

## **Developing a medication assistance program for uninsured and underinsured patients with metastatic breast cancer**

### **Organizations:**

**The University of North Carolina at Chapel Hill** (Lineberger Comprehensive Cancer Center; School of Public Health; School of Medicine; School of Nursing; UNC Health Care Systems)

**HarborPath, Inc.** (a non-profit organization that facilitates the provision of free medications to qualified low-income patients)

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### **Abstract:**

With cancer care costs rising rapidly, patients are often burdened by the cost of their treatments, yet financial toxicity is rarely discussed in the clinic setting, and many patients and providers have little guidance as to where to turn for assistance with this burden. As a result, many cancer patients and their families face difficult decisions on their own, foregoing, skipping, delaying, or discontinuing potentially life-prolonging cancer therapies in light of competing financial demands. Medication assistance programs directly serve patients to help them afford treatment, but these programs are often unknown to patients and providers, unequally distributed across geographic regions, cumbersome to use, ineffectively coordinated, and/or logistically difficult to navigate. In this study, clinicians and public health investigators will partner with HarborPath, a non-profit organization serving uninsured and underinsured individuals, to adapt for the metastatic breast cancer (MBC) setting a successful existing medication assistance program that can effectively coordinate services and fill the medication gap in a timely manner. Our overarching goal is to develop medication assistance programming that optimizes outcomes for MBC patients (MBCPs) and can be disseminated regionally and nationally. Our specific objectives are to: (1) assess medication needs and financial toxicity among MBCPs; (2) map the processes by which patients, their caregivers, and their providers attempt to access financial support; and (3) develop a rigorous implementation and evaluation plan for expanding a novel medication assistance program in the context of existing care coordination and navigation services.

**Table of Contents**

- Table of Contents.....2
- Overall Goal & Objectives.....3
- Current Assessment of need in target area.....4
- Target Audience.....6
- Project Design and Methods.....8
- Evaluation Design.....16
- Detailed Workplan and Deliverables Schedule.....17
- References.....18
  
- Organizational Detail.....22
  - Organizational Capability.....22
  - Leadership and Staff Capacity.....23
  
- Budget Narrative.....25
  
- Staff Biosketches.....30
  
- Letters of Commitment.....61
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## **Overall Goal and Objectives**

**Rationale:** With cancer care costs rising rapidly, patients are often burdened with distress over the affordability of their treatments (1-3), yet very rarely do physicians discuss cost and patients' access to medications during medical encounters (1). As a result, many cancer patients and their families face difficult decisions on their own, foregoing, skipping, delaying, or discontinuing potentially life-prolonging cancer therapies in light of competing financial demands (1, 2, 4). Cost-related non-initiation and non-adherence to guideline-recommended treatments may have dire consequences for patients' health. Government programs providing deep discounts on drugs (e.g., the federal 340B program) have extended financial benefits to providers rather than indigent patients (5). Medication assistance programs, by contrast, directly serve patients to help them afford recommended treatments (6-8), but these programs may be unknown to patients and providers, unequally distributed across disease areas and geographic regions, cumbersome to use, ineffectively coordinated, and/or logistically difficult to navigate (9, 10).

**Overall Goal:** Our overarching goal is to improve access and adherence to recommended medications for uninsured and underinsured patients with metastatic breast cancer (MBC). We aim to reach this goal by tailoring and implementing a novel medication assistance program in the context of existing care coordination and navigation services. In this proposed study, clinicians and public health investigators at a large academic medical center that serves a highly diverse patient population will partner with HarborPath, a non-profit organization serving low-income individuals, to inform the adaptation of a medication assistance program for uninsured and underinsured metastatic breast cancer patients (MBCPs). Our specific objectives are to:

1. Assess needs, gaps, and processes of accessing MBC medications, with a focus on the role of financial toxicity in treatment-related decision making among uninsured and underinsured patients
2. Map processes by which patients and families, oncology care providers, navigators, social workers, and others attempt to identify and access financial support for uninsured and underinsured MBCPs
3. Develop an implementation and evaluation plan for a tailored MBC medication assistance program
  - a. Formulate a strategy to implement the medication assistance program within existing oncology care coordination and navigation services, considering organizational capacity and constraints, operational and logistical feasibility, technical support and training, and education and outreach needs
  - b. Devise a strategy for evaluating program implementation success, including a system for monitoring patient applications and drug delivery, educating oncologists and other providers about this resource, understanding operational efficiency and reach, and tracking outcomes

## **Current Assessment of Need in Target Area**

### **Problem Statement and Rationale for Proposed Study:**

The rising cost of cancer care is an increasingly recognized problem, not only on a societal level, but as a potentially devastating facet of the cancer experience for individual patients (11). Recent studies suggest high levels of financial distress, financial crises such as bankruptcy (12), and worry about finances among cancer patients. This financial toxicity has been shown to adversely affect cancer patients' quality of life (13). Prescription drug costs account for roughly 36% of cancer patients' out-of-pocket health care costs (14) and studies indicate that treatment-related costs are a key barrier to cancer treatment (15, 16). Financial burden may prompt patients to adopt potentially harmful care-altering strategies such as not filling prescriptions or taking less medication than prescribed (17).

Having health insurance does not necessarily protect against financial distress associated with cancer, as many insured cancer patients experience some degree of underinsurance. For example, one study found that 42% of insured cancer patients reported significant or catastrophic financial burden (2), and a large majority had applied for copayment assistance for medications. Cancer patients with higher co-pays are 70% more likely to discontinue their medication and 42% more likely to be non-adherent (18). As the global problem of financial toxicity in cancer patients becomes clear, more specific and in-depth studies are urgently needed to better understand the extent of medication assistance needs in specific cancer patient populations. Additionally, studies are needed to examine which interventions may best relieve this toxicity and how patients can access them most effectively.

