

A. Cover Page

1. **Title:** Personalizing patients' metastatic breast cancer treatment and supportive care plans

Grant ID: 22896331

Main Collaborators:

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- Northwestern Maggie Daley Center for Women's Cancer Care in Prentice Women's Hospital and Northwestern Lynn Sage Breast Cancer Program
- Northwestern Lake Forest Hospital's Posy Krehbiel Breast Care Center
- Northwestern University, Feinberg School of Medicine
- The Center for Business Models in Healthcare / Executive Frameworks, Ltd.

2. **Abstract:**

This project's **overall goal** is to improve quality, appropriateness and timeliness of delivery of comprehensive care to metastatic breast cancer (MBC) patients by implementing a personalized, patient-centric care planning and coordination model, and disseminating implementation results.

Our proposed project will implement the innovative care delivery "4R in Oncology" model at participating sites, and disseminate the results of the implementation. The 4R (**Right** Information and **Right** Treatment to the **Right** Patient at the **Right** Time) model uses project management discipline principles to implement a comprehensive care plan and pathway which helps cancer patients and their clinical care teams to create personalized, patient-specific "care project plan" of treatment, support services, genetic assessment and testing, overall care and quality of life, incorporating the patient's goals, decisions and choices, including end-of-life decisions.

To achieve the overall goal of our project, we will achieve key objectives:

1. Conduct current state and gap analysis of MBC care delivery at participating sites, using the pre-developed 4R metrics of care delivery and coordination. Data collected via pre-developed surveys of patients, family/caregivers, and providers; and review of electronic data warehouse data. Resulting in baseline measurements.
2. Educate / inform participating sites and stakeholders on the 4R methodology and collaboratively develop 4R implementation plans for the sites. We will accomplish this using the adaptive workshop method.
3. Implement 4R plans for MBC patients at participating sites; Measure post-implementation results and compare with baseline.
4. Disseminate results and the 4R methodology for MBC care delivery improvement.

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B. **Reviewer Comments – only If Applicable** (not to exceed 1 page) *Please briefly describe how you addressed any review panel comments you were provided following their review of your letter of intent.*

No reviewer comments were received following the letter of intent.

C. **Main Section of the proposal** (not to exceed 15 pages):

1. **Overall Goal & Objectives**

This project's **overall goal** is to improve quality, appropriateness and timeliness of delivery of comprehensive care to metastatic breast cancer patients by implementing a personalized, patient-centric care planning and coordination model, and disseminating implementation results.

Currently, comprehensive care for metastatic breast cancer (MBC) patients is highly complex, requires multiple components (cancer treatments, co-morbidity care, supportive care, care coordination, family and caregiver support, other) and is delivered by a number of clinical specialties and organizations. Due to complexity, fragmentation across specialties, and difficulty coordinating, timing and sequencing interdependent care events, care is disjointed, suboptimal and many guideline-recommended components are missed.

Our proposed project will address this problem by implementing our innovative care delivery "4R in Oncology" model at participating sites, and disseminating the results of the implementation. The 4R (**Right** Information and **Right** Treatment to the **Right** Patient at the **Right** Time) model uses project management discipline principles to implement a comprehensive care plan and pathway which helps cancer patients and their clinical care teams to create personalized, patient-specific "care project plan" of treatment, support services, genetic assessment and testing, overall care and quality of life, incorporating the patient's goals, decisions and choices, including end-of-life decisions. This "care project plan" is a vehicle facilitating and optimizing coordination, consistency, explicit responsibility for various care components, quality and satisfaction of care, as well as communication amongst the care team, the patient, and the caregiver / family. The 4R model includes an extensive supportive oncology component (care goal/wishes definition, palliative care, distress management, symptom management, end-of-life care), weaved into the overall cancer care delivery for a patient in a personalized fashion based on patient's wishes and preferences. The 4R model therefore is highly conducive to improving care for MBC patients, which is complex, time-sensitive, needs coordination across many clinical domains, patient and caregiver/family, and requires incorporation of supportive oncology into the overall care process.

To achieve the overall goal of our project, we will achieve key objectives:

1. Conduct a current state and gap analysis of MBC care delivery at our participating sites, using the pre-developed 4R metrics of care delivery and coordination. This will be done via a pre-developed patient survey, family/caregiver survey, provider survey, and review of electronic data warehouse data, and will result in development of the baseline measurements. The current state and gap analysis is completed during the first 4 months of the project.
2. Educate / inform participating sites and stakeholders on the 4R methodology and collaboratively develop 4R implementation plans for the sites. We will accomplish this using the adaptive workshop method which we previously developed as a vehicle for care process education and improvement. These adaptive workshops will take place during year1-quarter 2, year 1- quarter 3, year 2 – quarter 1 and year 2- quarter 4.

