement has been lacking in this area and may explain the low rate of meaningful use in clinical care and also in registries.

Our team has conducted preliminary work, which underscores the need for more robust assessment and documentation of PROs. As part of a national prospective study to assess chemotoxicity in non-metastatic breast cancer patients, our team has enrolled 48 breast cancer patients receiving care at YNHH, age 65 and above who have been treated with neoadjuvant or adjuvant chemotherapy. In pre- and post-treatment assessments, data on PROs is collected on all patients as part of the study. Although PRO questions were selected from standardized instruments, there was no patient input and these data were not included in the EHR nor were the summary scores communicated to the patients. Also noteworthy, we have observed the complete absence of PROs captured in our post treatment assessment in the provider notes.

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Our conceptual model of purposeful patient engagement is based on the Rowe and Frewer public engagement typology, which highlights the flow of information, with minimal distortion, between the patients and their families and clinicians as an indicator for the strength and equity of the engagement (Table 1). The lowest level is “communication,” in which there is a unidirectional flow of information from the clinician to patients. The inverse but more equitable stage of engagement is “consultation”, in which information flows from the patients to the clinicians. While this increases the voice of the patient, this level alone may lead to tokenism—where in our case, the patient is merely a set of symptoms, and has little influence after providing information. In Rowe and Frewer’s highest level of participation, “collaboration” the flow of information is bidirectional between patients and clinicians.
context of MBC would indicate the sharing of information between patients and clinicians to ensure the EHR has adequate components from both sources. Our proposed study will go beyond collaboration to build a “partnership”. Both patients and clinicians will be involved in identifying the PROs of interest to MBC patients to be included in My PROfile. Information on collected PROs will be available to both patients and clinicians, with the goal of enhancing shared decision making during MBC care.

There have been prior efforts to share PRO data with patients at the point of care. A Swedish Rheumatology Registry provided patients with a “summary overview” that could be given to patients immediately after supplying PRO data. American models such as the SAM of Memorial Sloan Kettering Cancer Center and UCSF also provided patients with reported data after completion. However, to our knowledge, these reports were not created in partnership with patients, nor empirically tested to determine the effect of its receipt.

3. Target Audience:
3a: Participant commitment

We have identified patient and stakeholder engagement as a crucial component for the successful implementation of this project. As such, stakeholder partners including our local breast cancer advisory panel and Smilow Cancer hospital providers, have been involved since inception of this project. We have also engaged advocates from local breast cancer support groups and they have agreed to engage in developing MY PROfile. All partners in this grant will attend monthly research team meetings either in person or by teleconference, to assess project progress. Finally, the proposed work has the full support from Yale-Smilow’s breast cancer leadership team (See letter of support).

3b: Target audience and stakeholders impact:

The target audience for our proposed work includes patients, their caregivers and families, providers, and administrative staff here at Yale-Smilow Cancer Center. During the first phase of our proposed project, patient groups will help determine the critical features of the registry to increase long-term participation—beyond simply the selection of which PROs are important, patients will be crucial in identifying the best format(s) for PRO collection, PRO information sharing, and to determine the components and layout of MY PROfile. Focus groups—which will be filled with the help of community recruitment activities—will be the initial level of contact on identifying key components of the patient platform. Quality improvement leaders at YNHH, providers and IT personnel will be represented in these focus groups. In the second phase, Smilow cancer hospital providers and patients groups will play a crucial role in patient participation. Documents developed for recruitment and consent will be developed with community groups, to help target the materials specifically towards individuals in the YNHH catchment area. Three months after the launch of MY PROfile for MBC patients, a PRO completion update will be generated to identify MBC populations and reason for non-participation. At the next monthly meeting, patient partners will meet with community members to determine how to best address non-participation to increase the representativeness of the MBC sample.
In the second phase, all patients with MBC receiving care at Breast Centers at Smilow Cancer Hospitals at YNHH who are able to understand English will be invited by providers during a treatment planning encounter to participate in the initial test of MY PROfile. Patients are eligible if they are undergoing systemic cancer treatment with any type of targeted agent, immunotherapy, or chemotherapy, and are within 12 weeks of initiating treatment with the specific regimen that they are receiving. We are restricting the sample to patients within 12 weeks of starting a regimen because adverse events and toxicity are more likely to begin within the first 12 weeks of starting a new therapy. Recruitment should be brisk, as many providers at the YNHH breast center are actively engaged in health outcomes research, several of whom are members of the Yale Cancer Outcomes, Public Policy and Effectiveness Research (COPPER) Center team.