Many patients report wanting to discuss the costs of treatment options, but not having had such conversations with their doctors (19, 20), possibly because cost and benefit information is often opaque to providers as well as patients, and/or because providers do not know where to direct their patients for financial assistance. No studies, to our knowledge, have examined the processes of delivering financial assistance for medications to uninsured or underinsured cancer patients, or identified targets for process improvements.

### **Medication Assistance Needs in Metastatic Breast Cancer Patients:**

Uninsured and underinsured women with MBC are a particularly compelling population in which to expand medication assistance programming because: (1) uninsured and underinsured women are more likely than women with comprehensive insurance to be diagnosed with MBC (21-23); (2) the relevant treatments and palliative/supportive care costs can be prohibitively expensive for many patients (24); (3) high cancer treatment costs can deter cancer patients from adhering to treatment (18); and (4) other important support services (e.g., supportive care for treatment-related side effects, education, lay patient navigators) are commonly used in the metastatic setting and may provide opportunities to introduce medication assistance options.

In the US, approximately 155,000 women currently live with MBC (25). Compared with their stage I-III breast cancer counterparts, MBCPs are more likely to be African-American/Black, lower income, and uninsured (21-23, 26-28). Moreover, cancer patients who are racial/ethnic minorities are more likely to report cost-related barriers associated with

medications (15). Characteristics of the MBCP population highlight persistent and overlapping disparities in disease burden and treatment access by race/ethnicity and socioeconomic status.

MBCPs may be a particularly high-need population with regard to medication assistance because they are often treated for an indefinite duration and change treatments frequently (including transitions between oral and infused therapies). The frequency of treatment changes and the different insurance coverage provisions for infused versus oral therapies in most plans may create a particularly complex financial picture for these patients to navigate. MBCPs are a particularly well-suited group for the study of treatment-related financial burden because they have a relatively long survival time as well as a number of effective treatment options in the metastatic setting, leading to a high need for navigation and assistance through treatment transitions. Medication costs constitute about 51% of medical care costs among MBCPs receiving chemotherapy (24), yet little is known about MBCPs' out-of-pocket medication costs, the extent of their medication assistance needs, or the process for delivering medications to uninsured and underinsured patients in this population.

### **Metastatic Breast Cancer and Medication Assistance Needs in North Carolina:**

North Carolina is an ideal state in which to examine these issues because of its large size, racial/ethnic and socioeconomic diversity, and profile of cancer burden. Of North Carolina's 9.9 million residents, nearly 30% are minorities, and 22% are African American compared to 13% African American in the overall United States, slightly over a quarter are college-educated, and 18% of people live below the poverty line (29). State-specific estimates of metastatic cancer burden are limited due to lack of systematic collection of information on recurrences and metastases by cancer registries. However, based on mortality data from the North Carolina Central Cancer Registry, using data from 2009-2013, a total of 6,373 women died of breast cancer in North Carolina, the vast majority of whom would have had metastatic disease. Many more women in North Carolina are living with and being treated for MBC.

Moreover, compared with MBCPs in several other states, North Carolinian MBCPs face additional barriers to adequate insurance coverage and affordable chemotherapy options due to state legislature opposition to Medicaid expansion and "oral chemotherapy parity" laws which would make oral chemotherapy more affordable (30). The North Carolina Cancer Hospital (NCCH) remains the state's only public cancer hospital, treating patients from every county in North Carolina. During the 12 months immediately preceding this application, 402 new patients with MBC were seen for new patient visits at the NCCH, of whom approximately 30% were non-white. At least 8% had no reported insurance, although others are likely to have no or insufficient coverage for oral medications and/or unaffordable co-pays. These patients are only a partial sample of all prevalent MBCPs currently under treatment at NCCH. However, to date, there has been no comprehensive assessment of the needs, gaps, and delivery of medications to uninsured and underinsured MBCPs at the NCCH, which treats the largest proportion of North Carolina's uninsured and underinsured MBCPs.

There is an urgent need for research on the medication assistance needs of MBCPs and their providers as well as the development of support tools that (1) match patients to resources for medication assistance, (2) can be delivered broadly across a variety practice settings, and (3) are user-friendly enough to facilitate discussions between patients and providers about addressing financial barriers to treatment. Examining these issues in the NC context provides a

ripe opportunity for expanding knowledge on these topics, improving access to much needed medications, and enhancing quality of life and clinical outcomes in MBCPs.

### **Target Audience**

#### **Participant Commitment and Recruitment:**

As previously discussed, minority women, uninsured women and low-income MBCPs experience disproportionately higher morbidity and mortality. Therefore, the identified target population of this project includes racial and ethnic minorities, uninsured and underinsured, and low-income MBCPs who are currently either in active treatment or require post-treatment surveillance and support. These patients represent approximately 22% of the total breast cancer case population that the North Carolina Cancer Hospital (NCCH) serves.

Commitment from potential participants (both patients in Objective 1 and system stakeholders in Objective 2) is evidenced by support from the following resources and entities, which have committed to assist with patient recruitment and/or systems process mapping and implementation planning (see **Letters of Support**):

The NCCH has a robust nurse navigation program with 3 full-time nurse navigators working in the breast cancer clinics. The nurse navigators work closely with MBCPs supporting and addressing education, clinical and symptom management concerns, and supportive care needs, including referrals to financial counseling, throughout the continuum of care.

The UNC Volunteer Program has played a significant role in further developing a model of patient navigation utilizing volunteers. Since 2013, the NCCH has been recruiting volunteers to serve as lay patient navigators within the breast cancer clinics. Additional training and ongoing education is required in order to help these volunteer navigators develop confidence with providing additional non-clinical support. This includes the identification and resolution of barriers to care for patients facing a breast cancer diagnosis. Navigators are equipped to refer patients to additional resources to address barriers to care including financial obstacles.

