Project Title**:** **Access to Genetics Counseling in Northwest Montana**
Grant ID: 42230189
Collaborators: Kalispell Regional Medical Center
Dr. Melissa Hulvat and Dr. Amanda Beer, Project Co-Directors

The goal of the **Access to Genetics Counseling in Northwest Montana** project is to increase the rates of BRCA testing for appropriate patients with early or metastatic breast cancer. We will do this by increasing the access to genetic counseling services and by coordinating care within our multidisciplinary team and educating the medical community to increase the volume of referrals for eligible patients.

Our target population is patients with a personal history of breast cancer. Approximately 1/3 of newly diagnosed breast cancer patients are appropriate for referral to a genetic counselor and genetic testing.

The 12 month project will cover the backlog of identified patients with personal history of breast cancer that have to wait due to a scarcity of available genetic counselors. We will also provide tuition to the online City of Hope *Intensive Program in Cancer Risk Assessment* for two mid-level providers to assist with coordination of care as it pertains to cancer genetic counseling and testing.

Data collected will follow the ACCC Preliminary Guidance for BRCA Testing. The increase in genetic counseling visits and educational opportunities surrounding cancer genetics will be disseminated to the oncology program and the general public via our cancer program website where we routinely publish outcomes and information: krh.org/krmc/services/cancer-care.

We are grateful to Pfizer for providing this important opportunity to the BRCA community.

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A. Proposal

1. Overall Goal & Objectives:

The goal of the **Access to Genetics Counseling in Northwest Montana** project is to increase the rates of BRCA testing for appropriate patients with early or metastatic breast cancer. The objectives to reach that goal will include:

- Increase access to genetic counseling services
- Coordination of care within our multidisciplinary team and educating the medical community to increase the volume of referrals for eligible patients

Increase access to genetic counseling services:

Genetic counseling services have been provided at KRH for the last 10 years via telehealth. We contract with third party Certified Genetic Counselors (CGC) to provide consultations free of charge (the cost to KRH ranges from $200-$265 per consultation). This cost is incurred as a loss to our health system, no bill is submitted to the patients as genetic counseling is not a recognized certification and therefore the cost is not covered by Medicare, Medicaid or many private insurers in the state of Montana. In 2017, our third party CGCs performed a total of 201 patient consultations. Our current genetic counseling services are fully utilized, with an average wait time for an appointment up to 3 months. This is due to CGCs handling the volume of patients affected by cancer as well as counseling for high risk due to family history of cancer. Quite simply: our current system is severely over taxed. We are not adequately meeting the needs of our cancer patients. The current practice of relying on third party genetic counselors via telemedicine is inadequate to meet our needs. We have recruited a CGC to be on-site in Kalispell, Montana as a full time employee of our hospital to begin in the fall 2018. This will remain a non-billable service based on current Montana law. She will offer genetic counseling services to patients at elevated risk of cancer based on family history, and to patients with a personal diagnosis of cancer who are eligible for genetic counseling and testing. This CGC available in our community to counsel women with early or metastatic breast cancer will increase the rates of BRCA testing for appropriate patients.

Coordination of care within our multidisciplinary team and educating the medical community to increase the volume of referrals for eligible patients:

Midlevel providers are crucial to the operation of our rural, community based cancer program. Without a large contingent of resident/trainees, and without a large research division dedicated to investigating our patient population for trial eligibility, nurse practitioners and physician assistants are often the team members best positioned to identify necessary genetic counseling and testing for our patients with a personal diagnosis of early or metastatic breast cancer. We have identified two nurse practitioners to better coordinate this kind of care for our multidisciplinary care team if we are able to provide them with additional education.

The City of Hope offers a distance-only curriculum *Intensive Program in Cancer Risk Assessment* which we want to offer to these two advanced practice providers. This course is specifically designed to address the need for professional training in clinical cancer genetics and research collaboration for community-based clinicians such as ours. KRH is willing to support these staff members for three hours each Friday for 14 weeks, and is requesting grant funding for two tuitions of $1,500 each.

2. Current Assessment of need in target area

Our target area is the area that our health system serves and the women with early or metastatic breast cancer eligible for BRCA testing within it. Annually, Kalispell Regional Healthcare (KRH) serves nearly 800 patients with a new diagnosis of cancer. Approximately 150-170 of these patients carry a new diagnosis of breast cancer. The average 10-year survival rate for a woman diagnosed with breast cancer is 83% (https://www.cancer.net/cancer-types/breast-cancer/statistics/), and therefore we expect that there are thousands of breast cancer survivors in our community diagnosed and treated here, in addition to women diagnosed and treated elsewhere who now reside in our community.