3c: Potential beneficiaries

In an effort to improve care among patients with MBC, our interdisciplinary team of medical oncologists and COPPER’s experts in quality improvement and cultural diversity will be crucial in this effort to enhance our ability to incorporate PRO collection into patient care. We strive to have a local impact on patients and providers here at Yale, as well as a national impact on MBC care. Our project embodies patient-centered clinical care through patient engagement and improved patient-provider communication with the overall goal of improving patient care. If funded, not only will this project have substantial impact locally (in the Smilow/Yale Health System), but we intend to disseminate a “toolkit” that highlights this approach nationally, both online and at national conferences. We aspire to have a national impact.

Primary local beneficiaries from the project will be patients with MBC receiving care through YNHH as well as providers working at the Breast Center at Smilow Cancer Hospital who will have a new tool to tailor an individualized plan of care for patients with MBC. Our ultimate deliverable is a functional and user-friendly interface that is linked to the EHR and accessible to patients and providers alike; all patients receiving care through the YNHH system and YNHH providers will ultimately benefit. This additional clinical care tool can be used to improve care quality across the hospital system in other disease areas.

Our toolkit will outline the protocols we have developed to routinely capture and include PROs in the EHR and optimize patient engagement in PRO reporting. As a result, other hospital systems could use our toolkit and methods to develop similar patient platforms within their EHRs. We also intend to build upon the current proposal with a larger controlled prospective study to assess PRO reporting and patient satisfaction over a longer duration among women with MBC, and in patients with other cancers in the YNHH system. Other comparative effectiveness researchers could benefit from the availability of PROs in patients registries, in designing and assessing specific patient outcomes, as well as overall care quality metrics.
4. Project Design and Methods:

4a: Overall strategy

Our specific aims will be achieved using a mixed methods approach. Mixed methods research employs both qualitative and quantitative approaches to understand and measure constructs. We will initially focus on the collection and analysis of qualitative data on PROs of interest, and optimal PRO collection and sharing formats (phase I). Results from phase I will then guide the development of the patient platform for PRO collection and sharing, with the final approach to be determined by patient feedback. We will subsequently assess the feasibility and impact of the new MY PROFILE tool in sample of women with MBC (phase II). The team will be led by Dr. Cary Gross, who oversees the Yale Cancer Center Outcomes program as well as Quality Improvement effort in the Primary Care Center at Yale New Haven Hospital. Study Team will include individuals with expertise in implementation science (i.e. Director of Quality at Smilow Cancer Hospital) as well as clinical trials, and substantive involvement of patient partners.

4b: Addressing Established Need and Producing Results

The proposed work is addressing key needs of the MBC population in general, and specifically the patients being cared for by the teams affiliated with the Yale Breast Center at Smilow Cancer Hospital. In the first phase of our proposed project (Optimizing Patient Engagement and Participation in Reporting PROs), we will conduct focus groups with patient representatives from the local breast cancer support group, MBC patients and family members, Breast Center providers and IT personnel. Patient focus groups will be conducted to generate thoughts regarding specific PROs of importance to patients with MBC, methods of data collection, and how PROs should be shared with the patient.