The UNC Health Care's Charity Care Program (CCP) provides medically necessary health care to the citizens of North Carolina, regardless of their ability to pay. Although CCP financial counselors are available to guide and assist patients, the process of identifying and linking patients to financial assistance resources (e.g., HarborPath) is often fragmented, circuitous, and frustrating for patients, caregivers, and healthcare staff. Thus, partnering with the CCP to identify existing pathways, gaps, and obstacles to financial support is essential to improving the care process of uninsured and underinsured patients.

The UNC Pharmacy and Medication Consultation Program supports pharmacists and other pharmacy professionals in providing one-on-one counseling with patients regarding their medication plan, including drug interaction and symptom management. This program will be a key partner in this study, as prescribed treatments for the MBCPs often change, thereby impacting dosage schedules, side effects, and patient out-of-pocket costs.

#### **HarborPath's Existing Resources and Experience:**

HarborPath is a not-for-profit 501(c)(3) that was launched in 2012 with the mission of providing streamlined and improved access to medications for uninsured people living with chronic illness. Recognizing the existence of many barriers to medical care for the uninsured living primarily at or below the Federal Poverty Level, the initial program was designed to efficiently serve those living with HIV/AIDS through development of an online portal. The portal provides a single application to access multiple medications from participating manufacturers, and is used by healthcare professionals on behalf of their uninsured patients. Much time is saved by case managers who typically need to fill out individual patient assistance program applications for each manufacturer, which can now be requested efficiently in one place, at one time. Patient eligibility is determined upon application submission, and medication is shipped out within 48 hours directly to the patient or healthcare facility (Figure 1). Refills can be processed easily through online requests by case managers. HarborPath is currently working to expand its medication assistance program into the cancer setting and recently received a small pilot grant to modify its existing web-based portal to support this oncology expansion. In order to achieve its mission, HarborPath relies upon: (1) strong relationships with clinical and supportive care partners to provide high-quality and efficient patient-focused services in a timely, confidential and dignified manner; (2) effective collaborations and communication between its pharmaceutical partners and patient stakeholders; and (3) cutting-edge technologies and innovative approaches to maximize the reach and benefits of its programming. HarborPath has become known as a safety-net solution for the uninsured due to the portal program's quick response and fulfillment time. Data from the portal are used to report on medication adherence and patient demographics, which can be expanded or modified to collect data for any disease.

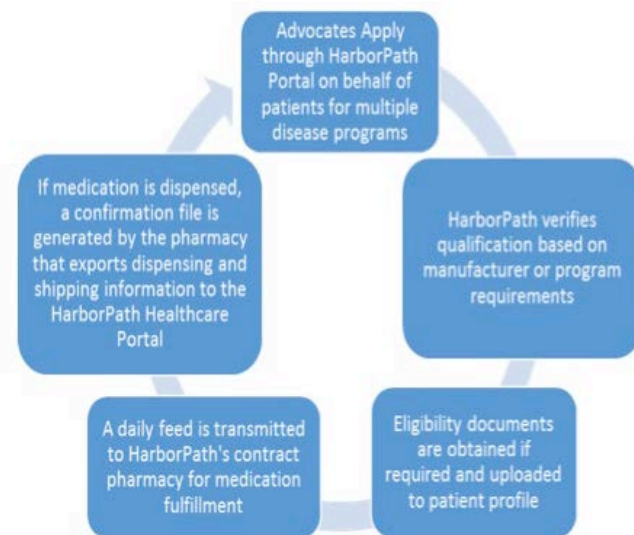


Figure 1. HarborPath's health portal overview (fully HIPAA compliant)

#### Linkage between Target Audience and Project Goals and Objectives:

Implementing a tailored MBC medication assistance program has the potential not only to improve patients' access and adherence to much needed medications, but also to reduce financial distress, optimize clinical outcomes (including quality of life), and enhance patients' overall satisfaction with their healthcare experience. A collaboration with HarborPath will enable us to incorporate a streamlined, coordinated medication assistance program into the current cancer navigation program at UNC, with the long-term goal of expanding these services and lessons learned throughout the Southeast and nationally (as HarborPath has done successfully with HIV/AIDS programming).

#### Expected Target Population Impact:

This research has the potential to: (1) elucidate and refine the operational/logistical processes needed to deliver integrated medication assistance programming within the oncology setting; (2) quantify the benefits of medication assistance for uninsured and underinsured MBCPs; and (3) improve coordination of care for indigent cancer populations by addressing an important barrier to high quality cancer care—financial access. In the long-term, the results of this evaluation will be used to plan for the dissemination and implementation of oncology medication assistance programming for patients in need in other care settings (e.g., the Southeastern Cancer Control Consortium) and with different types of malignant disease (e.g., leukemia), with the potential to reduce disparities and improve health outcomes across a range of patient populations (See **Dissemination** section for further specific details).

## **Project Design and Methods**

### **Overall Strategy, Methods, and Analytic Plan:**

#### **1. Assess needs, gaps, and processes of accessing MBC medications**

**Study Design.** We will employ a mixed methods approach to understand quantitatively and qualitatively the experiences of MBCPs seeking cancer treatment, as related to medication assistance needs/gaps. Specifically, this objective will involve 2 phases: (1) surveying MBCPs (or their caregivers as proxies) regarding medication costs (oral and infusion chemotherapy, as well as supportive medications) and how women access resources to support paying for medications, knowledge of existing assistance programs and resources, the importance of financial concerns in their treatment decision making, and sociodemographic characteristics, including insurance status during treatment; and (2) conducting semi-structured interviews with a subset of uninsured and underinsured MBCPs regarding the extent and impact of financial concerns on treatment-related decisions, the processes by which they attempted to access charity care or other medication assistance resources, and their reactions to, and recommendations for, a coordinated medication assistance program (like HarborPath). These data will be systematically analyzed (further described below) and will inform the process mapping approach (Specific Objective 2) as well as the adaptation of HarborPath program design and selection of appropriate evaluation metrics (Specific Objective 3).

