

**Clinical Pathway for the Timely and Appropriate Treatment and Support of
Young Women Diagnosed with Breast Cancer
Grant ID# 36030539**

Lead Cancer Center

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Fred & Pamela Buffett Cancer Center, Omaha, NE and cancer centers at:
Nebraska Medicine Bellevue & Village Pointe**

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A. Abstract

Goal: Improve the efficacy and efficiency with which oncology care providers (OCP) recognize and systematically address physical, psychosocial, and decision-making needs of young breast cancer patients in a manner that: a) extends to rural Nebraska populations, b) supports adherence to clinical guidelines, and c) minimizes burden to patients and the medical system.

Target Population: OCPs and approximately 100 women with breast cancer, < 50 years old, seen in six cancer centers throughout Nebraska.

Methods: A clinical pathway focused on young women with breast cancer will be developed with input from a 14 member multidisciplinary team (including breast cancer survivor). Pathway introduction to collaborating rural cancer centers will occur via live webinar event. The pathway will be hosted on a website accessible by collaborating cancer centers and patients. Throughout the project, eight pre-recorded educational webinars will be presented by specialists. Collaborating cancer centers will present young patients' cases at any of 3 weekly; real-time multidisciplinary conferences (MDC) held at UNMC-facilities using telemedicine capabilities, allowing OCPs to concurrently review radiology/pathology data and receive recommendations from multidisciplinary specialists for same-day patient consultations. Additional telemedicine consultations between UNMC specialists and collaborating OCPs will be offered.

Assessment: Patient decision-making satisfaction, treatment adherence, side effect management, psychosocial outcomes, and quality of life before pathway introduction, and 6 and 12 months (unique patients) after introduction will be assessed. OCPs' pathway and educational webinar access, pathway and NCCN guideline adherence, MDC and consult participation, knowledge, communication, and satisfaction will be assessed at 6 and 12 months.

Table of Contents

A.	Abstract	1
B.	Table of Contents	2
C.	Reviewers Comments (not applicable)	--
D1.	Overall Goal & Objectives	3
D2.	Current Assessment of Need in Target Area	4
D3.	Target Audience	8
D4.	Project Design & Methods	8
D5.	Evaluation Design	11
D6.	Work plan & Deliverables Schedule	12
E.	References	14
F.	Organizational Detail	17
G.	Budget (uploaded separately)	
H.	Biosketches	20
I.	Letters of Commitment	
I1.	Lead Cancer Center Institutional Leaders (UNMC/Fred & Pamela Buffett Cancer Center & Nebraska Medicine Clinics)	
I2.	Collaborating Cancer Centers (Callahan, St. Francis, Carson Cancer Centers)	
I3.	Multidisciplinary Consultative Team (Drs. Maclin, Rooney, Fletcher, Mills, Hannan, Wahl, Mudgapalli (Research IT), Ms. Blase, Rauth-Reisinger, & Schmidt)	

D1. Overall Goal & Objectives

D.1.a. Goal: Improve the efficacy and efficiency with which oncology care providers (e.g. MD, PA, NP, DNP, CNS) recognize and systematically address physical, psychosocial, and decision-making needs of young breast cancer patients in a manner that: a) extends to rural Nebraska populations, b) supports adherence to clinical guidelines, and c) minimizes burden to patients and the medical system.

D.1.b. Alignment of goal: This goal aligns with the goal of this RFP by addressing: a) a rural (underserved) population; b) care at diagnosis to affect patient outcomes throughout the survivorship continuum, and c) oncology care providers' learning and adherence to clinical guidelines. The project goal aligns with the University of Nebraska Medical Center (UNMC) mission to, "lead the world in transforming lives to create a healthy future for all individuals and communities through premier educational programs, innovative research and extraordinary patient care" by leading a continuing education and consultative initiative for Nebraska oncology care providers in conjunction with a clinical pathway to support extraordinary care for young women in rural communities that are beyond our usual catchment area.

