INSTITUTION-DIRECTED QUALITY IMPROVEMENT OF GENETIC COUNSELING AND TESTING FOR COMMUNITY ONCOLOGY PATIENTS WITH BREAST CANCER

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Heredity breast cancer accounts for 10 percent of all breast cancers currently diagnosed in the United States.¹ About 30 percent of the known inherited breast cancers are associated with pathogenic (or likely pathogenic variants) in BRCA1/2,²,³ the most understood germline mutations. These cancers occur earlier in life and more often in patients with cancer susceptibility genes. The mean age of patients with germline BRCA1/2 pathogenic variants who develop breast cancer is considerably lower, compared to the mean age of patients with sporadic breast cancer (42 years vs. 64 years, respectively), which clearly factors into decision making. There is a higher prevalence of triple-negative breast cancer (estrogen receptor [ER]-, progesterone receptor [PR], human epidermal growth factor receptor 2 [HER2]-) among those with a pathogenic BRCA1 variant, while individuals with a pathogenic variant in BRCA2 more commonly develop ER+ breast cancer and lower grade tumors.⁴ Additionally, patients with a pathogenic variant in BRCA1/2 have a higher risk of developing a second primary breast cancer and other cancers, including pancreatic cancer, ovarian cancer in women, and prostate cancer in men.³,⁴

Evidence-based guidelines continue to evolve, with current National Comprehensive Cancer Network (NCCN) Guidelines⁵ for genetic/familial high-risk assessment in breast, ovarian, and pancreatic cancers emphasizing comprehensive family history assessment in deciding on who is eligible for testing. Current NCCN Guidelines recommend that women who are diagnosed with breast cancer at age 45 years or younger be considered for germline testing, even in the absence of family history or other risk factors.⁵ At the time of data collection for this study (Jan. 1, 2018, through Oct. 10, 2020), the NCCN Guidelines for high-risk assessment of breast and ovarian cancers recommended that patients 60 years or younger with triple-negative breast cancer and those with metastatic HER2-negative breast cancer be tested for high-penetration breast cancer susceptibility genes, including BRCA1 and BRCA2.⁵ Other organizations advocate for comprehensive testing of all women with breast cancer, citing the lack of significant family history in many patients with a pathogenic variant and omission of criteria that would identify carriers of non-BRCA variants.⁶-⁸ These guidelines continue to evolve annually and currently include other cancer susceptibility genes.⁵

The presence of any pathogenic germline mutation, especially a BRCA1/2 mutation, has the potential to influence primary treatment choices for patients with breast cancer. For example, when choosing between bilateral mastectomy vs. breast conserving surgery, the provider and patient should consider a shared decision-making model by discussing the chance of developing contralateral breast cancer after breast-conserving surgery because second (synchronous and metachronous) cancer rates are considerably higher in patients with germline BRCA1/2 mutations.⁵,⁹ Despite this association and the presence of recommendations to test early, the timeliness of genetic counseling and the completion of testing prior to primary surgical decision-making remains an ongoing issue in the U.S.¹⁰-¹³

Many academic medical centers and large community health systems have hereditary cancer risk assessment programs that are fully staffed by board-certified medical geneticists, genetic counselors, and other highly trained genetic professionals. Objectives of such programs often include providing patients with comprehensive information about hereditary cancer and the process of genetic testing. Since 85 percent of patients with cancer receive treatment in community-based oncology programs, these services may not be as readily accessible.¹⁴,¹⁵

Development of an Institution-Directed QI Initiative
In 2018, the Association of Community Cancer Centers (ACCC)¹⁶ surveyed community oncology practitioners to assess the status of BRCA1/2 testing for patients with breast cancer. Most respondents (approximately 80 percent) reported that less than
half of their patients with early onset (age 45 years or younger) or metastatic breast cancer had undergone germline BRCA1/2 testing. Identified barriers to genetic testing included:17

• Patient-related barriers
• Challenges with respect to identification of patients who meet testing criteria
• Reimbursement for genetic counseling and testing
• Limited access to genetic counselors geographically
• Timeliness for genetic counseling
• Systems-based challenges related to ordering tests and communicating results
• Lack of clarity regarding the clinical benefits of testing.

