Title: Improving the Quality of Breast Cancer Care in an Underserved Rural Setting

Abstract:

Introduction:

Because of the multi-disciplinary nature of cancer care, the treatment of cancer generally and breast cancer specifically is a major challenge in rural regions of the US. The overall goal of this proposal is to assure that women, diagnosed with breast cancer in rural community health centers, have the opportunity to receive safe, timely, patient center, evidence based and efficient care for their newly diagnosed breast cancer in their geographic community's health care system.

Target Audience:

The primary target audience for this project are the interdisciplinary team of physicians, nurse, and ancillary personnel within Vidant Health rural health care centers of eastern North Carolina who are involved in the care of patients with newly diagnosed breast cancer.

Methods:

1) Engage Stakeholders throughout our rural health care system to become an integral part of a system wide Breast Cancer Program based upon the NCCN and NAPBC Standards, 2) operationalize a system wide Virtual Breast Cancer Conference and 3) develop enhancements to EPIC EHR to assist in compliance with evidence based clinical pathways and guidelines in breast cancer care.

Assessment:

We will utilize compliance with nationally accepted Standards from the NCCN and NAPBC as the metrics to address areas for improvement in quality of care in our own Breast Cancer Program at the Leo Jenkins Cancer Center and our rural health care center partners caring for breast cancer patients. The source of the data to evaluate the effect of change will be obtained through reports generated from EPIC EHR.

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Main Proposal

Overall Goal and Objectives:

The overall goal of this project is to assure that women, diagnosed with breast cancer in rural community health centers, have the opportunity to receive safe, timely, patient center, evidence based and efficient care for their newly diagnosed breast cancer in their geographic community health care system. Implicit in this overall goal, is that patients with social economic and racial/ethnic barriers to care will receive equitable care. The American Society of Clinical Oncology notes that "the use of clinical pathways in oncology care is increasingly important to patients and oncology providers as a tool for enhancing both quality and value"1. We propose to accomplish this overall goal, by integrating evidence based clinical pathways into our health system wide electronic health record (EHR) and the utilization of an interdisciplinary Virtual Breast Cancer Conferences to assure that women in rural communities with newly diagnosed breast cancer will have access to and be able to receive the same essential interdisciplinary services that they might receive at any cancer center in any urban area in the country, but within their geographic community. Patients with cancer report that psychosocial support, responsibility for care, and coordination of care are important aspects of quality care and lack of communication as barriers to quality care², all of which are likely to be bests delivered in their home communities with the care givers they know best. This overall goal aligns fully with the focus of the NCCN Oncology Research Program RFP of improving outcomes by improved adherence to clinical pathways and improving and supporting multidisciplinary collaboration as well as the mission and goals of both Vidant Health, the regional hospital system in Eastern North Carolina (ENC), and the Health Sciences Schools of East Carolina University (ECU) which is to improve the health and well-being of the citizens of Eastern North Carolina.

Key Objectives:

We propose to accomplish this overall goal through the following key objectives:

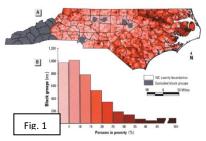
- Utilize a structured Virtual Breast Cancer Conference format to provide access to an interdisciplinary team of individuals who specialized in the care of Breast Cancer to physicians caring for women with breast cancer in rural healthcare centers of Vidant Health.
- 2. Integrate clinical pathways into the workflow of the EHR that will provide Best Practice Alerts and Required Element Completions to improve compliance with clinical pathways.
- 3. Utilize existing reporting mechanisms or develop enhancements to the EHR that will provide rapid and timely assessments of compliance with evidenced based clinical pathways and quality standards.