**Population and Recruitment.** Phase 1 will involve recruiting 200 women of all ages, races, and insurance statuses with MBC (or their caregivers as proxies), who are affiliated with the Metastatic Breast Cancer Network (MBCN), to participate in a survey. The MBCN is a “national, independent, nonprofit, patient advocacy group dedicated to the unique concerns of women and men living with metastatic breast cancer” (<http://mbcn.org>), providing these patients with educational resources on treatments, coping strategies, and supportive care, including information about financial assistance. However, MBCN does not provide direct financial assistance or advocate on the behalf of, or advise, patients. Therefore, a partnership with our team and HarborPath is a natural extension of MBCN’s activities. We will send an email (and up to 3 reminder emails) to each eligible participant, inviting them or a proxy to participate in our 20-25 minute online survey about the financial impact of cancer on their lives. Survey participants will receive a small incentive (\$10 gift card) for participation.

Phase 2 will involve conducting semi-structured, in-depth interviews with uninsured and underinsured MBCPs (N=24 total) receiving care at the NCCH. For the purpose of this study, we



will define “underinsured” as anyone with insurance who reports some or a lot of difficulty paying for medical bills (deductibles, copays, co-insurance). We will use two approaches to recruit patients: (1) fliers in the breast cancer clinic and other areas within the NCCH (e.g., restrooms); and (2) targeted recruitment of patients using the breast cancer clinic staff. In the latter case, clinician members of our team (i.e., Drs. Muss and Reeder-Hayes and Ms. Sellers, RN) will flag MCBPs who may be eligible for participation. The Project Coordinator will then contact those patients at a clinic visit or via phone call to tell them about the study. If patients indicate interest in participating, the Project Coordinator will screen them to determine their insurance status and if insured, whether they experienced financial hardship in meeting their insurance plan’s obligations for premiums, deductibles, copays, or coinsurance as a result of their cancer diagnosis. The Project Coordinator will work with patients (or their caregiver proxies, where appropriate) to schedule 30-60 -minute interviews.

**Quantitative Survey Items.** We will design our online survey with assistance from the Odum Institute, which provides survey methodology consulting services, including survey design (e.g., measure selection and layout), data collection, and psychometric and statistical analysis for a range of social sciences studies ([www.odum.unc.edu](http://www.odum.unc.edu)). We will focus on the following survey domains: (1) demographic and socioeconomic information, including insurance coverage; (2) cancer treatment; (3) financial concerns in cancer treatment decision making; (4) financial toxicity of cancer, including impact on patient’s and caregiver’s psychosocial wellbeing; and (5) utilization of financial support services and communication with providers concerning costs and access to medications. We will use existing and validated instruments, where possible, to capture these domains. Table 1 summarizes candidate instruments for the survey. Because we aim to collect as much detailed information as possible and simultaneously minimize responder burden (consistent with a survey length of approximately 20-25 minutes), we will work closely with Odum survey methodology staff to focus our selection of measures to a minimum set of instruments and ad-hoc items that best represent the domains of interest.

Table 1. Domains and representative items and instruments to be captured in online survey

Domain	Instruments	Concepts Measured	# of Items
Demographic and Socioeconomic Status	Study-Specific Survey	Age; race; rural residence; education; occupation; marital status; insurance status; social support	-
Medication Adherence	Study-specific survey	Measure of patient initiation and adherence to recommended medications and treatments	-
Financial Toxicity	InCharge Financial Distress/Financial Well-being scale (31)	General measure of financial well-being	8
	Comprehensive Score for Financial Toxicity (COST) (32)	Cancer-specific measure of financial toxicity	11
Care Experience	Cancer Services Responsiveness Questionnaire (33)	Cancer-specific measure of care responsiveness. Concepts include: prompt access, patient-centered response, communication, quality of care environment	19
	Study-specific survey	Evaluate patient decision making about care and treatment	-
Patient Anxiety	Metal Adjustment to Cancer (MAC) (34)	Patient ability to cope with cancer diagnosis/treatment. Concepts include: fighting spirit, anxious preoccupation, helplessness and fatalism	33
	Impact of Event Scale for Cancer (35)	Cancer-specific measure of subjective stress caused by diagnosis of cancer, including avoidance and intrusion	15
	PROMIS-Cancer Anxiety (36)	Cancer-specific measure of anxiety	4
Patient Depression	PROMIS-Cancer Depression (36)	Cancer-specific measure of depression	4

Quantitative Analysis. Survey data will be analyzed using chi-squared and t-tests to examine variations in medication adherence, financial toxicity, and care experiences, by demographic and socioeconomic indicators. From this information, we will be able to characterize financial vulnerability (in terms of the InCharge financial well-being scale and the COST financial toxicity scale) by demographic and socioeconomic indicators. We will also be able to characterize the impact of financial toxicity on clinically-relevant behaviors (e.g., medication adherence), psychosocial well-being (e.g., patient anxiety and depression), and economic outcomes (e.g., bankruptcy).

In-Depth Interview Approach. Semi-structured interview guides will be developed for uninsured and underinsured MBCPs that capture the extent and impact of financial concerns on treatment-related decisions, the processes by which patients and their caregivers attempted to access charity care or other medication assistance resources, and their reactions to, and recommendations for, a coordinated medication assistance program (like HarborPath). Probes will elicit more detailed responses to questions, as dictated by the interview discussion (e.g., probe on coping strategies for handling financial hardship, such as selling personal belongings).

Interviews will be conducted in person or over the phone by the Project Coordinator, who is an experienced interviewer, and assisted by the Graduate Research Assistant (GRA), who will take detailed notes. At the end of the interview, the Project Coordinator will ask, “Is there anything else you would like to share with us about your experience with understanding the costs and paying for your cancer treatment?” Both the interviewer and GRA will document their overall impressions of each session in a debriefing log. All interviews will be audio-recorded and fully transcribed.

Qualitative Analysis. All interview transcripts will be organized and analyzed using Atlas.ti software. We will begin by dividing transcripts into textual units, which provide a common unit of analysis for duplicate coding and facilitate data organization. These textual units, like well-formed paragraphs, are intended to capture a single thought, experience, or “gist” of meaning (37). Coding and interpretation of transcripts will be conducted using thematic content analysis, where initial codes are informed by and derived from domains specified in our interview guide. Additional emergent categories of meaning will be used to identify emerging specific thematic codes; together, these codes and definitions will form our working codebook (37). Two coders will code transcripts concurrently. We will systematically and regularly compare coded text to identify new categories of meaning emerging from interviews and discuss and resolve overlapping codes. We will identify and reconcile coding inconsistencies and then refine our codes and the codebook using an iterative process (38, 39). Coded textual units regarding financial barriers to cancer treatment will be pile-sorted to identify super-codes or more encompassing categories of meaning. We will gauge relative importance of codes and super-codes by tabulating frequency and distribution of codes. Finally, we will search for explicit attributions of connections among person-level, provider-level, regimen-based, and social/structural factors by examining co-occurrence patterns (e.g., frequency and type of interrelationships between coded text). For example, we will examine coded textual data to determine whether women attribute their lack of treatment adherence to providers not warning or preparing them to deal with financial toxicity. Concept maps developed in Atlas.ti will depict interrelatedness of codes.

**2. Map processes by which patients and families, oncology care providers, navigators, social workers, and others attempt to identify and access financial support for uninsured and underinsured MBCPs**

Study Design. Systems support mapping describes a set of qualitative tools that can be used to articulate the complexities of detailed and dynamic systems to better inform decision making and systems re-engineering. Importantly, systems support mapping allows for decision makers and stakeholders to conceptualize a non-linear system that is dynamic and responsive to change. Health systems mapping consists of a variety of tools and approaches, including, but not limited to, process flow diagramming, circle of care modeling, social network mapping, and systems dynamics causal loop diagramming. These approaches to understanding complex systems allow stakeholders to jointly define important structures, processes, events, bottlenecks, feedback loops, “dead-ends,” unintended consequences, and outcomes that are relevant for stakeholders and decision makers focused on improving system design to reach mutually agreeable goals and objectives. Process mapping, in particular, provides “a visual depiction of the process and creates a common vision and shared language for improving work... by eliminating wasteful steps or consolidating steps in a process” (40). A process map can also elucidate gaps between what is ideal and what is actually happening within a system. For example, process mapping has been used to improve the Medicaid application and renewal processes, by implementing changes to the eligibility determination system (40).

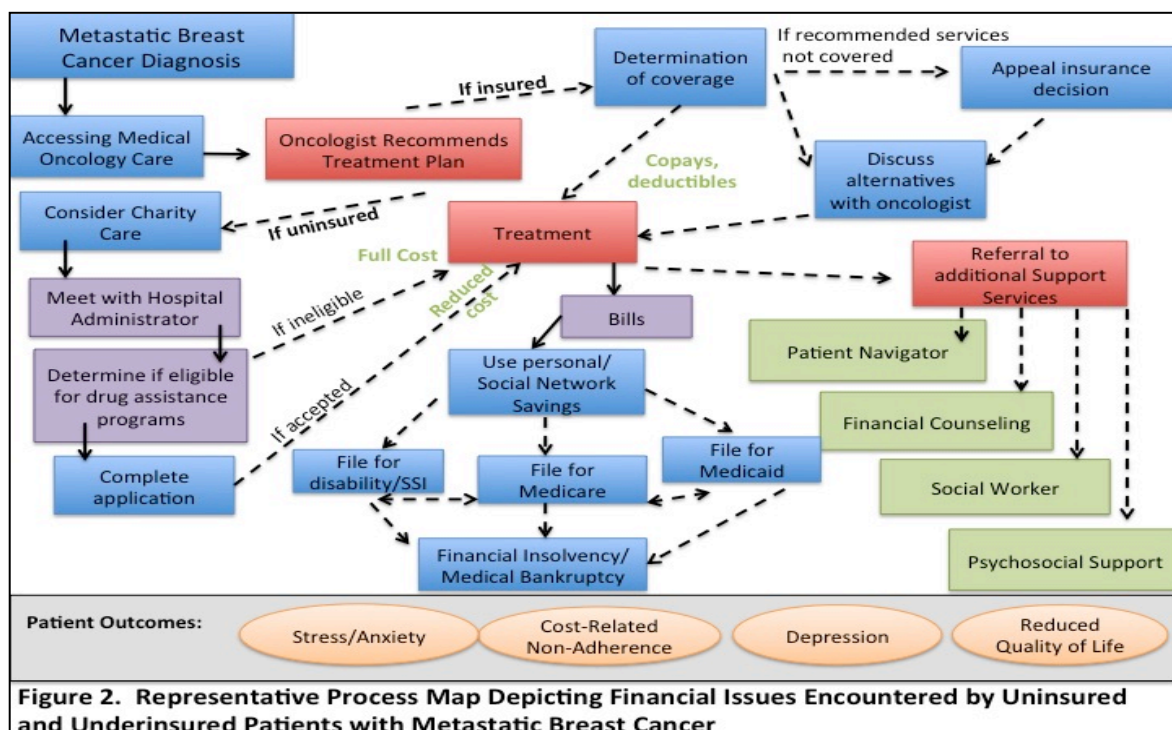
We intend to use this approach to (1) define and diagram existing processes surrounding access to financial assistance for uninsured and underinsured MBCPs; and (2) engage stakeholders in reviewing and revising process maps and developing recommendations to improve access to financial assistance for MBCPs in need. This information will then be used to adapt a novel medication assistance program for the MBC setting, considering organizational capacity and constraints, operational and logistical feasibility, technical support and training, and education and outreach needs, as articulated by stakeholders.