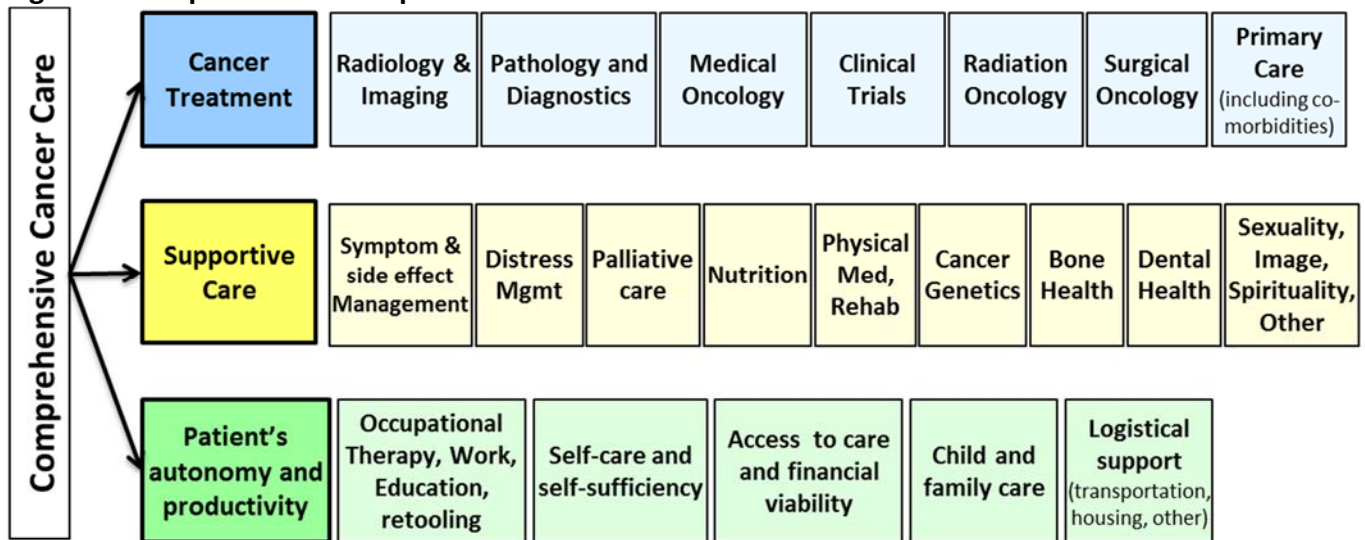
3. Implement 4R plans for MBC patients at participating sites; Measure post-implementation results and compare with baseline. The 4R plans will be implemented with metastatic breast cancer patients starting in quarter 4 of the 1st year and will continue through the end of quarter 2 of the 2nd year.
4. Disseminate results and the 4R methodology for MBC care delivery improvement. Dissemination will occur during the 4th quarter in the 2nd year of the project.

2. Current Assessment of need in target area

a. Describe the need for this project in your target area.

Comprehensive metastatic cancer care is highly complex and fragmented across care domains, institutions and geographies.

Figure 1. Components of Comprehensive Metastatic Breast Cancer Care



Complexity and fragmentation result in serious care delivery challenges. Challenges are addressed at varying levels at the leading academic centers, but are substantial in many other settings (IOM 2011, 2013).

These challenges include:

- a) Care is not appropriately timed, sequenced, or tailored to patient sub-groups.
- b) No one is responsible for many services that “fall through” between care domains
- c) Lack of one cross-domain care plan across care domains along the continuum from diagnosis through treatment.
- d) No one physician “quarterback” across care domains along the continuum from diagnosis through treatment.

Examples of resulting care quality problems:

- Patients are overwhelmed “shuttling” between care domains and managing their care.
- Biomarker, gene expression, genetic testing done ad-hoc, not in sufficient advance of treatment decisions, delaying treatment initiation, or missing from decisions
- Supportive, palliative care not offered or not delivered timely, when it can most impact

quality of life.

- Clinical trial participation is discouraged or not offered timely.
- Second opinion is discouraged or not offered timely
- Dental health and bone health are not addressed prior to therapy initiation, resulting in lost opportunity and/or negative patient outcomes

b. Please include quantitative baseline data summary

4R model: developed by a health services research program (since 2008), as a result of:

- Care delivery studies and 3 multi-organizational roundtables - providers, national payers, patients (Trosman 2010, 2011, 2013; Schink 2010; Doll 2011; Weldon 2012)
- Examination and survey of breast cancer care practices at 32 Chicago sites (Weldon 2011, 2012, 2014; Trosman 2012, Dupuy 2013; Murphy 2014)
- Patient focus groups.
- Guidelines (NCCN, ASCO, CoC, NAPBC, ADA), IOM reports (‘05, ‘08, ‘11, ‘13), literature.

The 4R model was developed prior to The Institute of Medicine’s 2013 report “Delivering High-quality Cancer Care”, but is aligned with its recommendations. Furthermore, the 4R Model offers an innovative mechanism for implementing key IOM recommendations.

Using guidelines / recommendations (NCCN, NAPBC, ADA, IOM) and peer-reviewed literature (62 studies) we developed and conducted a survey on BC care practices at 32 treatment sites in a large Urban area with a mix of academic, community and public treatment sites. We found that less than 50% of sites provide key, guideline recommended supportive care:

- 29% of sites screen patients for distress at initial visit, at intervals and at changes in disease status (NCCN DIS A)
- 45% of sites screen patients for pain at each contact (NCCN PAIN A,C)
- 25% of sites screen for palliative care needs at care initiation and/or regularly during care (NCCN PAL 1 2)

Preliminary unpublished data (confidential) from The Coleman Supportive Oncology Initiative, led by Trosman and Weldon, based on supportive care processes at 6 cancer treatment sites. n=843 patients all stages, n=452 patients with stage IV solid tumor cancer/ refractory hematologic malignancies.

Percentage of patients with a documented discussion on understanding of illness/ treatment expectation/or quality of life within 30 days of full diagnosis date	45%
Percentage of individual patients who were told a prognosis timeframe (days to weeks, weeks to months, months to years, years+) within 30 days of full diagnosis date	20%
Percentage of patients with documented discussion of their health care agent name based on validated health care power of attorney within 90 days of diagnosis date	4%
Percentage of stage IV solid tumor cancer/ refractory hematologic malignancies with at least one supportive oncology screening (distress screening) within 14 days of diagnosis date	4%
Percentage of stage IV solid tumor or refractory hematologic malignancy patients with any documented palliative care specialist referral	13%

3. **Target Audience:** *Describe the primary audience(s) targeted for this project.*

Primary Target: **Metastatic Breast Cancer Patients**

- a. Level of commitment: The majority of metastatic breast cancer patients are very engaged in their care. This proposal will request a patient survey conducted at two points with different patients. The first point will be a patient survey during the current state and gap analysis, the second point will be after the 4R plans are implemented. Patient's will be offered the survey during their medical oncology appointment. The survey will contain no protected health information, it will be de-identified, and will focus on care delivery.
- b. Impact on goal: MBC patient input is essential to the project goal of improving quality, appropriateness and timeliness of comprehensive care.
- c. Benefit from project outcomes: Metastatic breast cancer patients receive a care plan that is personalized to their specific needs, wishes and treatment.