After receiving input regarding which PROs should be assessed (Aim 1), we will then determine the optimal approach to sharing PRO data with patients and their providers in partnership with patients and stakeholders (Aim 2). In a second set of focus groups, we will elicit patient preferences about acceptable platforms for the MY PROFILE tool for sharing the data with patients and their clinicians in conjunction with providers and IT personnel, using different model platforms of MY PROFILE. These models will illustrate the different formats and presentation of the PRO measures such that information is user friendly for patients, easily understandable and actionable from a clinical perspective in regards to addressing QOL.

After completing the initial version of the PRO collection approach, and the MY PROFILE tool based on the information learned in Phase I, we will conduct cognitive interviews to refine and test the MY PROFILE tool to ensure it embodies patient centeredness with easily understandable information and an appropriate literacy level (Aim 3).

We will then empirically evaluate the feasibility of incorporating MY PROFILE into clinical care, as well as perform a preliminary assessment of the impact of MY PROFILE on longitudinal PRO
instrument response rates, patient satisfaction, and documentation of new symptoms or quality of life concerns in the medical record. Patients with MBC of any performance status, who are able to understand English and provide consent will be included in our patient sample to determine PRO assessment participation and patient satisfaction following cancer treatment. Eligible participants will be identified by the patient care team and recruitment will take place at the point of care, when the patients are required to complete a pre-treatment PRO assessment. All patients will receive MBC treatment at the discretion of the treating health care provider and their patient.

Upon consent to participate, MBC patients enrolled in the study will be contacted once before their scheduled three months follow up to complete PROs online. If individuals have not completed the questionnaires by the time of their visit, further outreach will take place before the visit, and if this outreach is unsuccessful, once more within 15 days after the visit. This gives patients a 30 day window to complete their PROs for that scheduled time-point. With help from our various engaged patient representatives, we will determine the most patient-friendly way to approach all patients.

The primary outcome of this phase of the project will be the response rate (patients completing >90% of PRO survey items at each time interval). In addition, participants will be asked to complete the Consumer Assessment of Healthcare Providers and Systems Survey for Cancer Care (Cancer CAHPS) after six months. Secondary outcomes will include the documentation in the medical record of new PROs or symptoms that impacted care (as described below in the “before-after” comparison of participants vs. historical controls).

Research ethics and Integrity: Each phase of the proposed work will not begin until after the Yale Human Investigations Committee reviews and approves the protocol. All participants will undergo an informed consent process prior to enrolling in the study. Participants in Phase II will be asked upon enrollment to sign HIPAA release and medical record consent forms to enable review of all of their medical records relating to receipt of care over the 6-month follow-up period. We will also obtain HIC approval for a medical record review of the 75 patients in the control group.

Fidelity to the proposed plan is of great importance to the team. All RAs will complete a training period under the supervision of the PI prior to data collection. The training will include review and discussion of the informed consent process and patient interviews and assessments. Similarly, the medical record reviews will be conducted by the physician co-investigators, with a training period and reliability checks performed independently on random charts throughout the study period.

4c: Ascertaining Engagement

We will work closely with our local breast cancer advisory council, MBC patients and Smilow providers (see participant engagement above). Our local breast cancer advisory council has expressed interest in greater patient involvement in breast cancer care decision-making and planning, and will be prominent in identifying focus group participants.
Engagement in Phase I: Patients and stakeholder engagement will be crucial in phase I of our project, as they will be key actors in the design of MY PROfile. They will help determine the critical features of the registry to increase long-term participation—beyond simply the selection of which PROs are important, patients will be crucial in identifying the best format(s) for PRO collection, PRO information sharing, and to determine the components and layout of MY PROfile. First, focus groups—which will be filled with the help of community recruitment activities—will be the initial level of contact on identifying key components of the registry. We will then go back to the larger community groups to elicit more feedback—in person—about the results of the focus group, i.e. have we reached theoretical saturation of ideas? What is missing? Finally we will work with our online communities (such as the her2community), and gather larger feedback via electronic surveys.