Rural health care centers often times face unique barriers to the implementation of widely accepted treatment guidelines. Prominent among these is the fragmentation of multidisciplinary care (RF Holcombe, personal communication). Key Objective 1 is designed to address this crucial aspect of breast cancer care in geographically isolated settings, by operationalizing a Virtual Breast Cancer Conference that will utilize an established

interdisciplinary Breast Cancer Care team at Leo Jenkins Cancer Center at ECU and virtually interact with rural physicians caring for breast cancer patients throughout Vidant Health. This Virtual Breast Cancer Conference will assure that each individual patient will have access to prospective multidisciplinary consultation which support multidisciplinary collaboration and will improve communication between care givers without patients having to travel great distances and at great expense. Key Objective 2 will provide the EHR support to improve compliance with clinical pathways by providing reminders (best practice alerts) and/or required elements be completed) prior to closing a patient encounter. The utilization of a structured Breast Cancer Conference format in conjunction with the integration of clinical pathways in to the work flow of the EHR will allow reporting of adherence to clinical guidelines and improve the quality of care and allow rapid feedback to assure compliance with clinical care guidelines (Key Objective 3).

Current Assessment of need in Target Area:

The treatment of cancer generally and breast cancer specifically is a major challenge in



rural regions³. Eastern North Carolina (ENC) is a large, underserved geographic area that includes 1.4 million people who reside in 29 of the 100 counties of North Carolina. The population is poor, older, and less well educated than the rest of the US⁴. The proportion of African Americans is generally above 30% in most counties (Figure 1). These are factors known to be associated with poorer health outcomes. Cancer,

in particular, disproportionately affects the region⁵. Cancer (all site) mortality is 11% greater and breast cancer mortality is 19% greater than in the rest of North Carolina⁵. This is the



The reasons for these poorer outcomes are assuredly multifactorial but gaps in care and compliance with accepted Standards have been identified. A previous analysis of the North Carolina Tumor Registry suggested women in ENC are more likely to have delays in adjuvant chemotherapy delivery which has been

geographic region served by Vidant Health and ECU (Figure 2).

associated with poorer survival⁶. Women in ENC were less likely to be white (P < 0.001), estrogen receptor (ER)-positive (P < 0.001), progesterone receptor (PR)-positive (P < 0.001), or to receive adjuvant chemotherapy (P = 0.02). Improved median survival was associated with ER status (P < 0.001), PR status (P < 0.001), race/ethnicity (P < 0.001), and delivery of timely chemotherapy (P < 0.0001)⁶. Because of the impact of adjuvant chemotherapy on outcome, assuring that all women who meet criteria for adjuvant systemic chemotherapy are treated in a timely fashion (<120 days) is critical^{7,8}.

An examination of the frequency of genetic counseling in 968 patients with breast cancer treated at Vidant Medical Center identified that 46.2% of these individuals met NCCN criteria

for genetic risk assessment⁹, yet only 59.6% were referred for genetic counseling and risk assessment indicating a significant gap in this aspect of care. We believe that at least 85% of patients who merit cancer risk assessment, genetic counseling and genetics testing should be offered and or receive this service¹⁰. The completion of a Family History with special attention to a family history of cancer should be obtained in all patients with newly diagnosed cancer generally and breast cancer specifically.

A review of our utilization of breast MRI and the impact on the rate of re-operation for positive margins in patients with either dense breast or for lobular histology on core biopsy demonstrated similar reoperation rate between the 2 groups (19.1% in the MRI group vs 17.6% in the no MRI group, P = .91) suggesting that even in selected populations, there as an over-utilization of breast MRI¹¹. We believe that the routine utilization of breast MRI should be abandoned except in the setting of mammographically occult tumor and utilized only after careful consideration in a multidisciplinary conference in other settings⁹.

NCCN clinical pathways are detailed, evidence-based processes for delivering cancer care for specific patient presentations and are therefore dependent upon the Clinical Stage at diagnosis. Although clinical stage of patients maybe present throughout the EHR, when not documented in the designated site of the EPIC EHR (Problem List) can be difficult to readily identify. In our Breast Program at the Leo Jenkins Cancer Center at ECU, staging documentation within the designated site of the EPIC EHR (Problem List) in all breast cancer patients has been required. However an audit of compliance with this critical standard in our Vidant rural health care centers identified less than 50% of breast cancer patients as having clinical staging documented in EPIC EHR Problem List. Achieving documentation of clinical staging within the Problem List of EPIC EHR is a critical goal and in patients who have undergone a surgical procedure, pathologic staging in the Problem List of EPIC EHR.