While most respondents indicated that board-certified genetic counselors most often ordered genetic testing at their cancer program, 16 percent of practitioners did not routinely utilize a genetic counselor, often due to lack of access or long wait times.

As genetic counseling and testing has become more relevant in precision medicine and critical to treatment decision-making, it is important to gain a better understanding of the different models that are used by various cancer programs in community settings and implement quality improvement interventions to improve rates of genetic counseling and testing. To increase rates of guideline-concordant genetic counseling and testing in patients with Stage 0 to III breast cancer where results could impact care, ACCC coordinated a national, institution-directed quality improvement (QI) initiative for community oncology programs and practices. The aim of this project: to determine the impact of QI efforts on the rates and timeliness of genetic counseling and testing compared to baseline and the availability of genetic test results for providers prior to surgery.

Study Methods
ACCC sent a request for proposals (RFP) to address issues related to genetic counseling and testing for patients with Stage 0 to III breast cancer to 694 cancer program members. The RFP included the previously collected background data on rates of genetic counseling and testing, as well as the various barriers to these services. Forty-three cancer programs (6.2 percent response rate) from across the U.S. submitted QI proposals to increase genetic counseling and testing; 15 community cancer centers (institutions) were awarded grants based on criteria set by the ACCC-appointed peer review committee. Applications were graded based on how the implemented change(s) would directly affect patient care and provide sustainability (e.g., integration with an electronic health record) and scalability (e.g., plan for dissemination/applicability beyond the proposed institution) within the specified timeframe. Successful applicants were expected to describe specific clinical practice gaps for their own providers, healthcare system, or patient community and what they would do to close or overcome these challenges. The RFP highlighted the following specific areas of interest:

1. Systems-based challenges related to ordering genetic tests and communicating test results
2. Access to genetic counselors
3. Turnaround time for genetic testing
4. Patients’ emotional needs, psychosocial support, and advocacy issues
5. Coordination of care within the multidisciplinary cancer care team.

Each institution implemented and conducted a unique QI project based on their own identified gaps and needs. Baseline and post-QI data were collected on adult, female patients at least 18 years old with a diagnosis of Stage 0 to III breast cancer. Patients with Stage IV disease were not included in this report, although some institutions provided this data. Baseline cohort data was provided for patients diagnosed between Jan. 1, 2018, and Dec. 31, 2018, and the QI cohort data included those diagnosed starting on the QI launch date at each institution and ending Oct. 10, 2020. Participating institutions provided patient-level data that was de-identified with a non-meaningful study ID; no protected health information was submitted. Prior to sending data to ACCC, each institution modified dates by adding or subtracting by a factor of seven. The factor of seven was determined independently by each institution and was not shared with ACCC. Baseline cohort data was submitted by July 31, 2019, and post-QI cohort data was submitted by Jan. 31, 2021, to maximize full registry data capture following the Oct. 1, 2020, cut-off date.

To facilitate aggregate data reporting, ACCC provided a data collection sheet for each institution to collect baseline and post-QI data. Data collection was voluntary and not a condition of the grant award. Each institution that chose to collect data went through its own internal quality committee and/or secured investigational review board approval.

Statistical Analysis
Descriptive statistics were used to evaluate de-identified demographic information. Differences in rates of genetic counseling appointments, documentation of genetic test results, and availability of genetic testing results before surgery between the baseline cohort and post-QI cohort were evaluated using two-tailed Fisher’s exact tests, calculated using GraphPad QuickCalc; a p-value less than 0.05 was considered statistically significant.