Engagement in Phase II: This project’s patient partners and collaborators will also play a crucial role in enrollment and retention activities of Phase II. First, recruitment and consent document will be developed with community groups, to help target the materials specifically towards individuals in the Yale-New Haven Hospital catchment area. Three months after the start of the study, an enrollment update will be generated to identify barriers to enrollment. At the next monthly meeting, patient partners will meet with community members to determine how best to address non-participation to increase the representativeness of the study sample.

4d: Originality of this idea

Innovation and patient-centeredness are the major themes of this proposal. Rather than seeking to implement currently available “best practices”, we seek to design a new approach to care. We propose an innovative approach to address an existing gap in MBC care at YNHH system – the systematic capturing of PROs. As mentioned above, a few large academic centers in the U.S. have launched electronic PRO capturing system and included data from PROs into their oncologic practice. None of this however is particularly tailored for patients with MBC, nor were the PRO questions selected with the input of the patients that will be completing these questionnaires. The patientviewpoint used by John Hopkins, for example, falls short of our approach because the provider selects the set of questions that are completed by the patient without any patient input.

Another important innovation of the proposed work is that we plan to take advantage of recent advances in technology to allow for rapid and convenient ascertainment of PROs. One example is the use of Apple ResearchKit©. ResearchKit is a mobile app development platform that allows for the creation of biomedical survey instruments and biometric tracking apps that can be disseminated via mobile phones and other portable platforms. Researchkit allows for consenting, and secure delivery of data from patient volunteers to researchers, and streamlines the process of obtaining and recording PRO data. Patients can directly download the app from the Apple App Store onto their mobile devices and immediately begin contributing data and receiving feedback in a secure and protected manner. Our group has already created a pilot app investigating the impact of prostate cancer treatment on patient reported quality of life that is in the process of beta testing. After obtaining consent via the mobile device, the app can
prompt patients on a regular basis to answer PRO survey questions. These scores can be tracked for the patient on their mobile device, and answers are downloaded onto a secure server. The creation of the app has involved a multistep process including software development (app development) as well as securing and managing a “triple lock” secure server appropriate for protected health information per our institutional standards for research data. Our proposed project will introduce this platform as a potential PRO reporting and sharing tool to patients and providers during our planned focus groups.

4e: Building upon existing work

As described above, we have identified a large gap in ascertainment of PROs among patients undergoing breast cancer care at Smilow (section 3b). Our proposal will build on an EHR system currently used by YNHH with a patient portal providing patient access to their health information. Our proposed project also aims to develop a PRO data collection system imbedded within the EHR, which is more patient-oriented and patient centered compared to some existing PRO systems currently in use at other academic centers such as the patientviewpoint and symptom tracking and reporting (STAR).19,20 These PRO reporting systems provide information to patients on changes to their PRO scores over time in the form of simple graphics, while STAR utilizes automatic reminders to complete PROs, but none of them engaged patients to identify disease specific PROs of relevance to the patient. Thus, to improve MBC care at YNHH, we propose to develop a set of PROs from standardized tools that are of interest to MBC patient with patient input and incorporate collection PRO information into the EHR in a format that improves patient-provider communication.

While we plan to use validated instruments to collect PROs, our proposed project will engage patients and stakeholders fully in the choice of PRO, mode of assessment (paper, tablet-based or web-based questionnaires) and presentation of information for the clinical encounter. This will be accomplished by using both qualitative and quantitative techniques mentioned above from our participants—both local and web-based. Outcomes we will include as possible PRO measures are general QOL, as measured by PROMIS or SF-36, cancer specific quality of life and symptoms such as Fact-B, auxiliary treatment measures of symptoms such as the FACT-ES for endocrine treatments in breast cancer, and symptom-based or financial toxicity to treatment (Table 2). Our protocol remains open to allow patient groups and partners to include other measures as they deem fit. In the case that currently validated instruments lack certain relevant items, we will draft additional items, pilot them to determine psychometric properties, and make them available both for the registry, and for future use.