Secondary Target: **Family and Caregivers of Metastatic Breast Cancer Patients**

- a. Level of commitment: Family / caregivers will be surveyed during the current state and gap analysis and a different set of family / care givers will be surveyed after 4R plans are implemented.
- b. Impact on goal: MBC patients rely on their family and caregivers during care and often try to shield them from the details of their care. Having a 4R plan available for patients to share with family and caregivers will help them support their MBC patient.
- c. Benefit from project outcomes: Clear care plan for the patient they are supporting.

Other Target: **Radiology & Imaging**

- a. Level of commitment: The project team has a solid working relationship with the leaders of the breast imaging center.
- b. Impact on goal: Radiology/imaging is often the entry point into care for MBC patients through an image guided biopsy. This audience supports the project goals by being aware of how care should be initiated for MBC patients.
- c. Benefit from project outcomes: structured timing and sequencing of imaging.

Other Target: **Pathology and Diagnostics**

- a. Level of commitment: The head breast pathologist at our sites Dr. Sizipikou supports this work and has participated in timing and sequencing work the team has done in diagnostic testing.
- b. Impact on goal: MBC patients may need additional tumor tests to determine personalized adjuvant therapy including clinical trial options.
- c. Benefit from project outcomes: structured timing and sequencing of diagnostic tests.

Other Target: **Medical Oncology:** medical oncologists, mid-level providers (MSN, APN, PAs), nurses, patient service reps, navigators, clinical trials support

- a. Level of commitment: Medical oncologists provided the initial impetus behind the 4R care model by providing sample patient cases where care was not optimal. They have been supportive of 4R care plans and they want patients to have the best care possible.
- b. Impact on goal: MBC patients often view their medical oncologist as their primary caregiver through their course of care. Medical oncologists will benefit from having a plan that includes all aspects of care.

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- c. Benefit from project outcomes: A holistic care plan that includes supportive care activities, addresses patient practical needs that often impact care delivery and provide a sequencing of direct care.

Other Target: **Radiation Oncology:** radiation oncologists, nurse, social worker, radiation therapists, clinical trials support; **Surgical Oncology:** breast surgeons, physician assistants, nurses

- a. Level of commitment: The radiation oncology and surgical oncology caregivers support MBC patients when they need palliative procedures/treatment to relieve pain and/or control size of metastases. The caregivers in this group are excited about a full view of the care each patient is receiving as they are on a separate EMR.
- b. Impact on goal: The 4R care plan will provide them a full perspective of their patient's care.
- c. Benefit from project outcomes: Clear inclusion on care team.

Other Target: **Primary Care:** patient's primary care team of physician, nurse, medical assistant, administration

- a. Level of commitment: A patient's primary care team is considered part of their metastatic management and assists patients with ensuring they are addressing all health needs and co-morbidities. Given the number of primary care providers that work with the project sites, commitment will be obtained at a patient level with specific interactions to share the patient's 4R care plan.
- b. Impact on goal: Most patients have a long term relationship with their primary care team and rely on that team to obtain high quality care. The 4R plan will help the primary team understand the full picture
- c. Benefit from project outcomes: With the primary care team linked into the 4R care plan they will have a more holistic perspective of the patient's care.

Other Targets: **Palliative care:** palliative specialist physicians, mid-level providers (APN, MSN), nurse, social worker, chaplain; **Supportive Oncology (Distress Management):** social worker, psychologist, psychiatrist, support groups **Cancer Genetics:** genetic counselor, geneticist physician; **Nutrition:** dieticians; **Physical Med, Rehab:** physical therapist, occupational therapist; **Dental Health:** dentist, hygienist

- a. Level of commitment: The project team has obtained commitment (letters of support) from palliative care and supportive oncology (distress mgmt.) resources within the sites and has an existing relationship working with those areas. The project team will inform Genetics, Nutrition and Physical medicine of the project through their participation in surveys and adaptive workshops. Dental health will be involved at an individual patient level.
- b. Impact on goal: For each patient to have a complete 4R plan, all appropriate care and services must be included.
- c. Benefit from project outcomes: Clear inclusion on care team.

Replication/Expansion: The 4R methods used on this project will be available for other sites to replicate for metastatic breast cancer patients. The 4R methods may also be expanded beyond metastatic breast cancer but would require content development for the 4R care templates.

Section 5c describes the dissemination plan for this project.

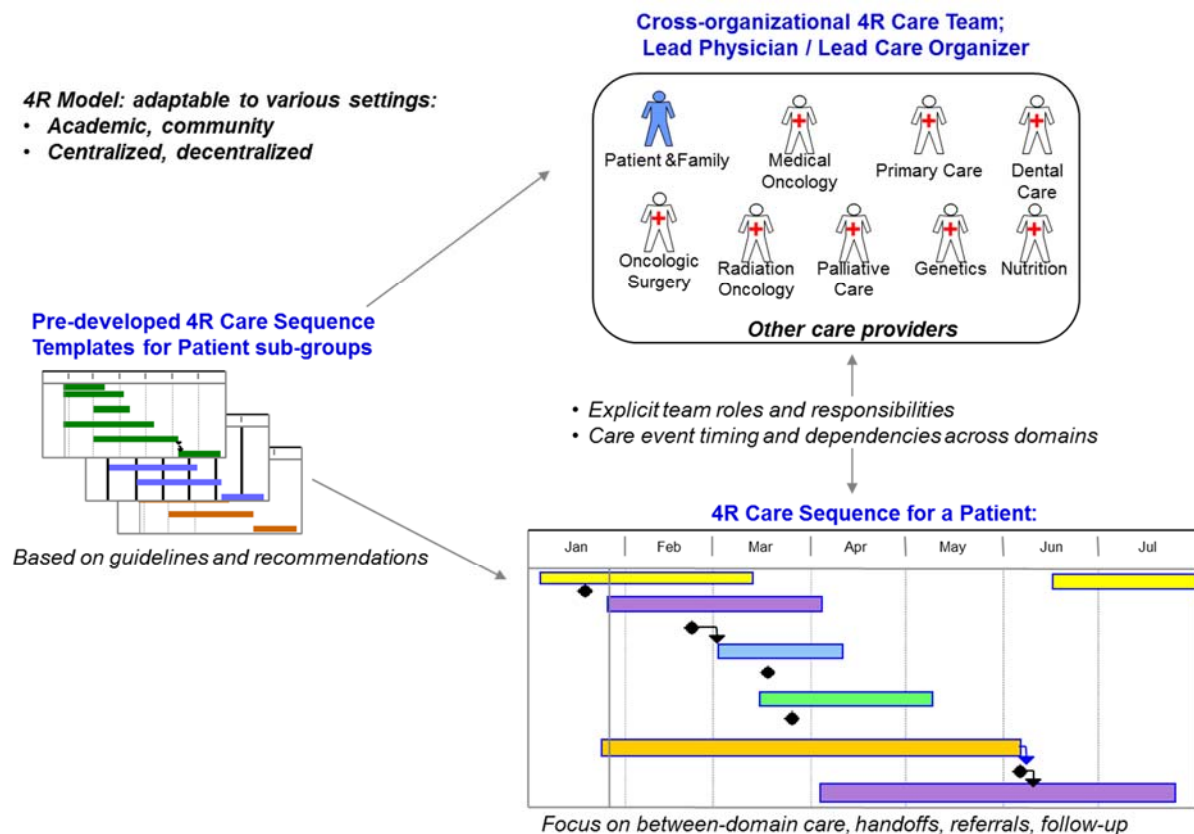
4. **Project Design and Methods:** Describe your project design and methods.
- a. Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.