Participating Cancer Programs
Participating institutions varied in size and geography. The smallest cancer program was a critical access hospital in rural North Carolina, and the largest was a university medical center in Kansas. Nine of fifteen (60 percent) participating institutions in
this QI program voluntarily shared project data with ACCC, which forms the basis of this report. The nine institutions conducted two or more types of QI interventions to impact the rate of genetic counseling and testing for eligible patients (Table 1, above).

**Patient Characteristics**

The baseline cohort contained 2,764 patient records; 73 records were excluded due to incomplete information, resulting in a total of 2,691 analyzable patients. The post-QI cohort contained 3,845 patient records; 315 records were excluded due to incomplete information, resulting in a total of 3,530 patient records. Baseline and post-QI cohorts had significant differences in stage of breast cancer, with 3 times more patients with Stage II or III disease in the QI cohort than the baseline cohort (Table 2, page 61). Cohorts were similar in age and familial breast and ovarian cancer risk as defined by NCCN Guidelines.18 There were significant differences in the rate of ER and PR positivity (e.g., 84 percent ER+ at baseline vs. 78 percent in the QI cohort), but similar rates of HER2+ and triple-negative breast cancer among the cohorts. Both cohorts had broad representation across patient characteristics, allowing for analysis by characteristic subgroups other than disease stage.

**QI Interventions**

QI efforts were grouped into five broad categories to allow measure of impact by type of intervention:

1. Telephone genetic counseling
2. Patient educational interventions about the need for genetic counseling and testing
3. Provider education about ways to improve testing
4. Added capacity (e.g., hiring more genetic counselors)
5. Identification of patients’ genetic counseling needs through some other process improvement.

**Timing of Genetic Counseling**

The rates of genetic counseling were analyzed to measure the impact of the specific intervention as shown in Figure 1, page 60, for each institution. The time interval from date of diagnosis of Stage 0 to III breast cancer to the date of genetic counseling averaged 37.3 days in the baseline period (of those referred) and 21.8 days post-QI for all patients collectively, reflecting an improvement of 15.5 days. The largest impact was a reduction by an average of 17 days from diagnosis to genetic counseling among the institutions that implemented telephone genetic counseling, followed closely by an average reduction of 16.3 days by the institutions that focused on patient education. The least impactful intervention, increasing the capacity of genetic counseling, was statistically the most significant by only 18 days.

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**Table 1. Institution QI Efforts, Rate of Genetic Counseling by Institution (Baseline to Intervention)**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Type of QI Effort</th>
<th>Baseline Cohort n=2,691</th>
<th>Genetic Counseling</th>
<th>QI Cohort n=3,530</th>
<th>Genetic Counseling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Process to ID Patients</td>
<td>Add GC Capacity</td>
<td>Virtual GC/GC Support</td>
<td>Provider Education</td>
<td>Patient Education</td>
</tr>
<tr>
<td>1</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>2</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>3</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>4</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>5</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>6</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>7</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>8</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>9</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

*p<0.05, **p<0.001

Abbreviations: Institution, Cancer Program; GC, Genetic Counseling; ID patients, identification of patients who meet criteria for hereditary cancer genetic counseling/testing; Add GC Capacity, addition of clinicians that are able to conduct genetic counseling; Tele-GC or Tele-GC support for providers, the addition of telephone/video based genetic counseling for patients and/or telephone/video based support of healthcare providers; Provider education, education for clinicians on NCCN Guidelines® for genetic/familial high risk assessment for patients with breast cancer; Patient education, specific materials or education regarding genetic risk/counseling directed to patients with breast cancer.
counselors, still improved the time from diagnosis to genetic counseling by an average of 9 days.