D.1.c. Key Objectives: Three objectives target oncology care providers (OCP) and breast cancer patients who are < 50 years of age and cared for at UNMC Fred & Pamela Buffett Cancer Center (FPBCC) and Nebraska Medicine clinics (lead) (fig. 1 – red arrow) plus three collaborating Nebraska Cancer Coalition (American College of Surgeons Commission on Cancer accredited)¹ clinics serving rural Nebraskans (figure 1 – black arrows):



Figure 1. Location of Nebraska Cancer Centers (UNMC/Nebraska Medical Center east, Carson Cancer Center 113 miles north, and St. Francis Medical Center & Callahan Cancer Center 153 and 280 miles west of Omaha)

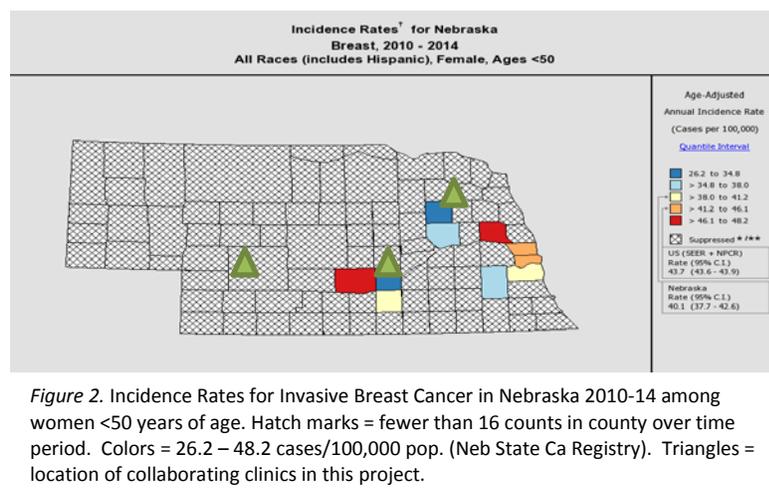
1. Develop and implement an Internet-accessible, evidence-based clinical pathway, with associated online educational resources, focused on the care of women < 50 yrs. old, newly diagnosed with breast cancer. H1a. OCPs accessing the pathway will *adhere* to NCCN or other clinical guidelines relevant to this population with greater frequency than prior to pathway introduction. H1b. Patients of providers accessing the pathway will report greater *satisfaction* with decision-making and physical/psychosocial treatment side-effect prevention/management, treatment *adherence* and *quality of life (QOL)* than prior to pathway introduction.
2. Initiate and support telemedicine access for collaborating NE Cancer Coalition clinics to present current patient cases at any of 3 multidisciplinary breast clinic conferences (MDC) hosted by the Fred and Pamela Buffett Cancer Center (FPBCC) and Nebraska Medicine clinics for the purpose of shared consultation regarding the care of young women newly diagnosed with breast cancer. H2a. Collaborating OCPs participating in MDC will report greater *knowledge* and *satisfaction* with their care (including communication) of young women with breast cancer, and adherence to NCCN and other clinical guidelines than prior to MDC access. H2b. Patients of providers participating in

MDC will report greater *satisfaction* with decision-making and physical/psychosocial treatment side-effect prevention/management, treatment *adherence* and *QOL* than prior to MDC accessibility.

3. Develop and provide telemedicine consultation and Internet-accessible education from specialists in areas relevant to the care of young women newly diagnosed with breast cancer (i.e. fertility, genetics, sexual dysfunction, lymphedema, plastic surgery, radiation therapy, weight management, and psychological wellbeing) for collaborating OCPs. H3a. Collaborating OCPs accessing specialist consultation will report greater *knowledge and satisfaction* with care (including communication) provided than prior to access to education and specialist consultation. H3b. Patients of providers accessing specialist consultation will report greater *satisfaction* with decision-making and physical/psychosocial treatment side-effect prevention/management, treatment *adherence* and *QOL* than prior to the implementation of OCP education and access to specialist consultation.

D2. Assessment of Need in Target Area:

D2.a. On average, 1,583 cases of breast cancer (invasive/in-situ) are diagnosed annually in Nebraska (NE). Two-hundred sixty-seven (267) of these cases are among women < 50 years of age (2010-2014 data). The majority of young women diagnosed live in 3 urban NE counties; Douglas County (fig. 2 – orange) where the FPBCC and Nebraska Medicine Village Pointe clinic are located, adjacent Sarpy (fig. 2 –orange)(where Nebraska Medicine Bellevue clinic is located) and nearby Lancaster county (fig. 2 light blue) in eastern NE.² The other approximately 107 annual cases occur among young women living in one of the other 90 Nebraska counties² across 76,000 mostly rural square miles, served by 6 north and western cancer centers in the NE Cancer Coalition.¹ Thus, for many OCPs, treating women under 50 years of age for breast



cancer occurs infrequently enough that time and energy is not expended to maintain expertise and resources for this population (fig 2 – hatch marks represent counties with fewer than 16 count over the 4-year period).