The project will further design and implement the 4R model for metastatic breast cancer patients.

The 4R Method and components include:

1. 4R-Care-Sequences:
 - Metastatic breast cancer care plan templates, from the point of care initiation - next generation of a checklist
 - Personalized to patient clinical characteristics, co-morbidities, life stage, needs & choices
 - Includes supportive care (palliative care, psychosocial/distress, nutrition)
 - Use of project management principles, with timing, sequencing, dependencies, clear roles / responsibilities for all care events, with milestones and checkpoints
2. Clearly defined goal of care (e.g., long-term management, palliation)
3. Cross-organizational, cross-domain 4R care team, including patient / family.
 - All members have assigned responsibilities, especially for care between domains
4. Lead Physician and Lead Care Organizer (e.g. APN) from diagnosis through treatment
5. Metrics aligned to the IOM dimensions of quality

Figure 2. Components of the 4R Model



b. Describe the way the project plan addresses the established need and produces the desired results.

4R Care Team Structure, see figure 3

- Each patient's 4R care team is assembled based on:
 - Specific care in the patient's 4R care sequence
 - Insurance network coverage
 - Patient preferences (e.g. geographic).
- Care domains / specialties that may be included are depicted in Figure 1. They are engaged based on the timing specified in the 4R Care Sequence.

4R Care team roles include 2 categories:

"Domain" roles – for specific clinical care by specialty domain, e.g. onco-therapy, surgery, radiation, dental care

"Assignable" roles – for care that is not domain-specific, where responsibility is not clearly defined or could be performed by multiple domains / specialties.

- These roles could be **assigned and transferred** across multiple care domains
- This care is often missing in many settings: responsibility of many is done by nobody, e.g.:
 - Assessment of supportive care needs and associated referrals, e.g. distress assessment / referral, genetic risk assessment / referral to genetic counseling, dental referral
 - Discussion and documentation of health care power of attorney and discussing patient's wishes for treatment
 - Follow-up activities
 - Palliative care (could be managed by medical oncologist, radiation oncologist, or referred to palliative specialist)

Team structure and 4R-Care-Sequence for individual patients will specify explicitly **who is responsible, and the timing for each care events**, with particular focus on 'assignable' roles and related care events. Assignable roles will be managed by the Lead physician (LP) and Lead Care Organizer (LCO) as a joint "quarterback" function:

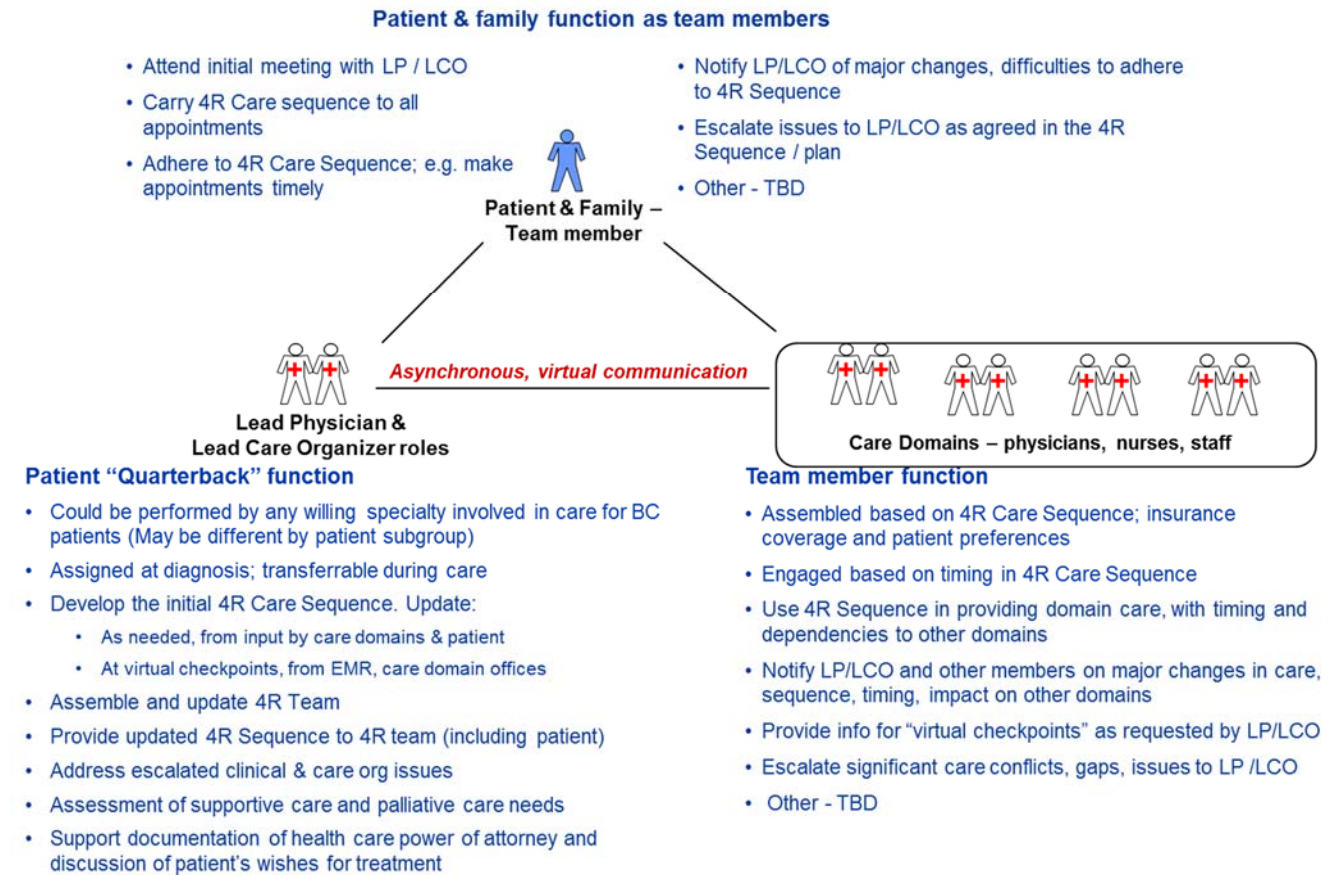
- Lead physician (LP) handles clinical decisions and issues at the physician level
- Lead care organizer (LCO) handles care coordination and communication and supports the LP.