| Table 2. Possible Validated Instruments to be Included in Registry |
|----------------------------------|------------------|----------|
| Validated Instrument             | Measure          | Items    |
| PROMIS Global Health Scale       | General Health   | 10       |
| SF-36                            | General Health   | 36       |
| FACT-B                           | Breast Symptoms  | 38       |
| FACT-ES                          | Endocrine Symptoms | 18  |
| COST                             | Financial toxicity | 11  |
| NCCN Distress Thermometer        | Emotional Distress | 1    |
| Cancer CAHPS                     | Patient Satisfaction | TBD |

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f. Dissemination: The patient platform for PRO collection and visualization, *MY PROfile*, will become part of the YNHH EHR system and will be available to all MBC patients and providers caring for patients with MBC. The other deliverable of our proposed project, a toolkit, will be made available to other clinical services within YNHH system and outside hospital systems that are interested in developing and integrating a similar PRO structure at no cost.

5. Evaluation Design

Metrics and Impact on Care

**Phase I Study Conduct and Evaluation:** We will conduct a series of 4 focus groups with MBC patients, each consisting of 4-6 participants. Participants will review different standardized PRO instruments measuring general and cancer-specific symptoms and QOL and be asked to discuss which instruments and items are most relevant and user friendly for their treatment decisions and cancer care. We will also ask the focus groups to review and select the best interfaces (web- or tablet-based) for completing these instruments in order to determine which method is most convenient (Figure 3). Transcripts from the focus groups will be analyzed to select MBC relevant PRO questions and the optimal PRO reporting interface. In the case of a tie, the full study team—including patient partners—will meet to reach a consensus about which instruments or interface to use.

Cognitive interviewing will subsequently be employed to elicit key information about the construction of *MY PROfile*.21 A convenience sample of MBC patients will be interviewed in order to identify cognitive issues with comprehension, recall or response processes for information presented in the *MY PROfile* document. We anticipate that a single round of testing (with 8-10 participants) will be sufficient, but will complete a second round if indicated. Individual interviews will be conducted in person by a trained research assistant and will be approximately one hour in duration. We will use the concurrent probe approach, in which the interviewer asks probes immediately after the respondent reads and reviews each series of related items on *MY PROfile* (for instance, after reviewing their summary score for each type of symptom or side effect that is reported). Comprehension probes include asking respondents to paraphrase a key phrase, define a term used in a question, elaborate on an aspect of their response, rate the clarity of a phrase or concept, and identify words or phrases that are difficult to understand. Upon completion of the first round of interviews, the research assistant will compile an annotated version of the *MY PROfile* tool that includes all of the relevant comments. This comprehensive document will be analyzed by research team members to identify recurrent problems across all interviews and potential resolutions. A second wave of interviews may be performed if revisions are substantial.

Upon completing of the initial *MY PROfile*, we will also perform two focus groups of medical oncologists and nurses who commonly treat MBC patients. Each focus group will consist of 4 to 6 specialists from a convenient sample from the YNHH system. The participants will be asked to review *MY PROfile* and discuss concerns and limitations of the tool with regards to
implementation in MBC care and successfully capturing PRO measures. Providers will also be asked to determine if, when, and how often responses to PRO measures should issue an “alert” to the providers, to highlight particularly problematic concerns. Following the focus groups, the investigators will modify *MY PROfile* and incorporate the relevant concerns from patients and providers. We will then preliminarily test the clinical integration on 5 to 10 MBC patients treated at the Smilow Cancer Center/Yale-New Haven Hospital. Any remaining issues with the successful clinical implementation of *MY PROfile* will then be addressed.