A critical standard of the National Accreditation Program for Breast Centers (NAPBC) is the Interdisciplinary Care of the Breast Cancer Patient as manifested by prospective presentations at a Multidisciplinary Breast Cancer Conference (Standard 1.2)¹⁰. Studies have reported improved processes of care resulting from multidisciplinary cancer conferences and compliance with NCCN Guidelines¹² and can results in changes in management¹³. An audit of patients diagnosed with Breast Cancer within the rural health care centers of Vidant Health could not identify documentation that patients with newly diagnosed with breast cancer were prospectively presented at a Multidisciplinary Cancer Conference in which recommendations for care were considered. Although many of these individuals may have been presented in cancer conferences, the absence of documentation, makes it difficult to determine whether multidisciplinary recommendations for care are consistent with accepted guidelines and that these recommendations are communicated across the interdisciplinary team. This is considered a critical deficiency by the NAPBC and results in a failure in the accreditation process. The goal of this proposal is to assure that at least 85% of patients with newly

diagnosed breast cancer are reviewed at a Multidisciplinary Breast Cancer Conference and a recommendation for care documented in the EHR to be compliant with NAPBC Standard 1.2¹⁰.

The surgical care of women in rural setting is impacted by the distance to radiation therapy centers^{14,15}. However, women opting to undergoing mastectomy who don't meet indications for post-mastectomy radiation⁹ should be offered and opportunity for Reconstructive Surgery consultation immediate reconstruction (NAPBC Standard 2)¹⁰. Because access to reconstructive surgery may be problematic in rural settings, these women may not be identified for this quality indicator¹⁰. A recent audit suggest this is maybe the case. Only 2 of 33 women undergoing mastectomy for early stage node negative breast cancer underwent immediate reconstruction in our rural health care centers.

Other target areas that are proposed to be examined are the number of patients receiving navigation¹⁶, the utilization of ancillary studies in the clinical work up early stage breast cancer⁹, sentinel node utilization, and completion axillary node dissection^{10,17}, evidence based adjuvant systemic therapy, and breast cancer survivorship¹⁰.

Target Audience:

The primary target audience for this project are the interdisciplinary team of physicians, nurse, and ancillary personnel within Vidant Health rural health care centers who are involved in the care of patients with newly diagnosed breast cancer. In contrast to large urban medical centers with cohorts of disease specific treatment groups, we recognize that oncology care givers in rural setting treat multiple different malignant disease entities and do not have luxury of focusing on a single disease site. We plan to engage all stakeholders including surgeons and medical oncologist who are involved in the care of breast cancer patients as part of their surgical and medical oncology practice to be part of this quality improvement project. We anticipate a strong level of commitment as they will be able to assure not only their referring physicians but the patients as well that they will receive the same quality of care in their geographic area as they might in any cancer center in the country because of the quality metrics that will be implemented in this proposal. Two of our regional rural health care centers have recently undergone successful accreditation by the Commission on Cancer and will be the focus of this project.

Physicians who work in relative isolation in rural health care settings will directly benefit from this projects outcome by being able to routinely engage in interdisciplinary care conferences and be assured that the care that is being delivered meets accepted guidelines of care¹⁸. Patients who opt to have their care in their own community will directly benefit by the proximity of their social support system(s)¹⁹ and being in their home environment without long, expensive, and time consuming travel to urban cancer centers and with the knowledge that they are receiving the same quality of care that they would receive in an urban cancer center. Finally, this project will demonstrate the feasibility and utility of virtual Cancer Care Conferences to assure that safe, timely, evidence based, efficient, and patient center care is

delivered to patients in their own geographic area as determined by compliance with clinical pathways of care and clinical guidelines for breast cancer and be a model for the care of other malignancies in rural geographic settings.