D2.a.1. Current state of care.

Breast cancer in young women is typically more aggressive than in older women,³ but mortality has been stable nationally and decreased in NE in recent years.² Therefore, planning for

decades of survivorship raises the importance of appropriate initial treatment planning and support of young women at diagnosis.

Nationally, gaps exist in the timely and appropriate care of young women with breast cancer.

- **Surgical decision making.** Young women increasingly choose contralateral prophylactic mastectomy (CPM) due to worry about recurrence and a desire for breast symmetry,⁴⁻⁶ despite no survival benefit of CPM for average risk women.⁷ Nationally, from 2004 – 2012

CPM increased among women 22 – 44 years of age from 10.5% to 33.3%.⁸ Five Midwestern states, including **Nebraska**, had the highest rate of CPM performance, with 42.8-48.5% of young women undergoing CPM from 2010-2012.⁸ Potential harms of CPM include doubling of the risk of surgical complications, and additional risks associated with reconstructive surgery, which in turn may have the deleterious effect of delaying the start of adjuvant therapy.⁷

Despite these risks, young women express confidence and independence in their decision to undergo CPM and less worry about recurrence afterward.⁶ Studies have identified young women who did not have CPM as desired, regretted this decision and felt “talked out of it” by their physician.⁹ On the other hand, young women may have the opposite response and express regret over losing a breast rather than having undergone lumpectomy when that was an option.⁹ Regardless of the surgical treatment decision, young women express regret in not obtaining sufficient information on treatment alternatives and potential adverse effects.⁹ Furthermore, treatment costs and financial burden are disproportionately born by younger¹⁰ and rural women¹¹ with breast cancer; the largest costs associated with physician office and hospital outpatient care.

Therefore, the rate of CPM can potentially be lowered, patient psychological wellbeing enhanced, and cost burden reduced through anxiety management, better physician-patient communication, and specialist consultation (e.g. plastic surgery, genetics) that provides risk communication, and appropriate, well-informed and efficient care along with shared decision-making support.^{6,7,9}

- **Genetic testing.** NCCN Guidelines indicate that women under age 50 diagnosed with breast cancer should undergo genetic testing,¹² however, “the clinical need for genetic testing may not be adequately recognized by physicians.”^{13(pg. 533)} Although one study identify a trend showing an increase in genetic testing for women with breast cancer under age 40,¹⁴ others found that women 41-50 years of age had twice the odds of women 40 and younger of not having genetic testing recommended.¹⁵ Overall about 50% of high-risk women receive a recommendation for genetic testing from their physicians.^{13, 15} This is concerning because young women’s genetic predisposition affects early treatment decisions. Also concerning is the lack of genetic counseling available to newly diagnosed women.¹³ Physicians’ knowledge of genetic risk, NCCN Guidelines, communication with patients and the availability of genetic counselors are areas of needed improvement for the treatment of women under age 50.^{13,15}
- **Fertility.** Women report being ill informed about the potential inability to conceive children after chemotherapy^{16, 17} despite NCCN Guidelines that all premenopausal women should be informed of the potential impact of chemotherapy on fertility and engaged in a discussion about their future childbearing.¹⁸ Discussion is also needed regarding the role of ovarian suppression and estrogen-receptor modulators in treatment. Such discussion may be particularly lacking among women over age 35 and those with children at the time of diagnosis.¹⁹ Efforts are needed to raise awareness about fertility issues and options on both the part of patients and OCPs to increase knowledge, communication and appropriate care of young women.¹⁹
- **Distress.** NCCN recognizes distress as a significant outcome of cancer diagnosis and therapy.²⁰ Young women with breast cancer experience distress from multiple sources

including worries and lack of information about fertility, surgical decision-making and body image.^{16,17,21} Despite a mandate to assess for distress, access to psychological care, resource insufficiency and patient acceptance are barriers to distress-management for 70-80% of cancer survivors.²² Unmanaged distress is associated with long term psychological issues of depression, anxiety and poor QOL.²³ Characteristics of people with cancer that make them more vulnerable to distress are young age, female gender, and being unmarried.²⁴ Nationally, rurality is also a risk factor for poorer mental health among cancer survivors.²⁵ Little attention has been paid to this disparity among women with breast cancer.^{26,27} Educational efforts must be implemented to increase OCPs' awareness of the importance and psychological impact of breast cancer diagnosis on new and long-term survivors, and the need for assessment and management according to NCCN Guidelines.