**Phase II Study Conduct and Evaluation** The design for this assessment will be a single-armed study, with a pre-post comparison based on medical record review. Specifically, 50 patients who consent to be enrolled will be asked to complete the PRO instruments prior to initiating a new course of chemotherapy. As mentioned above, we do have quantitative baseline data regarding routine capture and documentation of PRO from patients undergoing breast cancer therapy. Simply put, 0 of 48 patient charts reviewed had documentation that validated instruments were used to record PRO information.

After enrollment, patients will be followed for 6 months and will be asked to complete their PRO instruments at months 3 and 6. The primary outcome of this assessment is patient acceptance and satisfaction with the *MY PROfile* approach. Specifically, we will determine the proportion of women who completed their PRO instruments at each interval, and assess their satisfaction with care overall (using a modified version of the Cancer CAHPS instrument) as well as their satisfaction with their ability to discuss their health status with their health care team (using elements derived in conjunction with the focus groups in Phase I). Finally, we will perform a medical record review, in order to document the frequency with which new symptoms or quality of life concerns were addressed in the assessment and plan of portions of the medical record during the 3 and 6 month visit. We will compare the frequency of new concerns documented among the study participants with a group of medical records from 75 historical controls. The controls will be patients who otherwise meet eligibility criteria and started treatment during 2015; they will be matched to ensure that they were cared for by the same distribution of providers as the *MY PROfile* participants. We will assess differences in PRO ascertainment (through medial record review) and patient satisfaction between the historical control group and the study participants (Figure 2).
Last year, Yale Smilow Cancer Center and affiliates treated over 150 women with newly diagnosed MBC. After excluding those who do not meet our inclusion criteria we will have an adequate number of patients who agree to participate in our study. Patients will then complete MY PROfile at 3 months and at 6 months after initiating MBC care.

This project will have a measurable impact: For the assessment of patient experience, we will assess patient acceptability and feasibility among patients who enroll in our study sample. PRO questionnaire completion will be defined as fully completing questionnaires at baseline (pre-treatment), then at 3 and 6 months post treatment. Patient satisfaction will be measured using the Cancer CAHPS survey, plus additional instruments agreed upon while working with our patient representatives at 6 months. We will also include items exploring patient perceptions about our approach to ascertaining PRO information as well as their opinions about the MY PROfile tool. We will survey the oncology providers about their experience using the MY PROfile tool as well. In secondary analyses we will examine the independent associations with our primary outcomes and create multivariate models to adjust for confounding.

To compare the MY PROfile participants to routine care, we will perform a “before-after” comparison. Specifically, we will compare specific outcomes of the 50 women included in the study sample to a matched historical control of 75 women with MBC who were treated with systemic therapy at Smilow-YNHH or one of the affiliated care centers in the year 2015. We have selected this design rather than a randomized trial in order to include as many women as possible in the intervention arm, given the available funds. That is, rather than a RCT that assigns 25 women to each arm, this single-arm design will allow the most information about feasibility and impact of the MY PROfile approach to be obtained, from 50 participants in the MY PROfile group. Future work, after this foundational effort that will develop and refine the MY PROfile approach, can employ larger trials to assess the impact of MY PROfile.

For our before-after comparison, we will conduct a review of medical records to ascertain how often new symptoms and complaints including PROs were addressed in the assessment and plan of portions of the medical record at the visit closest to 3 and 6 months following initiation of MBC care. Specifically, the medical record pertaining to the office visit closes to each time points will be reviewed, to determine whether there were new concerns relating to symptoms, quality of life, or function (or other, similar PROs, as decided by the patient stakeholder groups in phase ) that are documented in the assessment and plan portion of the medical record. That is, each office visit note will be reviewed with a single question in mind “Was there a new PRO-related issue that was discussed during the visit, and mentioned in the plan of care?” Reviewers will be blinded to the intervention status of the patient notes (i.e. MY PROfile vs. historical control). Co-investigator (and breast cancer oncologist) Dr. Mougalian will oversee these abstractions.