Project Design and Methods:

Overall Strategy:

Based upon an examination of breast cancer care in our rural region, a need for well documented and communicated interdisciplinary care that adheres to cost effective clinical pathways across the transition from diagnosis to specialty care is evident. The overall strategy in this proposal will be to 1) Engage Stakeholders throughout our rural health care system to become an integral part of a system wide Breast Cancer Program based upon the NAPBC Standards, 2) Operationalize a system wide Virtual Breast Cancer Conference in which newly diagnosed breast cancer patients are prospectively reviewed **prior** to the first course of therapy (both local/regional and systemic) and at times of transitions of care (post-operative and recurrence) and in which evidence based recommendations for management will be considered based upon accepted guidelines and clinical pathways, 3) develop enhancements to EPIC EHR to assist in compliance with evidence based clinical pathways and guidelines in breast cancer care, and 4) will allow the timely reporting of compliance with quality metrics.

To accomplish the overall goal of this project, which is to assure that women, diagnosed with breast cancer in rural community health centers, have the opportunity to receive safe, timely, patient center, evidence based and efficient care for their newly diagnosed breast cancer in their geographic community, we will focus on areas of established need and those that may defined during a detail analysis of breast cancer care delivery as described in our Current Assessment of Need in Our Target Area section (see above).

Project Methods:

Virtual Breast Cancer Conference

A Critical Standard of the NAPBC is the prospective presentation at a Multidisciplinary Breast Cancer Conference, newly diagnosed breast cancers¹⁰. Non-compliance with this Critical Standard results in non-accreditation by the NAPBC. Rural environments present unique barriers to the implementation of multidisciplinary conferences that include lack of support for meetings, geographical distances between team members, and staff (physician) shortages²⁰. For these reason physicians may not have the ability to routinely participate in a multidisciplinary cancer conference and promote collaborative cancer treatment planning.

A Virtual Breast Cancer Conference is a key component of this proposal and will largely overcome these cited barriers. The alignment with and commitment to the overall Cancer Program goals of Vidant Health/ECU is seen as critical to addressing these barriers and is evidenced by Vidant Health having budgeted and already allocated the necessary financial

resources for a state of the art video conferencing infrastructure in a soon to be opened (March of 2018) Cancer Tower (Figure 3) on the Vidant Medical Center Campus **and** for video conferencing capabilities throughout the rural health care centers of Vidant Health. Construction of these video conferencing facilities are well



underway. The Virtual Breast Cancer Conference will overcome the geographic and intellectual isolation of rural clinicians caring for breast cancer patients. Prospective presentation prior to initiation of first course of therapy will provide rural breast cancer clinicians and their patients access to an interdisciplinary team of content experts who are committed to using the best scientific and clinical information available in treatment decision recommendations and allow rural clinicians to assure their patients they are receiving evidence based breast cancer care comparable to that in any urban cancer program.

Engagement of the Target Audience

Early engagement and buy in by key Stakeholders is critical to the success of this proposal. It is recognized that a significant barrier to participation are the time commitments of attending cancer conferences as they often conflict with busy clinical schedules¹⁸. We have already secured commitments from several key stakeholders at both the Administration Level and enthusiastic endorsement of the proposal by clinicians in the two Rural Health Care Centers that we will partner with in this proposal (See Letters of Support) an anticipate active participation in Vidant Health/ECU Breast Cancer Conference will be considered an integral part of membership in the Cancer Programs of Vidant Health/ECU. Engagement of the Target Audience will be ascertained by participation in the Virtual Breast Cancer Conference (minimum Standard will be 80% participation) and meeting or exceeding the 85% threshold for prospective case presentations.

Integrating Clinical Pathways into the EPIC HER and Building upon Existing Work

The ability to assure that newly diagnosed patients are receiving care that is compliant with evidence based clinical pathways and meets national quality standard, we are proposing to integrate breast cancer clinical pathways into the work flow of EPIC EHR. An established Advisory Group headed by Dr. Weil (co-investigator) is already examining clinical pathways in the delivery of systemic chemotherapy in Medical Oncology. Pathways to assure that best practices for the delivery of chemotherapy are being examined in which assuring accurate administration of systemic chemotherapy, based upon appropriate body weight are being built into the EPIC EHR. We will utilize this group's expertise, which the PI (JHW) is a member of, to

develop "Best Practice Alerts" not unlike those utilize to remind clinicians of the need for annual mammography or screening colonoscopy and "Required Element Completions" reminders for critical standards to increase compliance with pathways agreed upon by the Clinical Pathways Work Group as being critical to quality care of the breast cancer patient. Measuring the Effect of Change and Innovation