c. Indicate how you will determine if the target audience was fully engaged in the project.

We realize that this project will require organizational and behavioral change. Our team is confident that we have important success factors in place that will support the project and allow us to effectively prevent and / or mitigate challenges. We use two important methodologies to inform this project and mitigate challenges: (1) implementation science for health care interventions and (2) multilevel interventions in health care, advocating the necessity of addressing a multi-step care process, vs. addressing one individual care event at a time, and providing tools for mitigating challenges (JNCI Monographs, No. 44, 2012). In order to facilitate the project and perform change management, we will use the PDCA / PDSA approach (plan-do-check-act / plan-do-study-act) to react to unforeseen and unintended consequences in a timely fashion and incorporate participants' initial feedback. These include the impact on cancer care delivery / site operations and workflow. Feedback will be received through the

adaptive provider workshops and through survey feedback from patients, family/caregivers and providers.

Figure 3. 4R Care Team Roles and Functions at a Glance



d. Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.

Current oncology initiatives do not address the challenges of proper timing, sequencing, and cross-domain care delivery:

- Care coordination models don’t address fragmentation across domains or care organizations:
 - Patient navigation helps the patient shuttle between care domains, but typically does not connect physicians, care plans or treatment decisions
 - Oncology Medical Home is centered around a medical oncologist and does not address other domains and treatments / services
 - Multi-disciplinary care models are costly, cumbersome and do not act across cancer care continuum or organizations. Teams miss a “lead” or “captain”
 - Care checklists and plans do not provide timing, sequencing of care, and do not assign responsibilities for many care services
- Treatment pathways focus on cost containment, and on onco-therapy only (~25% of costs)

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- New payment models (Bundled payment, ACO) require care coordination but lack effective coordination approaches. Create disincentives to some care services.
- Seminal reports and recommendations, e.g. **IOM 2013**, provide recommendations but not tools and specific mechanisms.

e. If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

4R Oncology model - "Right Information and Right Care for the Right Patient at the Right time".

We recently completed a collaborative multi-disciplinary effort that defined and developed the detailed components of the 4R Model for breast cancer delivery. The effort involved multiple Northwestern Medicine sites and Mercy Hospital – a safety-net hospital. We are now in the process of implementing the 4R model for non-metastatic, stage I-III, breast cancer patients at several sites.

Development of the supportive oncology care component of the 4R model. In addition to developing the overall 4R model, we have developed the 4R component for supportive oncology, which is integrated into the overall care delivery for patients who need it, especially metastatic patients. This project is funded by The Coleman Foundation and is focused on palliative care, distress management, and hospice referral for cancer patients.

We developed the supportive oncology component working with 35 organizations in the Chicago area: 13 cancer treatment sites, 14 cancer support centers, and 8 hospice centers. The supportive oncology component is in the process of implementation at six Commission on Cancer accredited Chicago cancer centers and includes a supportive oncology screening tool (which is based on the NCCN distress tool, the PHQ-4, PROMIS short forms and item banks, FACIT-Spirituality, MNA-SF and input from over 100 stakeholders).

Adaptive Multi-Site Process Improvement Workshops Funded by the Susan G. Komen Foundation, we developed and implemented a framework for multi-site collaborative process improvement workshops in breast cancer. This workshop approach is collaborative and included multiple breast cancer imaging and treatment sites working through process improvement ideas and action plans, based on each site's current state, specific gaps and available resources.

Patient Navigator Studies. Patient navigation is an integral part of MBC care delivery and is included in the 4R model. Our team has held several NIH and foundation awards to study breast cancer patient navigation in a variety of health care and community settings. One such example includes leading the creation a state wide breast cancer patient navigation program under an IL law that was informed by our team's patient navigator data. In partnership with the Illinois Department of Healthcare and Family Services and the Department of Public Health launched the Breast Cancer Quality Screening and Treatment Initiative, we created patient navigator pilot projects at two hospitals and two Comprehensive Care Plans that serve Medicaid patients across Chicago, its suburbs/collar counties, and in downstate Illinois. This project evaluates the projects' different approaches in order to identify best practices in navigating Medicaid enrollees through the complexities of breast cancer treatment. Funding support is provided by the Illinois Department of Health and Family Services.

f. If your project includes the development of tools note if they be available publically at no cost. Yes, we will make content and tools available publically at no cost. We have done this with our past projects and would do so with this project as well.