**Genetic Counseling Appointment Rates**
Nine institutions submitted data measures of genetic counseling rates pre-intervention and post-intervention. Six of the nine institutions (67 percent) that provided data on its intervention demonstrated significant improvements in the rates of genetic counseling conducted for patients with Stage 0 to III breast cancer. Rates at baseline increased:
- From 19 percent to 64 percent for institution 1
- From 66 percent to 89 percent for institution 4
- From 57 percent to 100 percent for institution 5
- From 22 percent to 42 percent for institution 6
- From 53 percent to 84 percent for institution 8
- From 32 percent to 60 percent for institution 9.

Institution 3 also increased genetic counseling rates from 42 percent to 47 percent, which was not statistically significant. Two institutions had lower genetic counseling rates following intervention.

**Table 3**, page 62, compares the impact of specific QI categories on genetic counseling rates, the documentation of a test result (i.e., testing was done), and whether the results were made available before patients’ primary surgery. Results were analyzed in relation to:
1. Positive family history risk
2. No family history risk
3. Unknown family history
4. Age at diagnosis (45 years or younger)
5. Triple-negative receptors.

The various QI interventions statistically increased the number of genetic counseling appointments that were completed in total and in four of five of the specific genetic counseling measures. Proportions of patients in the post-QI cohort receiving genetic counseling ranged from 24 percent to 85 percent. The only group that was not statistically impacted was the triple-negative breast cancer group, which had pre-intervention and post-intervention rates of 56 percent and 64 percent, respectively, which were not significantly increased. The interventions significantly impacted all six genetic counseling measures for the...
sub-groups that implemented a process to identify genetic counseling needs and added genetic counseling capacity. The intervention significantly impacted five of six genetic counseling measures for the subgroup that added patient education. The subgroups that added virtual genetic counseling visits and/or continuing medical education focused on cancer genetics in practice showed a significant impact on total number of genetic counseling appointments.

**Table 2. Patient Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Baseline Cohort (n=2,691)</th>
<th>QI Cohort (n=3,530)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td><strong>Stage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>394</td>
<td>15%</td>
</tr>
<tr>
<td>I</td>
<td>1,025</td>
<td>38%</td>
</tr>
<tr>
<td>II</td>
<td>248</td>
<td>9%</td>
</tr>
<tr>
<td>III</td>
<td>85</td>
<td>3%</td>
</tr>
<tr>
<td>Stage I to III, specific stage missing</td>
<td>939</td>
<td>35%</td>
</tr>
<tr>
<td><strong>Age (Years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45 and younger</td>
<td>278</td>
<td>10%</td>
</tr>
<tr>
<td>46-49</td>
<td>180</td>
<td>7%</td>
</tr>
<tr>
<td>50-64</td>
<td>1,039</td>
<td>39%</td>
</tr>
<tr>
<td>65-74</td>
<td>746</td>
<td>28%</td>
</tr>
<tr>
<td>75-89</td>
<td>423</td>
<td>16%</td>
</tr>
<tr>
<td>90 and older</td>
<td>25</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Genetic Markers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ER+**</td>
<td>2,248</td>
<td>84%</td>
</tr>
<tr>
<td>PR+*</td>
<td>1,927</td>
<td>72%</td>
</tr>
<tr>
<td>HER2+</td>
<td>305</td>
<td>11%</td>
</tr>
<tr>
<td>Triple negative</td>
<td>219</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Genetic/Familial Breast Ovarian Risk</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High risk</td>
<td>1,284</td>
<td>48%</td>
</tr>
<tr>
<td>Not high risk</td>
<td>778</td>
<td>29%</td>
</tr>
<tr>
<td>Unknown HBOC Risk</td>
<td>629</td>
<td>22%</td>
</tr>
</tbody>
</table>

*p<0.05, **p<0.001

Abbreviations: BC, Breast Cancer; ER+, Patients with Estrogen Receptor Breast Cancer; PR+, Patients with Progesterone Receptor Breast Cancer; HER2+, Patients with HER2 positive Breast cancer; Triple Negative, Patients with ER negative, PR negative and HER2 negative breast cancer; Genetic/Familial Breast Ovarian Risk, patients with a risk factor(s) as defined by NCCN Guidelines® and/or history for hereditary breast or ovarian cancer

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Genetic Test Results

All QI interventions were able to significantly improve documentation of genetic test results, which held true across all intervention subtypes. Rates improved overall from 25 percent documented at baseline to 49 percent after intervention, a relative improvement by a factor of about 2.