Approach. The process mapping effort we plan to undertake will involve 3 phases of activity: (1) interviewing key system stakeholders about the process of navigating the health care system to identify and access financial support for medication assistance for uninsured and underinsured patients; (2) diagramming the process flow for identifying and accessing financial support, based upon key system stakeholder interviews as well as patients’ experiences articulated in Specific Objective 1; (3) reporting back to all system and patient stakeholders our draft process flow map, seeking input on how to improve the process flow map, and revising the process flow map to be responsive to stakeholders’ input. The goal of process flow diagramming is to develop an explicit representation of a group’s understanding of a specific process, as well as the pathways, roles, responsibilities, and resources (including time required) in it as well as the factors shaping those pathways, roles, responsibilities, and resources.

In Phase 1, we will identify key representative from each of the following stakeholder groups within the NCCH to participate in in-depth interviews: financial counselors, nurse navigators, oncologists, oncology nurses, social workers, and hospital administrators. We will leverage the full support of the NCCH’s administration and leadership (see **Letters of Support**), in recruiting hospital employees and other stakeholders to participate. We will use a structured interview guide with each stakeholder to understand the following: role/identity; most

important responsibilities; needs, as pertaining to medication assistance for uninsured and underinsured MBCPs; resources tried and used; wishes/desires for resources to address any unmet needs. At the conclusion of each interview, we will ask for referrals to other key stakeholders. Each interview will last 20-30 minutes, audio-recorded, and transcribed verbatim. Because the activities of this phase of the project are consistent with the expectations and activities of UNC Hospital employees, we have minimized the incentive payment amount (\$10) for this participant group.

In Phase 2, we will leverage data captured in Phase 1 to map the multiple and currently uncoordinated processes necessary to access financial support for uninsured and underinsured MBCPs at NCCH. A preliminary process map reflecting the complexity of this system is shown in Figure 2. This map will be refined in response to input from the research team and data obtained from key system stakeholders and patients.



**Figure 2. Representative Process Map Depicting Financial Issues Encountered by Uninsured and Underinsured Patients with Metastatic Breast Cancer**

In Phase 3, we plan to report back to key system stakeholders, as well as representative patients and caregiver stakeholders, the draft process flow map and seek their input, with a plan to revise the process flow map in real time. In order to do so, we will plan a half-day workshop with key patient and health system stakeholders who participated in the in-depth interviews to engage in this effort. In the first part of this workshop, we will ensure that every participant understands the rationale and goals of the workshop. Specifically, to be collectively impactful, stakeholders engaging in a systems mapping effort should share (1) a common agenda; (2) shared process and outcome measurement; (3) mutually reinforcing activities; (4) continuous communication; and (5) a backbone organization. Therefore, we will first articulate our agenda/goals (to define a process flow map that accurately captures the existing system with a long-term goal of optimizing medication assistance programming for uninsured and

underinsured MBCPs), define our vocabulary, and describe the procedure by which we will review and revise the draft process map. Then, we will discuss the draft process map and revise it in real time as a group. Once we have reached consensus on the process map created, we will discuss relevant outcomes for measurement (e.g., patient financial burden; medication non-adherence), other external organizations (beyond the backbone organizations of NCCHand HarborPath) and reinforcing activities that may contribute positively to our shared mission, and a communication strategy for stakeholders to move forward.

**Specific Objective 3. Develop an implementation and evaluation plan for a tailored MBC medication assistance program**

- a. Formulate a strategy to implement the medication assistance program within existing oncology care coordination and navigation services, considering organizational capacity and constraints, operational and logistical feasibility, technical support and training, and education and outreach needs**
- b. Devise a strategy for evaluating program implementation success, including a system for monitoring patient applications and drug delivery, educating oncologists and other providers about this resource, understanding operational efficiency and reach, and tracking outcomes**

Approach. Using quantitative and qualitative data from Objective 1 about patient needs and gaps in medication accessibility, and the refined process map from Objective 2 that identifies bottlenecks, “dead-ends”, and unintended consequences in patients accessing medication assistance, we will develop a strategy to adapt and implement the HarborPath program in the MBC setting, starting at NCCH, with a goal of expanding to other hospitals in the future. This action plan for implementation of the medication assistance program will include, but not be limited to, the following elements:

- The What: Development of training and informational materials to be disseminated to oncologists, financial counselors, navigators, and other stakeholders about HarborPath and how to use the web-based portal
- The When: Description of a minimum set of resources required to successfully implement the HarborPath medication assistance program
- The Who: Description of who, within an existing oncology health care team, could administer such a program within a health system and the relevant responsibilities and time required to do so
- The How: Design recommendations for HarborPath’s web-based portal and systems to (1) streamline and simplify the medication access process for applicants/their advocates and (2) improve data tracking and usability (e.g., including metrics such as time to medication delivery; numbers of applications denied and reasons for ineligibility)

With regard to evaluating program success, several metrics will be discussed and prioritized during the stakeholder engagement process to determine which metrics are most meaningful to health system stakeholders and to patients. For example, many of the metrics evaluated in Objective 1 (e.g., medication adherence, patient anxiety, financial toxicity; see Table 1) likely will be tracked as important outcomes in an evaluation plan. But additional metrics, such as time from application filed to medication receipt, numbers of applications processed and approved/denied, overall cost of administering the program (as well as cost

savings to patients), and patient perceptions of care coordination (see Table 2), cannot be tracked until the program has been fully implemented. Therefore, with stakeholder input, we will prioritize which evaluation metrics should be captured and how they should be captured upon program roll-out. The web-based portal design plays an important role in this evaluation effort, as it can be designed to passively collect much of these data, thereby automating the data collection and tracking process alongside service delivery.

**Table 2. Evaluation metrics for medication assistance program reach and impact**

Domain	Instruments	Concepts Measured	# of Items
Patient Access to Program	Study-specific Measures	Number of patients served; ratio of prescriptions filled to applications filed; time to medication receipt	-
System Resources	Study-specific Measures	Administrative resources; staff burden; training costs required	-
Patient and Provider Awareness and Confidence	Study-specific Measures	Awareness of medication assistance resources; confidence in accessing medication assistance resources	
Patient Knowledge	Knowledge of Care Options (41)	Cancer-specific questions to explore patient knowledge of curative, palliative, and hospice care options	11
Patient Self-Efficacy	PROMIS- Self Efficacy	Patient self-efficacy related to managing medication and treatments	8
Patient Activation	Patient Activation Measure (PAM) (42)	Patient knowledge, skill, and confidence for self-management	13
Care Experience	Picker Institute Patient Experience Survey (43)	Patient overall care experience with a focus on provider communication and care coordination	15

### **Project Responsiveness to Established Needs:**

This project is designed to address three specific aspects of medication access problems for MBCPs: (1) clarify the critical procedural steps by which patients request benefits from pharmacy assistance programs; (2) implement a coherent and improved process to receive these services by aligning the interests of several key stakeholders (MBCPs; oncology health care providers; HarborPath; UNC Health Care system administrators; and pharmaceutical companies); and (3) establish a tracking mechanism to evaluate the impact of pharmacy assistance programs on clinically relevant patient outcomes. We plan to reduce inefficiency and consolidate resources within and outside of our institution to create an effective process that can be disseminated both within and outside our cancer hospital.

### **Assurance of Target Audience Engagement:**

This project is a patient-centered initiative. We will obtain several concrete indicators of patient engagement by tracking the total number of respondents to the online survey, participants in focus groups, and the evaluations from focus groups, (including measures of patient satisfaction). In doing so, we will be able to confirm that we have engaged uninsured and underinsured patients as well as insured patients with MBC who experience financial toxicity. We will also design a feedback mechanism for the HarborPath portal to promote ongoing quality improvement of the online pharmacy assistance application process.

### **Project Originality and Innovation:**

Within the larger context of cancer-related financial toxicity, the problem of limited access to breast cancer medications remains virtually unexplored. This project will employ several novel approaches to create a first-in-cancer model medication assistance program. We will partner with the MBCN and UNC breast cancer clinicians to directly engage patients in

creative approaches to this problem. To our knowledge, process mapping to improve access to pharmacy assistance programs has not been attempted. A practical and meaningful innovation for MBCPs will be the construction of a web-based portal to streamline applications for medication assistance. Perhaps the most innovative aspect of this project is our plan to create a mechanism to link access to medications with measurable clinical outcomes for MBCPs.

### **Existing Work:**

Our investigative team possesses rich expertise in the areas of breast cancer clinical care, implementation science, health IT, decision support, social determinants of health and access to health services, and patient navigation and coordination. These investigators, working together and in collaboration with other UNC researchers, have completed or are conducting several studies of direct relevance to patients with MBC. Dr. Wheeler's group studies disparities in access to breast cancer care among low income and minority populations, including several studies with Dr. Reeder-Hayes and Muss (44-46). For example, Dr. Wheeler and colleagues analyzed North Carolina (NC) cancer registry data linked to Medicaid claims to assess oral endocrine therapy (ET) initiation among low-income breast cancer patients with hormone receptor positive (HR+) disease. Although guidelines recommend that HR+ patients receive ET, less than 50% had an ET pharmacy claim within 15 months of diagnosis (47). In addition, in survey data we collected from over 1,900 Carolina Breast Cancer Study (CBCS) participants, about 10% of breast cancer patients reported that cost of their cancer treatment medications was a problem for them and that they have skipped or delayed ET due to cost. Importantly, African American women more often reported cost-related barriers to ET use.

Dr. Rosenstein's team studies medical decision-making in patients with metastatic cancer (48, 49). Drs. Wheeler and Rosenstein were co-investigators on a recently completed mixed-methods study of the utility of treatment summaries and care plans for patients with metastatic cancer. In addition to these preliminary studies, the Comprehensive Cancer Support Program operates two clinical programs designed specifically for uninsured and underinsured patients: a foundation-supported financial assistance program; and a pro-bono legal clinic operated in conjunction with the UNC School of Law.

HarborPath recently conducted an evaluation of its existing HIV medication assistance program, which demonstrated significant improvements in medication adherence after program enrollment among low-income participants. Specifically, data from University of Alabama Birmingham patients from January 2013 to January 2015 were collected. Of the 495 patients for whom both baseline and follow up viral load was available, 60% has suppressed viral load at enrollment and 80.24% had suppressed viral load after at least 4 weeks of enrollment, a significant improvement over baseline.