5. Evaluation Design

a. *In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.*

The project outcome is the implementation of the 4R model for MBC patients and improvement in delivery and coordination of care that is included in patients’ personalized “care project plan” based on patient expressed preferences and clinical guidelines. This will be evaluated in accordance with our 4R metrics structure (table 1). We will use several data sources: (1) electronic medical record data analyses to compare baseline with post-implementation measurements of care delivery, and timing, in accordance with 4R metrics, and (2) pre- and post- surveys of each major stakeholder group: Patient, Health Care team (physicians, nurses, navigators, social workers, and other staff) and Caregivers/ Families.

Table 1 - Detailed Metrics Description and Sources

Metric	Description	How measured – implementation (data sources are in parentheses)	Guideline / quality metric	IOM dimension of quality
A. Appropriateness and Timeliness of Care (both baseline and implementation data will be collected)				
A1. Patient goals* discussion for newly diagnosed patients	A1.1. Percent of patients with whom discussion was held within the care episode*	<ul style="list-style-type: none"> Denominator: implementation population* Nominator: number or implementation patients with Patient Goals (EMR) 	IOM 2013; NCCN PAL-4, PAL-9, QOPI Core 9,10	Effective Timely Patient-Centered
	A1.2. Percent of patients for who Patient Goals* discussion conducted before treatment initiation or surgery, but no later than 30 calendar days after diagnosis*	<ul style="list-style-type: none"> Denominator: number of patients with documented Patient Goals* discussion Nominator: date of Patient Goals* discussion (care sequence) will be compared with the date of treatment initiation (EMR), surgery (EMR), or the date which is 30 days after diagnosis (EMR) - whichever of the three is earlier. 		
	A1.3. Percent of patients with current Health Care Power of Attorney (before first surgery but no later than 60 days of diagnosis*. (Current – newly created or previously created but confirmed or updated by patient).	<ul style="list-style-type: none"> Denominator: implementation population* Nominator: the date of updated / confirmed Power of Attorney (EMR) will be compared with the date of first surgery (EMR) and the date which is 60 days after diagnosis (EMR) – whichever of the two is earlier. 		
A2. Supportive Oncology and Distress screening after diagnosis and	A2.1. Percent of patients screened for distress before treatment initiation or surgery, but no later than 30 calendar days after diagnosis*	<ul style="list-style-type: none"> Denominator: implementation population* Nominator: all dates come from EMR 	CoC Standard 3.4; QOPI 106, 107, Core 24	Effective Timely Patient-Centered

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Metric	Description	How measured – implementation (data sources are in parentheses)	Guideline / quality metric	IOM dimension of quality
in the course of care episode	A2.2. Total number of distress screens per patient within 12 months of diagnosis*	Number of distress screens per patient will be determined from EMR. We will calculate statistical measures of increase of total screens per patient between baseline and implementation data		
	A2.3. Total number of symptom/pain/side effect screens per patient within 12 months of diagnosis*	Number of symptom/pain/side effect screens per patient will be determined from EMR. We will calculate statistical measures of increase of total screens per patient between baseline and implementation data		
A3. Dental referral, prior to initiation of systemic treatment	A3. Percent of patients receiving a referral to a dentist vs. those indicated	<ul style="list-style-type: none"> Denominator: Patients with the date of their last dental appointment longer than 6 months prior to diagnosis (care sequence/ EMR) Nominator: patients with documented recommendation to see a dentist prior to the date of systemic therapy initiation (EMR). 	ADA	Effective Safe Timely Patient-Centered
A4. Genetic assessment and testing	A4.1. Percent of patients with documented family cancer history, based on the NCCN HBOC family history questions*	<ul style="list-style-type: none"> Denominator: implementation population Nominator: number of patients with documented answers to the NCCN HBOC family history questions*(EMR) 	NCCN HBOC-1	Effective Timely Patient-Centered
	A4.2. Percent of patients with documented history and indications for genetic counseling who received a referral to genetic counseling	<ul style="list-style-type: none"> Denominator: Patients in A6.1 indicated for genetic counseling based on the NCCN HBOC family history questions (at least two “yes” answers) Nominator: documented referral to genetic counseling, or documented date of genetic assessment (if performed at the appointment by physician) (EMR) 		
A5. Referral to a Primary Care Physician (PCP) consult	A5. Percent of patients who received referral to a PCP before treatment initiation or first surgery	<ul style="list-style-type: none"> Denominator: all implementation patients who have not had a PCP appointment within the last 6 months of diagnosis (EMR) Nominator: patients with documented referral to a PCP, dated prior to the date of definitive surgery or date of systemic treatment initiation (EMR). 	AHRQ 2011 (Coordinating care in the medical neighborhood)	Effective Safe Timely Patient-Centered
B. Adherence to 4R model components and principles <i>(these metrics measure the feasibility of the 4R model, not impact on care. Baseline data will not be collected)</i>				
B1. LP, LCO responsibilities, as designed	B1.1. Percent of patients for whom LP / LCO were assigned within 3 calendar days of completion of diagnostic workup	<ul style="list-style-type: none"> Denominator: implementation population Nominator: based on comparing the date of LP/LCO assignment (Care 	IOM 2013, IOM 2011, AHRQ 2011	Effective Timely Patient-Centered