Genetic Test Results Available Before Surgery

All QI interventions improved the number of patients for whom genetic test results were available before surgery, regardless of (Continued on page 63)
Table 3. Comparing Impact on Guideline-Indicated Measures, between QI and Baseline (B) Cohorts, in Total and by QI Intervention

<table>
<thead>
<tr>
<th>Measure</th>
<th>Total</th>
<th>Process to ID Patients’ GC needs</th>
<th>Add GC Capacity</th>
<th>Virtual GC or Support</th>
<th>Provider Education</th>
<th>Patient Education</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B %</td>
<td>QI %</td>
<td>B %</td>
<td>QI %</td>
<td>B %</td>
<td>QI %</td>
</tr>
<tr>
<td>Genetic Counseling Appointment</td>
<td>35</td>
<td>58**</td>
<td>35</td>
<td>58**</td>
<td>34</td>
<td>59**</td>
</tr>
<tr>
<td>Familial high risk with GC appointment</td>
<td>57</td>
<td>85**</td>
<td>56</td>
<td>86**</td>
<td>51</td>
<td>87**</td>
</tr>
<tr>
<td>Not Family high risk with GC appointment</td>
<td>23</td>
<td>39**</td>
<td>23</td>
<td>40**</td>
<td>29</td>
<td>41**</td>
</tr>
<tr>
<td>Unknown family risk with GC appointment</td>
<td>6</td>
<td>24**</td>
<td>6</td>
<td>24**</td>
<td>6</td>
<td>24**</td>
</tr>
<tr>
<td>Age 45 and younger with GC appointment</td>
<td>72</td>
<td>81*</td>
<td>71</td>
<td>81*</td>
<td>71</td>
<td>82*</td>
</tr>
<tr>
<td>Triple negative (ER-, PR-, HER2-) with GC appointment</td>
<td>56</td>
<td>64</td>
<td>10</td>
<td>64**</td>
<td>54</td>
<td>64*</td>
</tr>
<tr>
<td>Genetic Test Result Documented</td>
<td>25</td>
<td>49**</td>
<td>24</td>
<td>49**</td>
<td>23</td>
<td>50**</td>
</tr>
<tr>
<td>Age 45 and younger with genetic test result</td>
<td>49</td>
<td>75**</td>
<td>48</td>
<td>74**</td>
<td>47</td>
<td>77**</td>
</tr>
<tr>
<td>Triple negative (ER-, PR-, HER2-) with genetic test result</td>
<td>26</td>
<td>56**</td>
<td>26</td>
<td>56**</td>
<td>22</td>
<td>56**</td>
</tr>
<tr>
<td>Genetic Test Result Available Before Surgery</td>
<td>12</td>
<td>27**</td>
<td>12</td>
<td>27**</td>
<td>11</td>
<td>27**</td>
</tr>
<tr>
<td>Age 45 and under with genetic test result before surgery</td>
<td>28</td>
<td>45**</td>
<td>27</td>
<td>44**</td>
<td>24</td>
<td>47**</td>
</tr>
<tr>
<td>Triple negative (ER, PR, HER2-) with genetic test result before surgery</td>
<td>13</td>
<td>28**</td>
<td>13</td>
<td>28**</td>
<td>10</td>
<td>28**</td>
</tr>
</tbody>
</table>