Although the feasibility of Virtual Cancer Conferences to engage rural practioners ¹⁸ has previously been demonstrate, the impact of these conferences and other interventions as is being proposed in this project on adherence to standard quality measures has not, to the best our knowledge, previously been rigorously examined. Although we have previously demonstrated in the bariatric surgery population the ability to document bariatric surgery excellence by capturing simple, categorical and easily analyzable data²¹ such approaches have not been utilized in cancer and is unique about our proposal. In conjunction with Vidant Health Information Technology This proposal in conjunction with the Advisory Group will develop a EHR platform in the Vidant Health/ECU Breast Cancer Program to not only enable the necessary communication between multiple providers, but to assure the quality of breast cancer patient care across a diverse rural health care system is comparable to any urban cancer center by the timely assessment of compliance with evidence based clinical pathways. We propose to have a structured Breast Cancer Conference Documented in which categorical data will be captured and be easily retrievable to determine compliance with clinical pathways and quality metric standards.

Evaluation Design:

We will utilize compliance with nationally accepted Standards from the NCCN⁹ and NAPBC¹⁰ as the metrics to address areas for improvement in quality of care in our own Breast Cancer Program at the Leo Jenkins Cancer Center and our rural health care center partners caring for breast cancer patients. The source of the data to evaluate the effect of change will be obtained through reports generated from EPIC EHR. The feasibility of this approach has been determined following discussions with our EPIC information technology experts.

To improve the prospective presentation of newly patients at Breast Cancer Conference, a Best Practice Alert will be developed when breast cancer is added as a new problem to the EPIC EHR Problem List to remind clinicians to submit that individual's name for presentation at the weekly Virtual Breast Cancer Conference AND to clinically stage the individual in the EPIC EHR Problem List. If necessary, the Completion of a Required Element will be institute prior to the closing of a patient encounter in EPIC HER to assure compliance with these critical elements of quality care. A project manager will have weekly reports generated to help facilitate the gathering of the appropriate materials (pathology slides and appropriate imaging) for presentation at the weekly Virtual Breast Cancer Conference.

In conjunction with an established Advisory Work Group, we will develop enhancements to the EPIC EHR that will allow timely reporting on the number of new breast cancer patients (denominator) and the number presented at Breast Cancer Conference and those who have

clinical staging in the EPIC EHR Problem List completed (numerators). Preliminary data from rural health care centers indicates that there is opportunity for improvement. Few if any patients are documented to have been prospectively reviewed at a Tumor Board and less than half of patients are having clinical staging completed in the EPIC EHR Problem List. As Critical Compliance Standards, the goal is ≥85% of patients prospectively presented at Breast Cancer Conference¹⁰ and 100% of patients clinically staged and documented in the EPIC EHR Problem List at the completion of this project. At the initial analysis of change we anticipated 50% of patients to be prospectively presented at 3 months and a 50% improvement in the number of patients clinically staged (75% of total) at 3 months.

We anticipated collecting the majority of data in real time at the time of review at the Breast Cancer Conference that is simple, categorical and therefore easily searchable and easily analyzable utilizing simple descriptive statistics and/or run charts to demonstrate shifts and trends in adherence to established guidelines and clinical pathways and to be able to initiate change where necessary to improve adherence to established guidelines.

Detailed Work Plan and Deliverables Schedule:

The Project will proceed in 3 phases (see Appendix)