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Metric	Description	How measured – implementation (data sources are in parentheses)	Guideline / quality metric	IOM dimension of quality
		Sequence) to the date of diagnosis* (EMR).	(Coordinating care in the medical neighborhood)	
	B1.2. Time between diagnosis* and creation of initial care sequence	Date of diagnosis (EMR) will be compared with the date of care sequence creation (Care sequence) for each implementation patient. Statistical measures will be calculated for the patient population.		
	B1.3. Number of transitions of LP/LCO responsibilities per patient from diagnosis through treatment	Data source – care sequence.		
B2. Use of care sequences, as designed	B2.1. Completeness of care sequence: we will review and code care sequences as (1) complete based on relevant care (2) somewhat complete (3) incomplete	Data source – care sequence. This will be done as a post-implementation review of care sequences and comparison with EMR for all implementation patients.	IOM 2013, IOM 2011, AHRQ 2011 (Coordinating care in the medical neighborhood)	Effective Timely Patient-Centered
	B2.2. % of patients for whom care sequences were updated at pivotal care points (change in care plan, change in prognosis)	<ul style="list-style-type: none"> Denominator: number of implementation patients with documented progression or change in care plan (EMR) Nominator: number of patients for whom the change in care plan is reflected in care sequence (care sequence). 		
C. Improved care coordination (both baseline and implementation data will be collected)				
C1. Provider: improved ability to deliver coordinated care	Key topics: <ul style="list-style-type: none"> Ability to deliver comprehensive multi-domain care, based on guidelines (focusing on care in metrics A1 – A7) Ability to conduct comprehensive care planning Ability to coordinate care with other care domains Effectiveness in enabling the patient’s journey through various domains in the care continuum 	Provider survey pre- and post-implementation	IOM 2013, IOM 2011, AHRQ 2011 (Coordinating care in the medical neighborhood)	Effective Timely Efficient
C2. Patient: receiving better coordinated care	Key topics: <ul style="list-style-type: none"> Understanding of the overall care plan Ability to better coordinate one’s care Communication / alignment between domains providing care 	Patient survey pre- and post-implementation Family/Caregiver survey pre- and post-implementation	IOM 2013, IOM 2011, AHRQ 2011 (Coordinating care in the medical neighborhood)	Effective Timely Efficient Patient-Centered Equitable

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Metric	Description	How measured – implementation (data sources are in parentheses)	Guideline / quality metric	IOM dimension of quality
	<ul style="list-style-type: none"> Impact of having an LP / LCO on the ability to coordinate and plan one’s care Ability to be in control of one’s care process, navigation through care and care transitions across domains. Whether the care sequence help the patient with adhering to appointment schedules 		neighborhood)	
C3. Institutional care coordination improvements	<ul style="list-style-type: none"> Duration between steps in care across domains: <ul style="list-style-type: none"> Between diagnosis and neoadjuvant therapy initiation Between neoadjuvant treatment completion and definitive surgery Between definitive surgery and initiation of next step in treatment (radiation or adjuvant therapy) Number of ED visits within the episode of care. 	Statistical measures related to these timelines. All timings will be retrieved from EMR. Number of ED visits to be obtained from EMR. Number of Hospital days to be obtained from EMR	IOM 2013, IOM 2011, AHRQ 2011 (Coordinating care in the medical neighborhood)	Effective Timely Efficient
D. Cost Impact				
D1. Resources necessary to fulfill LP / LCO responsibilities	<ul style="list-style-type: none"> Time spent by LPs / LCOs fulfilling these responsibilities 	LP/LCO timesheet – to be developed (no baseline)	N/A	Effective Efficient
D2. Episode of care cost impact	Percent change in costs for breast cancer care episode* for implementation patients (absolute costs may be infeasible to disclose).	EMR / internal institutional systems	N/A	Effective Efficient

*** Definitions for concepts used in Table 1 above**

- Implementation population will include: female patients newly diagnosed with metastatic breast cancer at an implementation site between implementation dates, who are assigned LP / LCO and receive a care sequence.
- Patient Goals discussion: per latest literature, defined as discussion of patient’s understanding of illness and patient expectations.
- Date of diagnosis: date when the full pathology report and work-up imaging report are returned and recorded in EMR.
- Episode of care: care from diagnosis (as defined above) through transition to end-of-life care (hospice enrollment).

b. Quantify the amount of change expected from this project in terms of your target audience, using measures from table 1:

A1. Patient goals* discussion for newly diagnosed patients

A1.1. Percent of patients with whom discussion was held within the care episode* **50% increase over baseline**

A1.2. Percent of patients for who Patient Goals* discussion conducted before treatment initiation or surgery, but no later than 30 calendar days after diagnosis* **50% increase over baseline**

A1.3. Percent of patients with current Health Care Power of Attorney (before first surgery but no later than 60 days of diagnosis*. (Current – newly created or previously created but confirmed or updated by patient). **30% increase over baseline**

A2. Supportive Oncology and Distress screening after diagnosis and in the course of care episode

A2.1. Percent of patients screened for distress before treatment initiation or surgery, but no later than 30 calendar days after diagnosis* **50% increase over baseline**

A2.2. Total number of distress screens per patient within 12 months of diagnosis* **100% increase over baseline**

A2.3. Total number of symptom/pain/side effect screens per patient within 12 months of diagnosis* **100% increase over baseline**

A3. Dental referral, prior to initiation of systemic treatment

A3. Percent of patients receiving a referral to a dentist vs. those indicated **30% increase over baseline**

A4. Genetic assessment and testing

A4.1. Percent of patients with documented family cancer history, based on the NCCN HBOC family history questions* **20% increase over baseline**

A4.2. Percent of patients with documented history and indications for genetic counseling who received a referral to genetic counseling **20% increase over baseline**

A5. Referral to a Primary Care Physician (PCP) consult

A5. Percent of patients who received referral to a PCP before treatment initiation or first surgery **20% increase over baseline**

B1. LP, LCO responsibilities, as designed

B1.1. Percent of patients for whom LP / LCO were assigned within 3 calendar days of completion of diagnostic workup **no baseline, goal is 85% of target patients once implemented**

B1.2. Time between diagnosis* and creation of initial care sequence **no baseline, goal is 7 days**

B1.3. Number of transitions of LP/LCO responsibilities per patient from diagnosis through treatment **no baseline, goal is 0.5 transitions of responsibilities (lower is better)**

B2. Use of care sequences, as designed

B2.1. Completeness of care sequence: we will review and code care sequences as (1) complete based on relevant care (2) somewhat complete (3) incomplete **no baseline, goal is an average of 1.25**

B2.2. % of patients for whom care sequences were updated at pivotal care points (change in care plan, change in prognosis) **no baseline, goal is 85% of target patients**

C1. Provider: improved ability to deliver coordinated care **25% increase over baseline survey**

C2. Patient and family/caregiver: receiving better coordinated care **15% increase over baseline survey**

C3. Institutional care coordination improvements **25% improvement from baseline**

D1. Resources necessary to fulfill LP / LCO responsibilities Time spent by LPs / LCOs fulfilling these responsibilities **no baseline, goal is to keep within 5% of existing responsibilities**

D2. Episode of care cost impact Percent change in costs for breast cancer care episode* for implementation patients (absolute costs may be infeasible to disclose). **5% reduction from baseline**

c. Describe how you plan for the project outcomes to be broadly disseminated.