*p<0.05, **p<0.001

Abbreviations: Familial High Risk is based on NCCN Guidelines® for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic; GC, Genetic Counseling; Triple Negative, Breast Cancer with negative results for Estrogen Receptor (ER), negative results for Progesterone Receptor (PR) and negative human epidermal growth factor receptor 2 (HER2) results; id GC needs, identification of a patient’s genetic counseling needs; Add GC Capacity, addition of clinicians that are able to conduct genetic counseling; Tele-GC or Tele-GC support, the addition of telephone/video based genetic counseling for patients and/or tele/video based support and mentoring of providers; CME on GC, provider education for clinicians on genetic counseling indicators/needs for patients with breast cancer; Patient education, specific materials or education regarding genetic risk/counseling directed to patients with breast cancer. G-Test, Genetic test.
The overarching goal of this project was to increase germline ACCC evaluated the impact of institution-directed QI interventions at 9 community cancer programs and practices across the U.S. to address guideline-concordant utilization of genetic counseling and testing in patients with Stage 0 to III breast cancer. The QI interventions were designed to improve rates of genetic counseling, genetic testing, and timeliness of test results relative to surgery. Prior background data pointed to the need to increase access to genetic counseling and testing and increase timeliness, as it potentially impacts primary shared decision-making.

Despite the various improvements demonstrated by this collective, several areas did not achieve “standard” practice. Genetic test results were available (i.e., done) for only 75 percent of patients 45 years old and younger and for only 56 percent of patients with triple-negative breast cancer regardless of age. While the message of young age at diagnosis was a positive predictor of genetic counseling (81 percent) and testing (75 percent), it was not enough to predict that germline BRCA (gBRCA) testing would be done. This is one of the reasons why a more broad-based testing guideline may help improve testing rates, especially in a younger population where the impact of breast conservation vs. mastectomy may depend on gBRCA mutation status.

While there was also significant improvement in the percentage of available genetic results before primary surgery because of QI efforts, total rates remained low (27 percent). If primary shared decision-making is designed to fully inform providers and patients of the risks and benefits of various treatment choices, this information is advantageous earlier in patients’ care. One cancer program that participated in this project found that the majority of its patients with high-risk (BRCA) mutations chose bilateral mastectomy over breast conserving surgery when they had their genetic testing information up front, which also potentially affects other primary therapies. In the same institution, with 100 percent prospective genetic counseling and testing post-QI, 85 percent of patients with pathogenic germline variants with significantly increased breast cancer risk chose bilateral mastectomies up front.

The overarching goal of this project was to increase germline testing over an established baseline for each institution and highlight how different this can be throughout the oncology community. The lowest percentage of testing at baseline was 19 percent, and the highest was 66 percent of eligible patients prior to intervention, which highlights the differences in community institutions’ readiness to offer genetic counseling and testing.

Study Discussion
ACCC evaluated the impact of institution-directed QI interventions at 9 community cancer programs and practices across the U.S. to address guideline-concordant utilization of genetic counseling and testing in patients with Stage 0 to III breast cancer. The QI interventions were designed to improve rates of genetic counseling, genetic testing, and timeliness of test results relative to surgery. Prior background data pointed to the need to increase access to genetic counseling and testing and increase timeliness, as it potentially impacts primary shared decision-making.

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One of the strengths of this project was the ability of each institution to choose its own QI initiatives based on existing resources. One institution within the smallest community hospital in North Carolina used a genetics extender model to increase access to counseling and testing where there are few formally trained genetic providers. This was accomplished by training a registered nurse through the “Intensive Course in Cancer Genetic Risk" facilitated by City of Hope and training a physician through additional online professional education resources that are updated annually. That institution increased cancer risk assessment, genetic education, and testing to include 100 percent of all affected patients with breast cancer, which improved overall concordance with guidelines and was done in an environment with limited resources. As a result of this same grant, the same institution also increased genetic education, counseling, and testing for its at-risk screening (unaffected) population using extenders, expanding its counseling and testing to potentially include more than 5,000 individuals a year as a population health initiative. It has plans to integrate this into an EPIC-based platform for its entire health system, including 8 other community hospitals in eastern North Carolina.19

As a collective of community participants in this study, 7 of the 9 institutions that provided data from specific interventions were able to increase genetic counseling rates, with 6 of 7 of these being statistically significant. Rates following intervention ranged from 42 percent to 100 percent of eligible patients with breast cancer.