We will compare study participants vs. historical controls regarding the proportion of patients who had a new issue addressed at each visit. Chi-square test will be used for these comparisons. We have estimated that with our sample size of 50 patient in the intervention group and 75 in the historical control group, we will have >80% power to detect a difference in the documentation of new PROs between the control and intervention arms, assuming a baseline 25% documentation rate and a relative risk of 2.0. We note, however, that the main
objective of this proposal is not to demonstrate the efficacy of the new PRO intervention in a statistically significant manner (which would require a large RCT), but rather to develop and gain initial assessments of the potential impact of the MY PROfile approach on clinical care, as Smilow seeks to increase PRO assessment throughout the continuum of breast cancer care.

Our analytic approach will also include patient-level multivariable logistic regression, to control for differences in patient sociodemographic and clinical characteristics. We will also compare satisfaction scores between participants and historical controls in a similar manner (using the patient satisfaction data that Smilow-YNHH routinely captures from breast cancer patients for our control group). We will dichotomize patient satisfaction scores and analyze according to “higher” vs. “lower” satisfaction). For each of these outcomes (documented incorporation of new PRO issues into care, and satisfaction), we plan to employ heterogeneity of treatment effect analyses on age strata (<45, 46 – 64, 65+); race (non-Hispanic white, non-Hispanic black, Hispanic, other); and literacy level to determine differential impact of MY PROfile. We recognize that the sample size may be too small to draw definitive conclusions across subgroups, but this information will be used to inform subsequent design modifications, and larger studies.

c. Overall Impact & Dissemination Plan

Our ultimate deliverable will be a functional and user friendly interface that is accessible to patients and providers. We will also develop a toolkit outlining protocols to routinely capture and include PROs in the EMR and optimize patient engagement in PRO reporting. We plan to disseminate our project deliverables in multiple domains. We will approach academic dissemination through peer-reviewed articles. For public dissemination, we will share results through institutional and local press releases and newsletters. The toolkit will clearly outline our protocol, results, and research suggestions in a comprehensive manner to allow for the protocol to be evaluated in other disease settings. We also intend to build upon the current proposal with a larger controlled prospective study to assess PRO reporting and patient satisfaction over a longer duration among women with MBC, and other cancers in the YNHH system.
6. Detailed Work plan and Deliverables Schedule:

The first year of our proposed project will be devoted mostly to Phase I. We will conduct focus groups with patients and providers, and also perform initial testing of our proposed PRO collection and sharing platform, \textit{MY PROfile}. In the second year, we will focus on the second phase of the project, enrolling patients who will complete the developed PRO assessment questionnaire for MBC through \textit{MY PROfile}, and collecting data from medical records on symptoms reporting and management. During the first part of the second year, we plan to report our findings from the qualitative part of our proposed project as well. In the last half of the second year we will develop our proposed tool kit for PRO integration into electronic records and report our findings from the quantitative phase of the project.

Table 3: Work plan and deliverable schedule

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<tr>
<th>Quarter</th>
<th>Year 1</th>
<th>Year 2</th>
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<td>1</td>
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<tr>
<td><strong>Phase 1 Implementation</strong></td>
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<td>Aim 1: Design patient-centered approach to PRO collection</td>
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<td>Aim 2: Design patient-centered approach to sharing PRO information</td>
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<td>Aim 3: Development and cognitive testing of \textit{MY PROfile}</td>
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<td><strong>Phase II Implementation</strong></td>
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<td>Aim 4: \textit{MY PROfile}</td>
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<td>Finalize Protocol</td>
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<td>Enrollment</td>
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<td>Follow-up</td>
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<td>Analysis</td>
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<td><strong>Milestones</strong></td>
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<tr>
<td>1. Descriptive report of qualitative findings</td>
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<td>2. Release of final \textit{MY PROfile} report</td>
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<td>3. Manuscript of Phase I results</td>
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<td>4. Enrollment Update</td>
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<td>5. Release of Patient-centered Registry toolkit</td>
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<td>6. Manuscript of study results</td>
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E: References


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