The following statistics will show that our current penetration of genetic counseling for patients with a personal history of cancer who are at risk of harboring a deleterious mutation of BRCA 1 or BRCA 2 is less than optimal, which is a result of the scarcity of available genetic counselors:

2017 KRH CGC visit/testing	**2017 % CGC visit**
Personal history breast cancer=31 consultations/152 cases	20%
Personal history epithelial ovarian cancer=8 consultations /9 cases	88%
Personal history pancreatic cancer=1 consultation /36 cases	3%
Personal history melanoma = 0/48 cases	0%
Personal history prostate cancer = 0/76 cases	0%

3. Target Audience

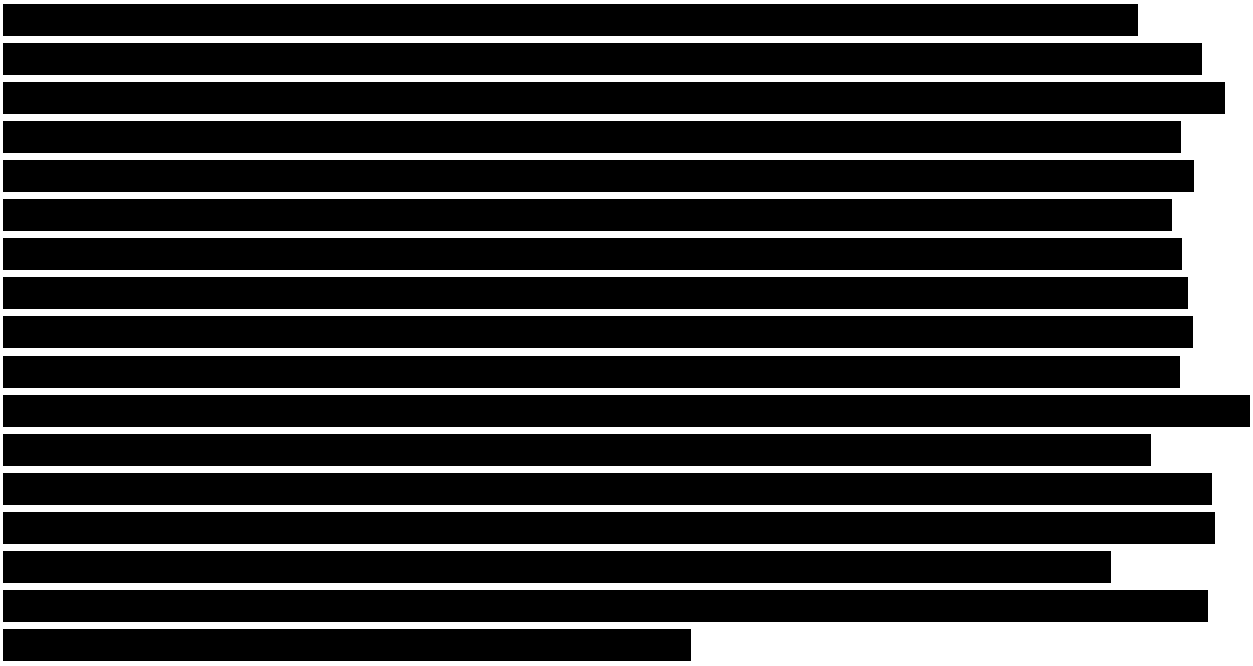
Patients with a personal history of breast cancer, pancreatic cancer, epithelial ovarian cancer, melanoma and prostate cancer should all be routinely evaluated for factors which would make them high risk for harboring a deleterious genetic mutation in BRCA1 or 2.
Approximately 1/3 of newly diagnosed breast cancer patients are appropriate for a referral to a genetic counselor and genetic testing. (1) National Comprehensive Cancer Network (NCCN) guidelines list referral to genetic counseling as a consideration for all al patients with localized or metastatic pancreatic cancer if there is a personal history of cancer, a family history of pancreatic cancer or a clinical suspicion of inherited susceptibility. (2) All patients with a diagnosis of epithelial ovarian cancer should be tested for, at minimum, BRCA 1 mutation carrier status and many are eligible for extended panel testing. There were no referrals to genetic counseling in 2017 for a personal history of melanoma (10% of patients with melanoma have a hereditary cause) (3) or for a personal history of prostate cancer (men diagnosed under the age of 50 or with metastatic disease should be seen by a CGC.) (2) We therefore deduce that significant barriers exist to those serving this population.

This is only an illustration of the shortfall in one year for newly diagnosed patients. If this shortfall extends backward in time for each of the last 10 years we have been offering telegenetic services, and the shortfall is assumed to have been even or more severe in years before this service was offered, there are hundreds of members of our community not receiving the counseling and testing they deserve. We are falling short, mainly due to the aforementioned scarcity of this resource.

We have recruited a CGC to better serve these people. We have nurse practitioners with oncology experience who are willing to acquire additional education to identify women who should have genetic counseling and BRCA testing. We require funding to make this a reality.

The launching of this new program will take the most time and effort in the first year to increase both community and provider awareness and build the referral base. Setting this up and launching this correctly will become a template for offering expanded genetic counseling and testing services for other at risk populations including our pediatric oncology population, cardiac population, and others. It is our hope that success in this area will be a model to expand genetic counseling services to these and other populations.