Another practice changing result of this project was the increased use of expanded panel (next-generation sequencing) testing. Although the proposal was focused on BRCA1/2 genes due to the highly penetrant nature of these well-known germline mutations, most investigators in practice used expanded testing with larger panels that include other moderate- to high-risk genes like ATM, BARD1, CDH1, CHEK2, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53, and others. Although not emphasized as part of this study, half or more of the pathogenic variants reported by the participating institutions were in non-BRCA genes. Future research should examine how knowledge of germline variants impact primary therapy, specifically if primary therapy for Stage 0 to III breast cancer is altered for patients with a highly penetrant gene, more than those who carry a pathogenic variant in a low penetrant gene. This would include...
the use of poly ADP ribose polymerase (PARP) inhibitors for metastatic breast cancer and high-risk non-metastatic gBRCA+ mutated breast cancers that are HER2-,

A recent development since this study was conducted. A third future research topic is the possible use of shared decision-making regarding radiotherapy use based on genetic test results. Guidelines for radiotherapy avoid recommending accelerated partial breast irradiation stipulate as an option for patients with germline mutations in certain genes, such as TP53.21

An unanticipated event during this project was the increased use of virtual genetic counseling and testing as a result of the COVID-19 pandemic. Most institutions reported heavy use of telephone- or tele-video-based genetic counseling during 2020 in response to the pandemic. Counseling pre- and post-testing lends itself nicely to a virtual platform, and this study found these practices to be the case at many institutions. Additionally, vendors were happy to mail test kits to patients’ homes, removing the need for clinic contact for those individuals concerned about COVID-19 and other potential infections.

**Study Limitations**

This study analyzed the impact of a self-directed QI project conducted at 9 of 15 total institutions who were awarded grant money; these institutions voluntarily chose to share baseline and post-intervention data with ACCC. Study authors do not know how data from the remaining 6 institutions may have impacted genetic counseling and testing rates. It is possible that the 9 institutions that provided data did not have typical results that could be expected widely in community practices, but, as the study had a range of providers from a National Cancer Institute-directed program to a critical access hospital, they are somewhat representative. Larger studies could therefore include broader representation. Additionally, all 9 institutions that voluntarily provided data utilized two or more QI projects that were customized to their cancer program, so it is difficult to isolate the specific impact of each initiative.

The QI interventions, while focused on addressing the same problem, were designed and implemented uniquely at each institution. In addition, baseline data included a substantial portion of patients that did not have a specific breast cancer stage noted, other than “Stage 0 to III,” which made comparisons between disease stages not analyzable at baseline compared to post-QI (Table 2). This is not something the study was specifically interested in comparing, as the overall goal was to increase genetic counseling and testing for all eligible patients.

**Study Conclusions**

Significant improvements in guideline-concordant genetic counseling and testing were achieved with institution-directed QI initiatives that were specifically designed to target easily identified populations of patients with Stage 0 to III breast cancer. Despite results indicating improvements in testing rates, there is a long way to go to meet national recommendations. This project demonstrates the importance of practice-directed strategies aimed at improving identification of high-risk patients and follow through to genetic counseling and testing. Further work is needed to understand the decision to undergo or forgo genetic testing and the timing of testing relative to surgical decision-making. Opportunities exist to examine additional facilitators and barriers to community-based and/or tele-genetic services to increase access to guideline concordant genetic counseling and testing for all eligible patients.

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**Disclosures**

Authors have no additional relevant interests to disclose.

**Data Availability**

The datasets generated and analyzed during the study are not publicly available but are available from the corresponding author on reasonable request.
References