- 1) Assemble a Team of Stakeholders. A Health System Breast Program Leadership Group (BPL) and Multidisciplinary Clinical Pathway Team (CPT) consisting of stakeholders²² throughout Vidant Health will be assembled and will perform a more detailed analysis of the current process of care across a large and diverse rural health care system. Although several gaps have initially been identified, this analysis will examine a number of quality indicators including prospective breast tumor board presentations, number of patients receiving navigation, breast cancer staging, diagnostic imaging performed, needle biopsy performance, and reconstructive surgery referrals as well as appropriate genetic referral and diagnostic imaging performed. The CPT will be charged with evaluating medical evidence and external practices, determining the clinical pathway format, and define minimal acceptable standards of compliance as well as determine target goals of improvement and/or excellence that have not been defined by national organizations.
- 2) Integration of Clinical Care Pathway into EHR. In concert with an established Advisory Group working on standardizing Medical Oncology care in EPIC EHR, the CPT will work to integrate clinical pathways into the workflow of physicians and providers of care to newly diagnosed, non-metastatic breast cancer patients. These will include Best Practice Alerts for recommended actions and Required Elements Completion for critical actions (Breast Cancer Conference, Stage of Disease, and Treatment Summary).
- 3) Documentation and Analysis of Variance. This proposal will develop and institute a real time data collection platform in which variance from clinical pathways (below minimally accepted standard or in excess of maximum utilization standard) are readily collected and analyzed. In a Structured Breast Cancer Conference Format, we are proposing a simple check list to capture

adherence to clinical pathway elements as part of a Breast Cancer Document. The CPT will analyze all variances initially to identify factors that have contributed to the variance and recommend interventions for system process improvement. The goals of the quality metrics and the specific percentage improvement over a defined times will be defined by the CPT and in those that have not been defined by either NCCN or NAPBC and will include but not necessarily be confined to 1) Preoperative diagnosis: the proportion of women with breast who had a needle biopsy as initial diagnostic procedure, 2) Breast MRI: The proportion of women undergoing breast MRI, 3) Breast Cancer Conference: The proportion of women prospectively presented at a multidisciplinary breast cancer conference (>85%), 4) AJCC 7th and then 8th Edition Staging: The proportion of women clinically staged prior to initiation of therapy and pathologically staged following surgery (100% of non-metastatic disease), 5) Nurse navigation: The proportion of women referred and seen preoperatively by a nurse navigator or surrogate (standard to be defined by CPT), 6) Plastic Surgery: The proportion of women undergoing mastectomy offered a referral for reconstructive surgery (standard to be defined by CPT), 7) Ancillary Studies: Proportion of preoperative ancillary studies for staging (standard to be defined by CPT), 8) Oncologic History: The proportion of women with a complete treatment summary (Oncologic History) within the EPIC EHR (100%), 9) Sentinel Node: The proportion of clinically node negative women undergoing sentinel node biopsy (Standard to be define by CPT), 10) Axillary Node Dissection: The proportion of clinically node negative, sentinel node positive patients undergoing completion axillary node dissection (Standard to be defined by CPT), 11) Genetics Referral: The proportion of patients who have a completed Breast Risk Assessment in the EHR (Standard to be defined by CPT).

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Appendix
Workplan and Deliverables Schedule. Start Date January 1,, 2018

Task	Time Table	Deliverable
Assemble a Health System Wide Breast Program Leadership Group and Clinical Pathways Team	Year 1, month 1	Formalize responsibilities of the BPLG and CPT.
Review current breast cancer process of care across the Vidanta Health Care	Year 1, months 2-3	Define and finalize the metrics to measure compliance with clinical pathways and standard of quality. Establish all baseline measurements.
Opening New Cancer Center, Vidant Medical Center	Year 1, month 3	Virtual Breast Cancer Conference Capability becomes operable.
Develop EHR enhancements and reporting mechanisms for agreed upon metrics of quality.	Year 1, months 4-12	Best Practice Alerts and Required Element Alerts Structured Cancer Conference Format with reportable categorical metrics.
Launch initiative for improved and standardized quality of breast cancer care in Pilot Institutions	Year 2, month 1	Go Live Date.
Evaluation of QI on key Elements: Prospective Case Presentation and Clinical Staging in EPIC EHR Problem List.	Year 2, month 1-3	First Analysis on Critical Standards Prospective Cancer Conference Presentation and Clinical Staging in Problem List of EPIC EHR and first potential change recommendation.
Ongoing evaluation of QI on NAPBC Standards	Year 2, months 1-10	Ongoing Model for Improvement evaluation of NAPBC Standards.
Project Evaluation	Year 2, months 11-12	Final Report