- ***Weight-gain, lymphedema & sexual dysfunction & body image.*** Breast cancer and its treatment pose myriad concerns for younger women. Physical activity decreases during treatment compounding the problem of weight gain in young women that may be more significant than in older women and brought about by chemotherapy and transition to menopause.¹⁶ Reduced physical activity and weight gain also affect women's body image and QOL. Body image and sexual function are concerns for young women especially post-mastectomy, when menopausal symptoms occur, or if lymphedema develops. Young women require more information than older women about all of these topics soon after diagnosis to influence treatment decision making and set realistic expectations and goals for prevention, when possible.^{16,17} The frequency and quality of these discussions, however, is lacking nationally.^{17, e.g.21}

D2.a.2. Achieving the expected outcomes of this project will address current gaps in the care of Nebraskan women with breast cancer, < 50 years old, and impact OCPs' satisfaction (and thus sustainable engagement), and patients' satisfaction with care and physical/emotional wellbeing by means of an increase OCP's:

- knowledge on current and changing guidelines regarding physical and psychological issues that must be addressed to achieve appropriate and timely treatment and through this knowledge;
- ability to communicate with and educate young women with complete, accurate and timely information about all treatment options, potential side-effects, and realistic expectations with attention to women's needs, thought, and concerns that drive their treatment decisions and QOL.

D2.b. Baseline national and local data pertaining to need. A search of the available published literature did not identify projects that specifically targeted both young and rural newly diagnosed women. No data were found that focused on the Midwest or Nebraska with the exception of the data reported by Nash et al.⁸ that identified the highest rate of CPM among Nebraska and four other Midwestern states in 2010-2012. An acknowledged limitation of that work, however, is that the researchers did not have access to data regarding the genetic testing status or patient-physician discussion that may have led to the CPM decision.⁸ Neither the Nebraska Cancer Registry nor the Cancer Coalition gathers such data and priorities are focused more for the Coalition on primary cancer prevention efforts. Therefore, local assessment is needed to identify the extent of adherence to NCCN or other applicable guidelines in the areas

of primary concern for young, newly diagnosed, Nebraska women. There is no evidence to demonstrate that gaps in care that exist nationally do not also exist in Nebraska.

D2.b.1. Project starting point. We will first conduct a baseline, retrospective assessment of UNMC/Nebraska Medicine and collaborating rural cancer centers' OCPs' practice patterns when caring for young women with breast cancer over the most recent 2 years for which these data are available.

Table 1. Baseline Assessment Practice Patterns (most recent 2 year period) Women < 50 years of age	
Topic	To Be Assessed from Electronic Medical Record (or hand searched as needed)
Surgery	# CPM, Mastectomies, and lumpectomies performed Documentation (yes/no) of multidisciplinary pre-surgical consultations (oncology/RT) Documentation (yes/no) of discussion of patient preferences
Hormonal therapy	# of women recommended estrogen-modulators # of women recommended ovarian ablation
Radiation therapy	# of women receiving radiation therapy in accordance with guidelines
Genetic testing	# of women referred for genetic testing & # of women undergoing genetic testing # of women referred to & # women receiving genetic counseling # of women for whom documentation of pre-op discussion on genetic testing is present
Fertility	# of women with whom issues of fertility were discussed # of women receiving referral to reproductive specialist # of women who underwent fertility preservation procedures (e.g. Lupron during chemo.) # of women receiving non-hormonal birth control counseling
Distress	# of women assessed for distress # of women referred to psychological for assessment and care
Knowledge & Satisfaction with care/communication	Score on test of NCCN guideline knowledge on topics pertinent to the young breast patient & Study derived survey of satisfaction with usual care/communication behaviors
Topic	Patient Baseline Assessment (mailed surveys)
QOL and sexual function	PROMIS Global Health Survey and PROMIS Sexual Function Profile (each 10 item Likert scale) ²⁸
Patient treatment decision satisfaction	Brief Subjective Decision Quality Measure (BSDQ) ²⁹ (30 item Likert scale) to measure # for whom decisions were offered, # regretting, satisfied, having sufficient time and information, & involvement in decision regarding genetic testing, MRI, gene assay surgery, chemotherapy, and radiation therapy. Plus added questions about hormonal therapy and plastic surgery decisions and reasons for responses on all.
Genetic& fertility counseling/preservation, distress management	# of women desiring each discussion/referral, # discussing with OCP, #receiving information they desired, #allowed to participate in decision making to the degree desired