### **Anticipated Challenges and Solutions:**

Since cancer is a new clinical area for HarborPath, one potential challenge is building a similarly robust level of engagement (and investment) from pharmaceutical companies who manufacture oncology medications as has been previously leveraged for HIV and Hepatitis C. Fortunately, HarborPath has strong relationships with pharmaceutical companies who market cancer medications and has already started paving the way for oncology medication acquisition.

Second, because MBC is a difficult diagnosis with complex treatment schedules, we acknowledge that recruiting interview participants from a single site (NCCH) may be challenging, due to the time and travel required of uninsured and underinsured participants. We plan to allow interviews to be conducted via telephone, to better accommodate patients. In addition, if we experience difficulty recruiting 24 participants from NCCH, we will reach out to colleagues at regional cancer hospitals, including Duke Comprehensive Cancer Center and East Carolina University's Leo Jenkins Cancer Center, to recruit participants from those settings.

Third, existing NCCH-specific sponsored programs for indigent patients may lead to underestimates regarding the need for and impact of HarborPath's program (as compared to non-NCCH-treated populations). However, UNC and the NCCH has a large network of community-based oncology provider affiliates and the capacity to extend this novel initiative to those less well-resourced settings within a year or two of initial roll-out.

## **Evaluation**

### **Impact Evaluation:**

As described above, once the HarborPath program is implemented, process evaluation metrics will be determined by key stakeholder input and most likely will include the following: numbers of patients served; ratio of prescriptions filled to applications filed; time to medication receipt; administrative resources; staff burden; and training and processing costs required. In addition, outcome evaluation metrics will include the following: patient and provider awareness of and confidence in accessing medication assistance programs; patient satisfaction; patient anxiety/worry; cancer-related financial toxicity; patient and provider perceived care coordination; patient-provider communication; and medication initiation and adherence.

### **Dissemination of Project Findings, Tools, and Recommendations:**

It is our anticipation that at the conclusion of this 2 year project, HarborPath will roll out the medication assistance intervention to NCCH's breast cancer clinic as well as other clinics, working closely with case managers and support staff to monitor the process of patient recruitment and medication delivery. During this time, evaluation data described above will be collected using the portal and staff and patient surveys. Such data will provide the basis for further adjustments to the implementation effort, as well as evidence of intervention reach, impact, and success.

The project will provide a foundation for oncology medication assistance programming that could be incorporated into our statewide UNC Cancer Network and Affiliate Organizations for dissemination and implementation. This includes 7 affiliate hospitals and 6 partnership sites that offer patient navigation within their cancer support services. Currently, the UNC Cancer Network offers monthly community outreach lectures and bi-monthly medical health lectures which will be excellent venues for dissemination of study findings. The Network also has a network of nurse navigators that meet on a quarterly basis in a forum where research materials could be shared and training could be provided. Downstream products of this line of research, such as online medication assistance interventions, also have the potential for extension to other patients in need in other care settings (e.g., the Southeastern Cancer Control Consortium) and within different malignant disease groups (e.g., leukemia, thoracic and prostate cancer).



### **Detailed Workplan and Schedule of Deliverables**

In the first half of Year 1 of this two-year project, the team will focus on assessing gaps in MBC medication assistance for uninsured and underinsured MBCPs (Objective 1) through quantitative surveys and qualitative interviews with MBCPs and their caregivers. In the second half of Year 1, the team will focus on conducting in-depth interviews with key stakeholders in the healthcare system, including hospital administrators, clinicians, social workers, financial counselors, and navigators to understand the process by which uninsured and underinsured patients access oncology drugs (Objective 2).

In the first half of Year 2, we will draft an initial process map reflecting the processes of navigating medication assistance in the MBC setting (based upon information shared by patients and stakeholders), and we will convene the half-day workshop to revise and finalize the process map with stakeholder input (Objective 2). In the second half of Year 2, we will adapt and tailor the HarborPath program to be applicable to the MBC setting, considering organizational capacity and constraints, operational and logistical feasibility, technical support and training, and education and outreach needs (Objective 3), including: (a) further developing and testing the online portal, (b) developing training manuals for accessing the online portal and requesting medications, and (c) developing an electronic patient records tracking infrastructure. As part of this process, we will develop and deliver to stakeholders: (a) a strategy to implement the medication assistance program within existing oncology care coordination and navigation services, and (b) a strategy for evaluating program implementation success, including a system for monitoring patient applications and drug delivery, understanding operational efficiency and reach, and tracking outcomes planning for effective implementation of HarborPath’s medication assistance program in the metastatic breast cancer setting.

Deliverables will include, but not be limited to: (a) revisions to HarborPath’s online portal to collect information important to monitoring and evaluation; (b) training manuals for staff on using the HarborPath online portal; (c) development and documentation of a streamlined process to identify and screen eligible patients; (d) partnership commitment; (e) standard operating protocols for provision of oral versus infused medications, medication dosage adjustments and switching, and coordination of palliative and other supportive care services; and (f) a compiled set of evaluation instruments (validated, where possible) for data collection. Such detailed documentation and training materials may then be disseminated to other sites and states interested in implementing HarborPath’s program in the future.

<b>Activity</b>	<b>Year 1, 1<sup>st</sup> half</b>	<b>Year 1, 2<sup>nd</sup> half</b>	<b>Year 2, 1<sup>st</sup> half</b>	<b>Year 2, 2<sup>nd</sup> half</b>
IRB approval				
Survey of MBCPs through MBCN				
In-depth interviews with MBCPs				
In-depth interviews with key system stakeholders				
Draft process map				
Revise process map with patient and system stakeholders				
Develop implementation and evaluation plan				
Disseminate implementation and evaluation plan				

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