We will disseminate project outcomes via several mechanisms with broad spectrum of audiences. We will submit our results as abstracts for presentation to oncology conferences, including: ASCO Annual Meeting, NCCN Annual conference, ASCO Quality Symposium and Lynn Sage Breast Cancer Symposium. We will write a manuscript for publication in a high-impact peer-reviewed journal, such as Journal of NCCN (JNCCN) or Journal of NCI (JNCI). The co-investigators already have a track record of publishing in these two and other cancer journals {Freund JNCI paper 2014, Schink JNCI 2014, Trosman JNCCN 2015}. We will also develop and conduct adaptive workshops with all remaining sites of Northwestern Medicine and a number of collaborating community institutions, including Mercy Hospital, Rush University, Sinai, University of Illinois Chicago, the Stroger Cook County Hospital and Healthcare system, Advocate Healthcare and others. We will also propose an on-line adaptive workshop for interested NCCN centers, if deemed of interest to NCCN.

6. Detailed Workplan and Deliverables Schedule:

Personalizing patient's metastatic breast cancer treatment and supportive care plans will occur over a two-year period, as described in the detailed workplan and deliverables schedule.

Key deliverables include:

- (1) a report of current state and gaps based on 4R metrics at participating sites
- (2) Implementation of 4R plans for metastatic breast cancer patients at participating sites
- (3) Adaptive workshops within Northwestern at four points during project and a dissemination workshop with Chicago area breast cancer treatment sites near the end of the project.
- (4) Report of implementation results, as compared with baseline data. The detailed workplan and deliverables schedule describes the detailed tasks, timing and deliverables for this project.

Detailed Workplan and Deliverables Schedule Table

Activity / task	Year 1				Year 2				Deliverable
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
Project startup									Project kicked off, protocol for surveys submitted to scientific review committee, protocol submitted to IRB. Expected that protocol will be determined “program evaluation” and not human subjects research.
1) Conduct current state and gap analysis of MBC care delivery at participating sites									
a) Conduct survey of patients at participating sites									Completed and analyzed current state / gap patient surveys
b) Conduct survey of family / caregivers of patients at participating sites									Completed and analyzed current state / gap family / caregiver surveys
c) Conduct survey of providers at participating sites									Completed and analyzed current state / gap provider surveys
d) Collect data using pre-developed 4R metrics of care delivery									EDW queries designed and run. Chart abstraction tool developed and data collected.
e) Develop baseline measures									Baseline data analyzed and measures developed
2. Educate/ Inform participating sites on 4R methods, collaboratively develop 4R implementation plans									
a) Conduct adaptive workshop focused on current state and gap analysis workshop with providers									Workshop completed with active participation from providers including adjustments to 4R implementation approach as determined in workshop.
b) Design MBC 4R-Care-Sequences and templates									Completed care plan templates, from point of care initiation with patient personalization: histology, biomarkers, patient/ family history, co-morbidities, patient’s life stage, patient’s personal needs & choices. Utilization of project management principles, with timing, sequencing, dependencies, roles / responsibilities, checkpoints
c) Design approach to clearly discuss patient									Documented care process for discussion of patient wishes and patient’s

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Activity / task	Year 1				Year 2				Deliverable
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
wishes (e.g., long-term management, palliation) and patient understanding of prognosis									understanding of prognosis, using national standards such as 5 wishes and NCCN palliative guidelines as basis.
d) Design lead physician and lead care organizer (LCO) roles									Detailed roles and responsibilities for team members
e) Conduct second adaptive workshop focused on 4R implementation including operational training									Completed implementation ramp-up and operational training, and adjustments to 4R care sequences and templates as determined in workshop.
3. Implement metastatic breast cancer 4R plans									
a) Implement 4R plans with newly diagnosed metastatic breast cancer patients (ramp up over first month of implementation)									Provide 4R care plans to newly diagnosed metastatic breast cancer patients at participating sites
b) Follow the 4R plan for each patient									Revised 4R care plans for each patient as their individual needs, wishes, and/or prognosis changes.
c) Conduct 3 rd adaptive workshop with providers focused on 4R implementation challenges with a focus to adjust/adapt to address each challenge.									Workshop completed with active participation from providers, including adjustments to 4R care plans and approach as determined in workshop.
d) Conduct survey of patients 2 months into treatment									Completed 4R patient surveys
e) Conduct survey of family / caregivers of patients 2 months into treatment									Completed 4R family / caregiver surveys
f) Conduct survey of providers after 4R implementation									Completed 4R provider surveys

Activity / task	Year 1				Year 2				Deliverable
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
g) Obtain and analyze post-implementation data (start collecting sequencing, tabulating data during implementation)									EDW queries designed and run. Data collected from 4R plans
h) Analyze post-4R surveys and data with baseline surveys and data									Comparison of baseline data to
4. Disseminate results and the 4R methodology for MBC care delivery improvement									
a) Conduct 4th adaptive workshop with providers focused on lessons learned from 4R implementation and to develop dissemination plan.									Documented lessons learned and detailed dissemination plans
b) Develop a summary report of results and findings									Summary report of results and findings
c) Submit abstract and/or manuscript for peer review									Completed abstract/manuscript
d) Conduct local workshop for breast cancer treatment sites to share findings from implementation and tools developed									Conduct of local workshop for breast cancer treatment sites sharing experience and tools from 4R implementation for metastatic breast cancer patients.
e) If of interest to NCCN, propose a (or a set of) online adaptive workshops for NCCN and other breast cancer treatment centers									Proposal of online adaptive workshops.
f) Complete other dissemination activities identified by provider workshop									Complete dissemination plan activities

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