The electronic medical record will be used when possible, and hand search of records when needed, to gather these data. Data will be entered into REDCap (electronic data capture system) at UNMC for management and then downloaded to SPSS25 for analysis. Descriptive statistics (frequencies, means, SD) will be used to identify a starting point for this project. If we find that certain data is unavailable, we will work with UNMC IT and the collaborating clinics to identify means throughout the project in which to gather these data that do not increase OCP or administrative burden. Patient data will be collected by standard measures of QOL, sexual function and decision-making plus a project derived mailed survey. It is estimated that this will involve mailing to approximately 280 patients cared for over the 2 year period and will yield results from about 70 patients (assuming a 25% survey response rate), although efforts will be made through reminder post-cards, etc. to achieve a higher response rate. The project manager (to be hired) will coordinate these efforts.

D3. Target Audience: The primary target audiences are OCPs and breast cancer patients < 50 years old in Nebraska. Age 50 or less was chosen as this is consistent with the literature and NCCN guidelines as defining the age of early onset breast cancer.¹²

D3.a. Commitment to participate in this project has been confirmed by the leaders of UNMC/Nebraska Medicine, Fred and Pamela Buffett Cancer Center to provide resources and access necessary to expand the current MDC conferences and specialist consultation to collaborating rural clinics. Oncology physician champions in the three rural collaborating cancer centers have also acknowledged their commitment. Commitment has been confirmed by the multidisciplinary team of specialists who will have input into the clinical pathway and engage in delivery of the educational content (see letters of commitment from all of the above). It is anticipated that given the gaps in care that exist nationally, Nebraska women will be willing to participate in surveys regarding their care. Surveys are voluntary and pose a low burden.

D3.b. This project is expected to reach approximately 53% of the women < 50 years of age diagnosed with breast cancer in Nebraska. The lead cancer center is located in and adjacent to counties with the highest populations and prevalence of breast cancer in the state.² The collaborating clinics are located from 113 to 280 miles from the lead center with two clinics adjacent to higher prevalence counties and the third in the middle of state with a catchment area of multiple counties given that no other cancer centers are present in that region (Fig. 1).² Given the geographic scope and prevalence of young women potentially impacted by this project, outcomes will be generalizable across the state.

D3.c. Direct benefit is expected for the OCPs within the UNMC/Nebraska Medicine and the clinics collaborating in this project through increased knowledge and access to expert consultation. Young women with breast cancer treated in these centers are expected to benefit as a result of informed OCPs, quality decision-making and improved physical and psychosocial side effect prevention/management.

D3.c.1. Because of telemedicine technology use to provide MDC collaboration and use of a new website by which to offer the clinical pathway and educational webinars in this project, the outcomes have the potential to expand to additional cancer centers throughout Nebraska. Outcomes are potentially translatable to cancer centers in Midwestern states that have a similar geographic configuration with a primary cancer center in a populated city and multiple centers in rural areas of the state (e.g. North and South Dakota). Dissemination of our results we will encourage expansion and replication throughout the Midwest.

D4. Project Design and Methods.

This project is aimed at improving the efficacy and efficiency with which oncology care providers recognize and systematically address physical, psychosocial, and decision-making needs of young breast cancer patients in a manner that: a) extends to rural Nebraska populations, b) supports adherence to clinical guidelines, and c) minimizes burden to patients and the medical system. The strategy to accomplish these goals is three-fold:

D4.a.1.1. Clinical pathway & OCP education modules: Led by Drs. Elizabeth Reed (PI), Lally (Co-I), and the Project Manager the multidisciplinary team of specialists (i.e. medical oncology, nursing, plastic surgery, reproductive medicine, urogynecology, psychology, physical therapy, genetic counseling, radiation therapy, exercise physiology and a breast cancer survivor) will review drafts of the clinical pathway for young women in an iterative process of review and modification. The collaborating rural cancer centers will then have an opportunity

to provide input into the pathway before implementation. The multidisciplinary team will communicate via email and have at least one face-to-face meeting conducted using Skype or other similar technology available at UNMC/Nebraska Medicine. The collaborating cancer center champions (Drs. Ramaekers, Vaziri and Fahed) will gather input from their clinical partners and relay this to Drs. Reed and Lally via email or phone due to their distance from UNMC. Dr. Reed will gather input from clinical partners at UNMC/Nebraska Medicine. These measures will promote transparency and OCP future engagement in adherence to the pathway.³⁰ Preliminary pathway review criteria for use by the team and clinic sites are in Table 2 and will be added to as deemed necessary by the team.

The pathway will undergo additional evaluation using the same criteria at 6 and 12 months after implementation to determine whether the pathway is meeting OCP's and patients' needs and whether further modifications would increase its use, function and practice according to NCCN (or similar) Guidelines for care.

Table 2. Criteria for Clinical Pathway Review (modified from review by Kinsman et al 2010)³¹

Recommended care is evidence-based.
Recommended care is sufficiently multidisciplinary.
Recommended care is logical and feasible given resources.
Care elements are documented in routine charting or can be easily monitored.
Pathway allows for sufficient variability based on patient needs & preferences.
Pathway facilitates translation of guidelines to patient care.
Pathway promote communication with patient about treatment options and stimulated shared decision-making

D4.a.1.2. The UNMC Research IT department and the Center for Continuing Education, will collaborate to develop a website to house the pathway and host a live webinar “Treatment and Support of Young Women and Breast Cancer”, which will be a kick-off event to introduce implementation of the final clinical pathway educational pathway-kick-off event. The pathway will cue OCPs to internal and external resources, evidence, and open research studies linked on the website. Patients will be able access the website through Nebraska Medicine’s My One Chart patient portal. Patients of collaborating rural clinics will be able to access the pathway through their patient portal or with a direct link to the project derived website.

D4.a.1.3. The kick-off webinar will be followed over the next year with 8 pre-recorded, approximately 1 hour, webinars presented by specialists on the multidisciplinary team, on the topics of: surgical decision-making, contralateral prophylactic mastectomy and reconstructive surgery; fertility preservation options and patient discussion, genetic testing and counseling, radiation therapy decisions, sexual dysfunction, psychological distress, weight management/exercise, and lymphedema. Continuing education credit will be offered for physicians and nurses for all webinars. UNMC Center for Continuing Education will establish a registration and credit record system for this project. ***Strategy 1 addresses goals: a) extending clinical expertise to rural Nebraska populations through the pathway and educational webinars, and b) supporting adherence to clinical guidelines by providing pathway protocols feasible and acceptable to OCPs as well as consistent with NCCN and other clinical guidelines.***

D4.a.2. Multidisciplinary breast clinic (MDC): UNMC/Nebraska Medicine currently hosts Breast Multidisciplinary Clinics preceded by Breast Conferences 3 times/week (Mon, Weds, Fri) at the Fred and Pamela Buffett Cancer Center, Nebraska Medicine Bellevue and Nebraska Medicine Village Pointe. UNMC’s telemedicine capabilities are used to conduct real-time multidisciplinary review of pathology and radiologic images and discussion by all physicians, nurses, genetic counselors, etc. in attendance at the Breast Conference at these

locations. Following this, patients are seen at the hosting clinic by surgery, radiation oncology and other medical professionals who will be involved in their care armed with the recommendations gained at multidisciplinary breast conference. Physicians may bring cases, with advanced notice, to any breast conference, but cases associated with patients to be seen that afternoon are reviewed first. For this project, access to bring young breast cancer patient cases to any of the three Multidisciplinary Breast Conferences will be extended to the three collaborating rural clinics in order that OCPs may receive the benefit of review of pathology and radiology findings, and discussion and recommendations of multiple FPBCC breast cancer specialists. It is expected that the collaborating clinic OCPs will see their patients as a team that afternoon or in the next few days armed with the recommendations of the FPBCC-based team. If clinics do not already have a Multidisciplinary Clinic system established by which patients are seen by multiple providers on one day, FPBCC resources will be used to guide practices wishing to establish MDCs. Physicians bring cases to MDC breast conference will follow the already established protocol of contacting the designated Office Associate in the Department of Surgery sufficiently prior to the conference and working with that Associate to coordinate the transfer of films and pathology specimens to UNMC/Nebraska Medicine for review at the conference.

D4.a.3. Multispecialty telemedicine consultation: To fill gaps in specialist care that may not be available at the rural collaborating clinics, the multispecialty team established for this project will offer telemedicine consultations with clinicians at the collaborating clinics as recommended during the MDC breast conference or cued by the pathway. A list of available specialty experts will be maintained on the project website for easy access by collaborating oncology providers. ***Strategies 2 & 3 address goal: a) extending consultation to rural Nebraska populations, and in turn by bringing consultation to them and supporting timely and appropriate care through such consultation addresses goal c) minimizing burden to patients and the medical system by reducing multiple procedures, missed and mistimed treatment opportunities, and financial and other costs associated with inconsistent care and travel to specialists for consultation from rural locations.***

D4.b. Addressing need & producing results. Table 3 (below) outlines how the project works to address the needs as described in Section D2 and achieve the outcomes hypothesized to result upon operationalization of the objectives stated in Section D1 as described in Section D4.

D4.c. Engagement. The project website will monitor OCPs' access of pathway, and webinars. MDC conference participation and additional consults are captured in clinical documentation. Practice (see Table 4) will indicate engagement in adherence to NCCN/other guidelines.

D4.d. Innovation. A search of literature in Medline Ovid and PubMed, with research librarian assistance, found no clinical pathways or MDC consultative programs specifically addressing young women or young rural women with newly diagnosed breast cancer. Pathways for breast cancer identified in the search pertained to: radiation hypofractionation,³² decreasing hospital stay in Germany³³ and China³⁴ and treatment in Belgium.³⁵

D4.e. Building upon existing resources. Proposed expansion of MDC conferences to rural collaborating cancer centers builds on the established MDCs conducted 3 times/week at the FPBCC, and Nebraska Medicine Bellevue and Village Pointe Cancers and in which telemedicine capabilities are used. The FPBCC offers educational webinars hosted by specialists, upon which we build in developing the 8 new webinars specific to needs associated with care of young

women with breast cancer. Finally, consistent with ASCO pathway recommendations for access to clinical trials,³⁰ the project website will inform OCPs and patients about clinical trials including the UNMC researcher (Co-I Lally) developed/tested Internet-based, patient-self management, psychoeducational program *CaringGuidance™ After Breast Cancer Diagnosis*. The program addresses issues consistent with young women’s needs and care gaps such as body image, sexuality, surgical decisions, and supports discussion on psychosocial issues.³⁶ It uses a cognitive behavioral and psychoeducational approach consistent with NCCN guidelines for cancer-related distress management.²⁰ This and other studies will provide an opportunity for young rural women to participate in innovative research. ***Building upon the FPBCC existing structures and capabilities and creating virtual education that can be reviewed and easily updated, support sustainability beyond the funding period.***

Table 3. Addressing Established Needs & Achieving Desired Results for Care of Young Women with Breast Cancer Project

Needs	Project Strategy	Expected Outcomes
Increase OCP’s knowledge on current & changing clinical guidelines	OCPs engage in pathway review & use OCPs present patients at MDC conference & apply to care	Knowledge acquisition Adherence to practice guidelines Reduced burden/cost associated with appropriate & efficient care
Promote OCP’s and patient communication about all treatment options, potential side-effects, and realistic expectations	OCPs and patients engage in specialist led webinars and MDC conferences OCPs use pathway & practice guidelines	Knowledge acquisition Physician-patient improved communication OCP & patient satisfaction with decision making and side effect management Patient treatment adherence
Promote OCP’s knowledge & attention to women’s needs, thoughts, and concerns that drive their treatment decisions and QOL	OCPs engage in specialist led webinars OCPs have access & seek specialty consultation	Knowledge acquisition Physician-patient improved communication Patient adherence to treatment & reported positive QOL OCPs & patient satisfaction with treatment decisions & process

D5. Evaluation:

D5.a.1. Data sources. Sources of data will be patient and OCP survey, NIH PROMIS measures and a standardized measure of decision-making quality, electronic tracking on project website of webinars accessed, tracking of continuing education credits awarded, and the electronic medical records. Surveys will be mailed with return envelope and coded to maintain confidentiality. All data will be entered into REDCap and analyzed using SPSS25.

D5.a.2. Collection & analysis. See Table 4.

D5.a.3. Relation of results to project implementation. In addition to the analysis in Table 4, we will explore post-implementation associations between OCPs’ pathway access, MDC and consult access, knowledge, and reported satisfaction with their care/communication with patients’ report of decision quality and communication satisfaction (expected to be affected by OCPs’ behaviors which we expect to affect with the project interventions). QOL and treatment adherence may be affected by many variables and may not be direct measures of project efficacy, but identification of a negative relationship between OCPs’ pathway use and QOL would be unexpected and will trigger additional exploration.

Table 4. Outcomes, Measures and Analysis Method

OCP Outcomes	Measures	Analysis method
Accessing pathway online	IP address tracking by website	Descriptive statistics will be calculated for variables including frequencies and percentages, means (SD). Data will be calculated by site as well as aggregated by rural and UNMC/Nebraska Medicine. Dr. Meza (statistician) will guide the repeated measures analysis for change over time from baseline to 6 and 12 months post implementation using parametric or non-parametric statistics as needed given this will be a small sample of the same OCPs.
Accessing educational webinars	IP address, quiz & credits awarded	
Accessing MDC breast conference	Conference record	
Accessing multi-disc. consultations	Medical record documentation	
Adherence to pathway & guidelines	#s of procedures, treatments, referrals, documentation of care discussions(see Table 1 – baseline for list)	
Knowledge acquisition	Post-webinar online quizzes	
Satisfaction with care/communication	Study designed Likert scale survey	
Satisfaction with pathway use	Study designed Likert scale survey	
Patient Outcomes	Measures	Analysis method
Accessing project website	IP address tracking	Descriptive statistics will be calculated for variables including frequencies and percentages, means (SD). Scale scores will be calculated when appropriate. Data will be calculated by site as well as aggregated for rural and UNMC/Nebraska Medicine. Dr. Meza (statistician) will guide the analysis for change over time from baseline to 6 and 12 months post implementation of pathway using parametric or non-parametric statistics as appropriate given these will be different samples of patients and a currently unknown sample size. Open ended questions will be analyzed with descriptive content analysis by Dr. Lally who is experienced in this analysis.
Satisfaction with treatment decision making on genetic testing, gene assay, MRI, surgery, chemo, radiation hormonal therapy & plastic surgery	30 item Likert scale (including “not offered”) Brief Subjective Decision Quality Measure (BSDQ) ²⁹ + added questions on hormonal therapy, plastic surgery & reasons for responses.	
Satisfaction with communication & receipt of services: genetic counseling, fertility counseling/preservation, referral to psychology for distress management	Study derived survey of # of women desiring each discussion/referral, # discussing with OCP, #receiving information they desired, #allowed to participate in decision making to the degree desired	
QOL (including psychological wellbeing & physical, mental, social ability, fatigue & pain) & sexual function	PROMIS measure of Global Health Scale v1.2 (10 Likert items) PROMIS Sexual Function Profile v1.0 (10 Likert items) ²⁸	
Adherence to treatment	Medical record documentation	

D5.b. Expected change. At 6 and 12 months, a 5% increase from baseline in OCPs’ knowledge of care of young women with breast cancer, and satisfaction with care/communication practice. At 12 months, pathway and guideline adherence of 75%. At 6 and 12 months, a 10% increase from baseline on mean patient decision quality scores and a 5% increase from baseline in satisfaction with communication and service offered.

D5.c. Dissemination. Presentation at the NCCN Annual Conference and at least two papers describing pathway development and extension of telemedicine multidisciplinary conferences to rural communities, and OCP and patient project outcomes, for submission to the *Journal of the National Comprehensive Cancer Network* and the *Journal of Clinical Pathways*.

D6. Work plan & Deliverables Schedule (Table 5): Year 1 –The pathway will be developed, and modified with input from the specialists and collaborating rural cancer centers. Patients and OCP surveys will be developed and reviewed for face and content validity. The project website will be designed, reviewed and brought online. Continuing Education will work with Research IT to plan webinar registration, tracking, etc. on the website. The baseline electronic medical record and chart review, and OCP and patient surveying will occur. Pathway kick-off will conclude the year. Year 2 – Development and filming of webinars will occur on an ongoing basis. OCPs will engage in pathway use, webinars, MDC conferences and specialist consultation. At 6 and 12 months evaluations of OCPs and patients will occur.

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