4. Project Design and Methods:



As we have historical data from 10 years of providing genetic counseling via a third party vendor using telemedicine, we will easily be able to measure the volume of women in the targeted group who are provided genetic counseling and testing in the 12 months covered by this project and measure the increase. Offering enhanced identification through training of midlevel staff and enhanced availability of counseling services with an on-site CGC is a logical extension of this service building on our 10 years of experience with providing oncology genetic counseling to women with early stage and metastatic breast cancer eligible for BRCA testing.

As an on-site genetic counselor that is able to see patients with a personal history of breast cancer in a timely fashion will be a new service for our health system, we anticipate that her first year will be essentially a “startup” year. She will be required to participate in both provider and community education, and to clear the backlog of patients who have been waiting for counseling. In subsequent years of this program, these elements will not be as necessary. KRH

has committed to providing the salary and resources needed to sustain this project beyond the grant funded period however Pfizer support is crucial to a successful launch both financially and as an affirmation of the gravity and worth of this project and the service we intend to provide.

5. Evaluation Design

Coordination of care is addressed by training the 2 healthcare professionals (NPs) to educate the multidisciplinary cancer care team of the advantages of testing all appropriate patients with early or metastatic breast cancer. The percentage of patients receiving genetic counseling will determine whether the practice gap was addressed. We currently track how many patients and for what indication they are seen by our third party genetic counseling services that are coordinated through the Bass Breast Center (breast clinic). We will simply continue collecting this data on our in house genetic counselor. The system will improve due to by-passing the 3rd party vendor for ordering and communicating results. Access will improve due to in-house availability and turn-around time will decrease. Data collected will follow the ACCC Preliminary Guidance for BRCA Testing. It will be analyzed by both our Breast Program Leadership Committee (part of our National Accreditation Program for Breast Centers NAPBC) and our Cancer Committee (part of our Commission on Cancer "CoC"). The increase in genetic counseling visits and educational opportunities surrounding cancer genetics will be disseminated to the breast program, oncology program and the general public via our cancer program website where we routinely publish outcomes and information: krh.org/krmc/services/cancer-care.

We anticipate there will be an improvement from testing 16% of eligible women diagnosed in a calendar year to the benchmark of 33% of eligible women, plus additional women diagnosed in earlier years who were not offered genetic counseling at the time of diagnosis.

6. Detailed Work plan and Deliverables Schedule:

We will send two nurse practitioners who can better coordinate genetic assessment for our multidisciplinary care team to the City of Hope distance-only curriculum *Intensive Program in Cancer Risk Assessment*. This course is specifically designed to address the need for professional training in clinical cancer genetics and research collaboration for community-based clinicians such as ours. We are in the process of on-boarding a genetic counselor to see oncology patients on site at our medical center. After she begins, she will embark upon community and provider education, grow the program, work with the two oncology NPs taking the City of Hope course, our Breast Imaging Department and the Bass Breast Center to develop processes to identify patients appropriate for referral to her, and offer these appointments in a timely fashion. The deliverables for the first year of this endeavor are detailed below.

Deliverable	**Completion date**
Hire Certified Genetics Counselor	In progress
Education to Primary Care Providers and Community	January-December 2019 Announce at all CoC mtgs: 1/29/19 4/16/19 7/16/19 10/15/19 12/17/19
Advanced Genetics Education for 2 Nurse Practitioners	11/2/2018-2/1/2018, plus 1 year post course phase 3 requirements (4)
Refer all eligible Breast Cancer patients based on NCCN guidelines (5)	January-December 2019
Evaluate efficacy (are 1/3 of all new BC diagnosis being seen by the GC?)	6 months and 1 year
Identify patient-related barriers to assessment	ongoing
Identify provider-related barriers to assessment	ongoing
Post intervention final assessment	December 2019 Reported 12/17 CoC mtg

ACCC Preliminary Guidance on Data Collection for BRCA Testing RFP-initiative

Example data set proposed by the Center for Business Models in Healthcare that can be collected from Quality Improvement projects:

- Date of breast cancer diagnosis or recurrence
- Stage at most recent breast cancer diagnosis or recurrence
- Age at most recent breast cancer diagnosis or recurrence
- Hormone receptor status
- HER2 status
- Date of referral for genetic counseling
- Date (s) of genetic counseling
- Documented reason if no genetic counseling was provided
- Date for genetic test
- Document reason if patient received genetic counseling but the test was not conducted
- Date of receiving the result back from the lab
- Date of reporting/providing genetic results to the patient
- Date of surgical/systemic therapy decision
- Surgical/systemic therapy details
- Was the genetic test result used to qualify for a clinical trial?

B. References

1. Kurian AW et al, "Genetic Testing and Counseling Among Patients With Newly Diagnosed Breast Cancer" JAMA. 2017; 317(5):531-534.

2. https://www.nccn.org/

3. https://aad.org/

4. https://www.cityofhope.org/education/health-professional-education/cancer-genomics-education-program/intensive-course-in-cancer-risk-assessment-overview/intensive-course-in-cancer-risk-assessment-description/intensive-course-in-cancer-risk-assessment-2019-track-2

5. https://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf