**Genetics Access Pilot (GAP) Project Details**

This pilot project seeks to better understand effective models for and barriers to offering genetic testing to newly diagnosed breast cancer patients.

**The aim of this QI Pilot is to:**

*Increase the number of newly diagnosed breast cancer patients offered genetic testing by 20% from baseline at CoC/NAPBC pilot sites from January 2025 to December 2025*

**The secondary outputs of this pilot project include:**

* Obtain baseline data of genetic testing in pilot sites for proposed population
* Identify structural and process barriers to achieve testing
* Develop and test interventions to address modifiable barriers to genetic testing
* Spread, scale, and disseminate findings

# Why does this matter?

National guidelines currently recommend genetic testing for BRCA1 and 2 mutations for newly diagnosed breast cancer patients. Genetic testing results not only inform people about the risk of second breast cancers for newly diagnosed patients but have therapeutic implications. Newly diagnosed patients who test positive for BRCA 1 or 2 may be candidates for a PARP inhibitor therapy based on tumor extent. Genetic testing results may also impact family members.

The American Society of Breast Surgeons (ASBrS) issued a consensus guideline in 2019 that stated that all newly diagnosed breast cancer patients should be offered testing for BRCA 1 and 2 and PALB2 and testing for other genetic mutations as the clinical scenario or patient’s family history dictates. This year the American Society of Clinical Oncology (ASCO) and the Society of Surgical Oncology (SSO) also issued a guideline recommending that clinicians and breast programs offer genetic testing for BRCA 1 and 2 for individuals under the age of 65 with a newly diagnosed invasive breast cancer).

National estimates show that only 26% of female breast cancer patients and 50% of male patients receive germline genetic testing. Strategies to increase access to testing and to increase the number of providers who have experience and knowledge in clinical cancer genetics so that more newly diagnosed patients can be offered testing are needed.

# Who should participate?

All CoC and NAPBC accredited programs are welcome to apply to participate in this pilot. Up to 20 CoC and NAPBC pilot sites will be selected to participate in this pilot.

Participating sites will complete a pre and post survey, submit baseline and 3 courses of data, participate in quarterly and/or as needed cohort calls, and have the opportunity to participate in a focus group or qualitative interview (optional).

This Pilot seeks to engage a diverse range of programs- including small and large programs, urban, rural, and suburban, programs that have a geneticist on staff, and programs that do not have a staff geneticist. This pilot is also interested in programs with a diverse patient population. Ultimately, sites will be chosen based on:

* Geographic diversity
* Size and scope of program
* Patient population
* Current available resources

Participation in this pilot requires the formation of a core QI team; the team must be made up of at least 3 people, and more than one person can fulfill the below roles. Note, for programs participating for CoC credit, the CLP must be a member of the Core QI team.

* Physician Champion (serves as a conduit between leadership and frontline staff)
* Project leader/manager (supports the day-to-date activities of the QI project)
* If available, Genetic Counselor/geneticist (provides input on processes, workflow, barriers, etc)
* Data analyst/data support/informaticist (collect, analyze, and submit data)
* Cancer administrative leader/ CLP, if applicable (champions QI team and pilot in cancer program activities, meetings)
* Oncology nurse/Oncology APP/Navigator (provides input on workflow, practice policies, etc)
* All others are welcome to participate.

# What will you do?

Step 1: Discuss project with the cancer committee, and, if appropriate, [apply here](https://redcap.facs.org/surveys/?s=L44Y3P9KCFEMJPH3) by December 20

Step 2: Once accepted (notification will be sent to programs by January 15), receive signature of support from Cancer Liaison Physician (template will be available on project [webpage](https://www.facs.org/quality-programs/cancer-programs/cancer-qi-programs/gap-quality-improvement-project/)). Form a core QI team. Complete pre-survey.

Step 3: For baseline data, review all newly diagnosed breast cancer cases from October-December **2023**. Tools and tracking sheets will be provided to support data collection. A more thorough data collection process is discussed below.

Step 4: Assess current process and documentation strategies for offering genetic testing to patients. Through a root cause analysis, identify barriers and consider building new or enhancing existing workflows and follow up systems. Resources for completing a root cause analysis will be given to all programs.

Step 5: Join small group calls to share innovations, challenges, and learn from peers.

Step 6: Submit quarterly data and annotate where/when interventions were implemented and how that impacted your program’s number of patients offered testing.

Step 7: Meaningfully participate and engage in the QI project. Over the course of the yearlong QI project, you will be submitting data (see below) and a member of your team will need to be present on small cohort calls, unless clinical care interferes with call schedule. Share status updates with cancer committee at least twice over the year and document progress in meeting minutes.

# What data will be collected?

**Pre/post survey**: Questionnaire related to current genetic testing practices, models, and perceived barriers.

* Collected via REDCap due February 28 and December 12

**Measures**: Collected Quarterly (Baseline, May, August, and November). Below is a brief overview of the measure strategy. See Appendix F for an example of the case form that the program will submit, per patient.

| **Description/ Definition** | **Measure Calculation**  **(Numerator:/Denominator:)** | **Data Source**  **Associated Data Collection Tool** |
| --- | --- | --- |
| % of newly diagnosed breast cancer patients diagnosed with triple negative offered genetic testing | **Numerator:** Number of patients diagnosed with triple negative breast cancer offered genetic testing  **Denominator:** All newly diagnosed breast cancer patients diagnosed with triple negative breast cancer | Review of Patient Health Records |
| % of newly diagnosed breast cancer patients 46-65 years old that offered genetic testing | **Numerator:** Number of patients aged 51-65 offered genetic testing  **Denominator:** All newly diagnosed breast cancer patients between ages 51- 65 | Review of Patient Health Records |
| % of newly diagnosed breast cancer patients aged 45 and younger offered genetic testing | **Numerator:** Number of patients aged 50 and younger offered genetic testing  **Denominator:** All newly diagnosed breast cancer patients aged 50 and younger | Review of Patient Health Records |

Exclude: Patients that have already undergone surgery.

# What is the benefit of participating?

* Improve provider understanding of genetic testing and increase patient access to tests.
* Streamline operational processes and enhance workflows related to genetic testing.
* Access to asynchronous learning materials, toolkits, didactic webinars, and one on one coaching and technical assistance, as needed.
* Submit quarterly data to benchmark program progress against aggregate project benchmark
* Collaborate and network with peer programs and national leaders
* Earn credit for standards
* Showcase innovations and learnings at future ACS conferences

# What is the time commitment?

Your team will submit baseline data and 3 rounds of data [metrics]. A pre/post survey, collected via an online survey tool, will also be collected. Cohort calls will be offered 4 times over the year. One person from each team must be in attendance on each call, unless clinical care interferes.

We estimate approximately 15 hours of time dedicated to data entry and webinar/cohort call participation over the course of one year. This is dependent on eligible cases available for reviews, and this does not include time spent on team meetings or huddles to discuss data and iterative tests of change cycles.

# Timeline and Important dates

|  |  |
| --- | --- |
| **Date** | **Event** |
| **Nov 20** | Informational webinar at 12pm CT  [Register Here](https://facs-org.zoom.us/meeting/register/tJAldOyupjkuGdHMvs5nJLNZelTfLZ5PAXm7) |
| **December 20** | Applications are Due at 11:59p CT |
| **Jan 15** | Applicants are notified of their selection status |
| **Jan 31** | Applicant kick off call |
| **Feb 28** | Baseline and survey data due |
| **April 15** | Jan-March data due |
| **April 25** | Cohort Call |
| **July 15** | April-June data due |
| **August 22** | Cohort Call |
| **Oct 15** | July-Sept data due |
| **Nov 14** | Cohort call |
| **Dec** | Potential wrap up/summary call |

Optional and as needed “office hours” will be offered

References:

* Bedrosian I et al. JCO 2024; 42(5): 584
* Manahan E et al. ASO 2019; 26:3025
* Tutt An et al. NEJM 2021;384:2394
* Katz SJ et al JCO 2018; 36:1218
* Lapkus M et al ASO 2023;30:6108