Genetic Counselor Extenders Help Meet Growing Demand for Services

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Genetic testing for hereditary cancer is important to assess the risk of developing cancer and is becoming an increasingly important component in cancer treatment. Approximately 5 percent to 10 percent of all cancers are hereditary, and identifying individuals at increased cancer risk due to a hereditary predisposition allows for increased surveillance and preventive options, ultimately saving lives.[1-5] Despite the value genetic testing can add to the care of patients, most individuals who are at increased risk for hereditary cancer do not have genetic testing discussed with them by their healthcare provider, and even fewer actually undergo genetic testing. A recent study found that of women with breast cancer who were eligible for genetic testing based on national guidelines, 29 percent discussed genetic testing with their physicians, 20.2 percent were advised to undergo genetic testing, but only 15.3 percent ultimately had genetic testing.[6]

There is increased public awareness and interest in genetic testing, and the available genetic tests on the market has grown exponentially since 2013.[7] Additionally, the introduction of next-generation sequencing (NGS) has driven the cost of genetic testing down so that it is more accessible than ever. Along with these advances in genetic testing, choosing the appropriate genetic test and interpreting the result has become increasingly complex due to newly-identified genes, some of which have limited information about cancer risk.

Genetic counselors are healthcare providers uniquely trained to navigate the complexities of genetic testing, work with patients to help them understand their testing options, and help physicians incorporate genetic test results into a patient's care plan. Genetic counselors assess an individual's risk for cancer based on their personal and family history, facilitate appropriate genetic testing to offer to a patient, and discuss how results can be used for medical management according to national guidelines. Having genetic counselors on cancer care teams can help ensure that appropriate patients get the appropriate genetic testing and follow-up care.

To better meet the needs of our large patient population and to meet accreditation requirements, we implemented a collaborative method of care that uses genetic counselor extenders to increase patient access to hereditary cancer risk assessment and genetic testing.

There are more than 4,600 genetic counselors certified by the American Board of Genetic Counseling. According to the National Society of Genetic Counselors 2018 Professional Status Survey, 52 percent of the genetic counselors who provide direct patient care specialize in cancer genetics.[8] Genetic counselors most often work in academic institutions and hospitals in large cities, leading to reduced access in rural areas. Due to their high demand, wait times to see board-certified genetic counselors can be lengthy. Although the field is rapidly expanding to meet the growing demand for genetic testing, it could be 5 to 10 years before the number of board-certified genetic counselors in the US increases enough to fill the current gap.[9] New and innovative ways of

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delivering genetic counseling are needed for all patients to have access to high-quality genetic counseling services in a timely manner.[10-12]

Attempts to improve access include the use of telegenetics or group genetic counseling to address wait time and geographic distance. Embedding genetic counselors where they may have a greater impact, such as within a surgical center or gynecologic oncology clinic, may improve access.[13-16] Telephone genetic counseling is another approach, offering convenience in addition to access, and has been studied at academic institutions, demonstrating non-inferiority and acceptance by both patients and providers.[17,18] Some laboratories offer telephone genetic counseling at no charge to customers, although this potentially introduces a conflict of interest, particularly when this is provided pre-test. There are also private, remote non-laboratory-affiliated genetic counseling companies, which avoids the potential for conflict of interest. This may work in some instances, but any remote service genetic counseling, while convenient, should be approached with a plan for sustainability and how patients will be followed long-term. A program that does not have employed genetic counselors may not have the ability to grow, be a resource to local healthcare providers, manage long-term care for mutation carriers, update information as new cancers are diagnosed within a family, and update families as information within the field of cancer genetics changes (new guidelines, new testing options, etc.).

With all of these in mind, our cancer center opted to work with existing staff and resources to devise an innovative way to improve access to a community hospital system across the state of Indiana. We describe our current processes, recognizing that these continue to evolve, as well as things to consider for other cancer centers that would like to implement a similar service delivery model.

Extending Genetic Testing Services to Improve Access

The St. Vincent Cancer Genetics Risk Assessment Program is located at St. Vincent Hospital in Indianapolis, Indiana. We have 3 board-certified genetic counselors who see approximately 25 new patients per week combined, which is comparable to the national average.[19] However, that volume is inadequate to serve the needs of the entire St. Vincent hospital system, which encompasses 14 hospitals across a large portion of central and western Indiana. Three of these hospitals—St. Vincent Kokomo Hospital, located 45 miles north of the main site; St. Vincent Anderson Hospital, located 38 miles northeast of the main site; and St. Vincent Evansville Hospital, located 184 miles southwest of the main site—needed more convenient access to genetic counseling services for their patients.

To better meet the needs of our large patient population and to meet accreditation requirements, we implemented a collaborative method of care that uses genetic counselor extenders to increase patient access to hereditary cancer risk assessment and genetic testing.[20] In this program, our board-certified genetic counselors collaborate with trained genetic counselor extenders to improve patient access to genetic testing services. We started our collaborative care approach to offering cancer genetic services at St. Vincent Kokomo Hospital in 2009, St. Vincent Anderson Hospital in 2012, and St. Vincent Evansville in 2017. Due to this collaboration, more of our patients now have access to risk assessment, genetic counseling, and genetic testing.

Selecting Clinician Partners

A genetic counselor extender is a typically a nurse, nurse practitioner, or other mid-level healthcare provider. The genetic counselor extender collaborates with board-certified genetic counselors to identify patients at risk for hereditary cancer and provide pre-test risk assessment and education for patients with a straightforward personal or family history of cancer who clearly meet established guidelines for genetic testing. Patients with a more complex history are triaged to receive genetic counseling with a board-certified genetic counselor. Defining these roles in advance is important to determine boundaries.

In our program, genetic counselor extenders are required to have at least a bachelor's degree, experience in cancer care, and a clinical role. We've found that the ideal candidate for this role is someone already embedded in a mammography center or oncology clinic, such as a nurse navigator. Nurse navigators are particularly suited to be genetic counselor extenders because of their clinical knowledge of oncology and experience in educating and interacting with patients. They are likely to have an established relationship with radiologists and/or oncologists in their clinic, and they are familiar with local resources. These qualities allow for a more seamless integration of genetic counseling services into multidisciplinary patient care.

We have learned that for the process to run as smoothly as possible, the genetic counselor extender ideally has a set amount of time dedicated to this role. The most successful genetic counselor extenders have self-identified as having an interest in cancer genetics. Finally, training more than one genetic counselor extender at a facility is helpful for when there is a lapse in coverage due to vacation, medical leave, or staff turnover.

Physicians play a crucial role in our collaborative process, so we identify a physician partner at each participating site. These physicians are invested in the genetic testing process, and they

champion the program by helping educate other physicians and being available to write orders, make referrals, and manage patients identified as at increased risk.

If a site sees a significant number of patients for risk assessment and organizes more than a few telegenetics consults a week, the genetic counselor extender may need additional support for scheduling and obtaining orders and medical records. Each site requires staff to make reminder calls, register the patient, obtain required signatures, insurance verification, etc., just as needed in any outpatient office. Each team member brings expertise to the table, allowing for maximal use of each specialty's skills and training.

Training Genetic Counselor Extenders

Although we initially provided one-on-one education to train genetic counselor extenders, we quickly realized that this method was time-consuming and inefficient, especially with staff turnover and the addition of new collaborative sites. Therefore, we developed a series of web-based training modules, which have been approved for continuing education credits toward Certification for Nurse Educators. There are currently seven modules, each covering educational topics about risk assessment for hereditary breast and ovarian cancer, with knowledge checks at the conclusion of each module. The training is focused on hereditary breast and ovarian cancer because individuals referred for a personal and/or family history of breast or ovarian cancer make up the largest volume of our patients and it keeps the amount of needed education to a more reasonable level. The scope of practice for a genetic counselor extender could expand as the program and need for genetic risk assessment grows.

In addition to the web-based education, we have each genetic counselor extender observe several cancer genetic counseling sessions at the main site or via telegenetics (remote telehealth sessions with patients at satellite clinics to provide genetic counseling). We also hold a monthly virtual cancer genetic case conference with all team members involved in the collaborative program to discuss cases and provide updates.

Identifying and Triaging At-Risk Patients

Our program aims to enable each healthcare practitioner to work at the top of his or her scope of practice. Therefore, triaging patients is based on the complexity of the referral and family history. We schedule patients who require a higher level of evaluation for consults with a board-certified genetic counselor. Those who are less complex are seen by the genetic counselor extender to provide risk assessment, education, and obtain informed consent, optimizing our efficiency.

Each of St. Vincent's collaborative sites identifies individuals at risk for hereditary cancer differently, depending on their resources, needs, and workflow. Here, we focus on St. Vincent Evansville, a high-volume hospital with multiple nurse navigators who have trained to take on a genetic counselor extender role.

Patients access our genetic counseling services in multiple ways (see Figure 1, page 40). Women who present for a mammogram at the St. Vincent Evansville breast center are screened for risk status by the mammogram technician. At-risk individuals who desire consideration for further risk assessment complete a HIPAA-compliant, web-based survey consisting of medical and family history information. The board-certified genetic counselor remotely reviews the family history and triages the patient based on NCCN criteria to one of the following:

1. At risk for hereditary-breast and ovarian cancer: candidate for risk assessment with the genetic counselor extender.
2. At risk for non-breast-related hereditary cancer or complicated family history suggesting more than one hereditary syndrome: candidate for risk assessment with the board-certified genetic counselor.
3. Low risk: not a candidate for risk assessment.

The number of direct referrals for genetic counseling services has grown from an average of 8 patients per month in the first 6 months to an average of 20 per month in the most recent 6 months.

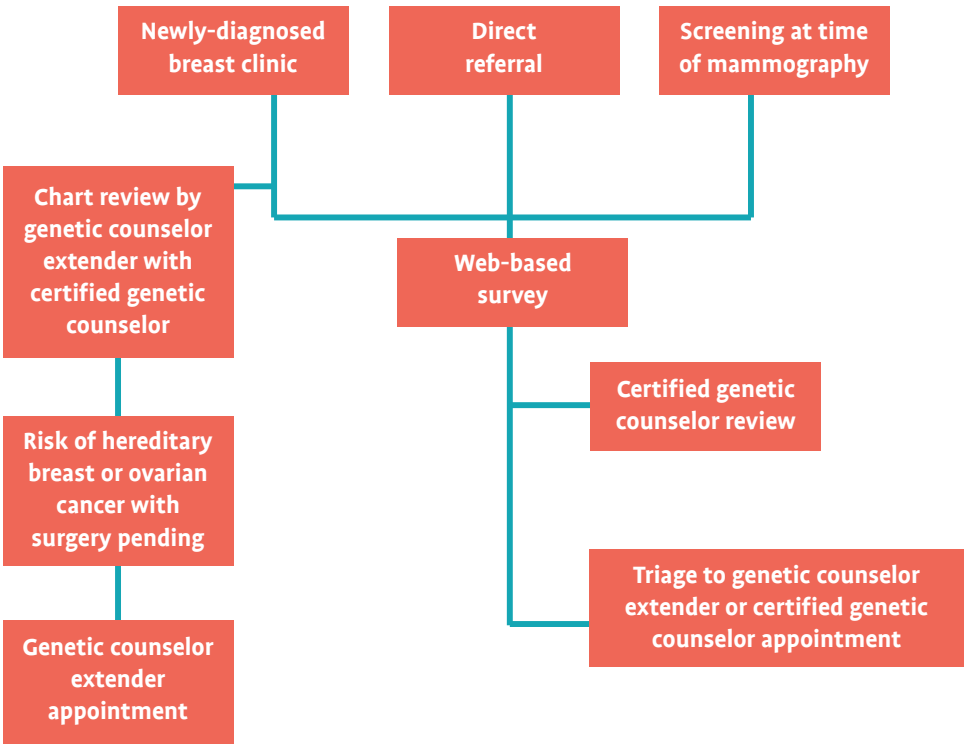
We also identify patients through a multidisciplinary, newly-diagnosed breast cancer clinic. Our genetic counselor extenders review the records of surgical-candidate patients who will be attending this weekly clinic, identifying those who meet established BRCA1/2 testing criteria, consulting with the board-certified genetic counselor as needed. Finally, some patients are directly referred to our collaborative program. Since the inception of the collaboration, these direct referrals have increased from providers throughout the local community without advertising, as they have realized the service is available. The number of direct referrals for genetic counseling services has grown from an average of 8 patients per month in the first 6 months to an average of 20 per month in the most recent 6 months. In the case of a direct referral, a patient is triaged via the web-based survey process as described above.

Genetic counselor extenders contact patients who are identified as at risk for hereditary cancer to offer an in-person appointment for hereditary breast and ovarian cancer or a telegenetics appointment with the board-certified genetic counselor when the patient's history is more complex. Staff at the collaborative site is responsible for obtaining an order from the patient's treating or primary care physician, ensuring that records are available in the shared medical record and that the web-based medical and family history survey is complete prior to a patient appointment (see Figure 2, page 41).

Risk Assessment and Genetic Testing

Patients with a straightforward history meet with our genetic counselor extenders in person at their local hospital for risk

Figure 1. Collaborative Identification and Triage Process



assessment, education, and informed consent and are offered genetic testing. We provide visual aids to assist in the education process. Genetic counselor extenders facilitate a rapid turn-around high-risk breast panel for newly-diagnosed breast cancer patients when a surgical decision is pending. Otherwise, a next generation sequencing (NGS) panel with breast and gynecologic cancer-focused genes is offered. Genetic counselor extenders collect the specimen for genetic testing, enter the test requisition into the online laboratory website, and arrange to send out the sample, completing insurance paperwork as needed (Figure 2, right).

All cases are reviewed by a board-certified genetic counselor once results are complete—before genetic counselor extenders call the patient. If a result is negative, the board-certified genetic counselor will review the family history to see if the case should be reflexed to an expanded panel. We have found that genetic testing laboratories that allow for electronic sharing of genetic test results and have the ability to reflex to a larger panel have made this process more convenient and smooth. In addition to reviewing the family history for appropriate reflexive testing, board-certified genetic counselors evaluate the family history to share surveillance recommendations according to published guidelines. Genetic counselor extenders discuss these with the patient and document them in the patient chart, using a template we created that incorporates a checklist for conducting a risk assessment and serves as documentation of the visit (see Figure 3, page 42).

All patients who have a pathogenic variant result are scheduled to meet with one of our board-certified genetic counselors via telegenetics. When a variant of uncertain significance is identified, board-certified genetic counselors assess for any potential conflicting laboratory interpretations that might complicate the discussion and identify potential studies available to the patient. Regardless of the test result, genetic counselor extenders call the patient with the result and arrange for necessary follow-up, including referrals to local specialists to provide management.

Selecting a Family History Tool

Our program uses a shared, HIPAA-compliant, web-based tool to collect family and medical history information. Patients enter their information either online or on paper (if a computer and internet access are unavailable), allowing board-certified genetic counselors to quickly and easily confirm that a patient meets criteria for genetic testing and determine if the patient should be seen by a genetic counselor extender or should be triaged to a board-certified genetic counselor.

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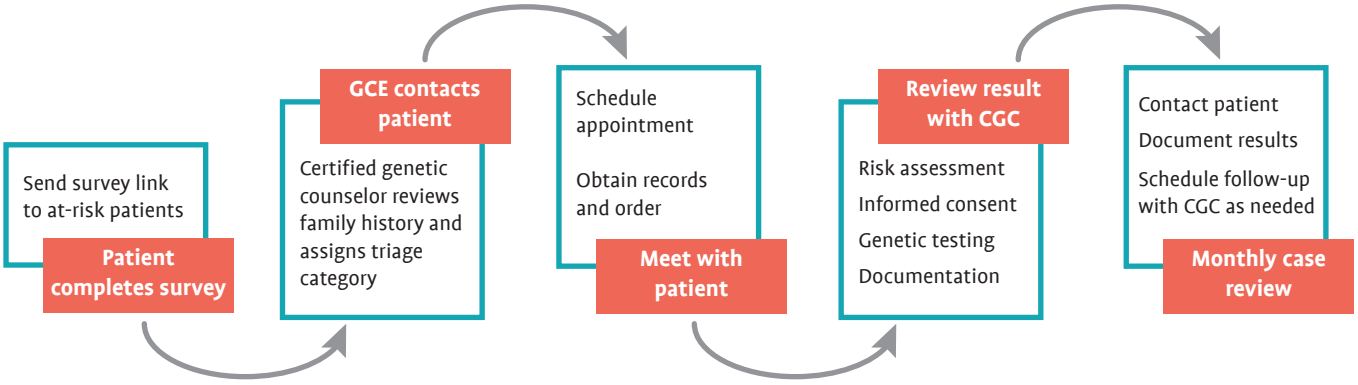
Figure 2. Genetic Counselor Extender Workflow



GCE= genetic counselor extender
CGC= certified genetic counselor

Patient view of a telegenetics appointment.

Figure 3. Genetic Counselor Extender Documentation Worksheet

Patient Name: [First Name, Last Name] **DOB:** **MRN:**

Appointment requested by: [Mammography ID/Newly Diagnosed Clinic/MD Referral]

Physician: [PCP or Referring MD]

Seen for risk assessment by: [Provider]

Date: [Appointment Date] **Time with patient:**

Personal History:

Claus (breast cancer) risk:

Family history: **Tyrer-Cuzick (breast cancer) risk:**

Reviewed:
☐ Cancer can be sporadic (70%), familial (20%-25%), or hereditary (5%-10%)
☐ Likelihood of breast cancer and likelihood for the presence of a mutation
☐ Possible test results (positive, negative, variant of uncertain significance)
☐ Limitations of testing (detection rate ~90%-95%, other genes may be involved in some cases)
☐ Best person in family to test (affected is ideal)
☐ Cost of test/insurance coverage
☐ Protections and limitations of Genetic Information Nondiscrimination Act (when appropriate)

Plan:
☐ Request additional records (list names)_____
☐ Test affected family member first
☐ Declines testing at this time
☐ Refer for high-risk breast monitoring (MRI/mammogram/etc.):
☐ Proceed with testing
  ☐ Consent signed
  Sample collection date: [Appointment date] Lab:
  Sample type:
  Test ordered:

Result: [Positive/Negative/VUS]

☐ Reviewed result with certified genetic counselor
☐ Contacted patient
☐ Reflex testing offered [Accepted/Declined]
  ☐ Result [Positive/Negative/VUS]
  ☐ Reviewed result with certified genetic counselor
  ☐ Contacted patient
☐ Refer for follow-up:

Notes:

(Left to Right) Stephanie Cohen, MS, LCGC; Claire Harwood, MS, LCGC; and Dawn Nixon, MS, LCGC.

(continued from page 40)

There are several options for electronic family history collection, some of which may have an associated cost. Considerations when choosing information collection software include:

- Is it HIPAA-compliant?
- Can you easily share data among different sites?
- Does the software allow users to mark patients/pedigrees for triaging purposes?
- Does the software allow for risk calculations, database tracking (including mutational status, research study participation, etc.), and documentation?

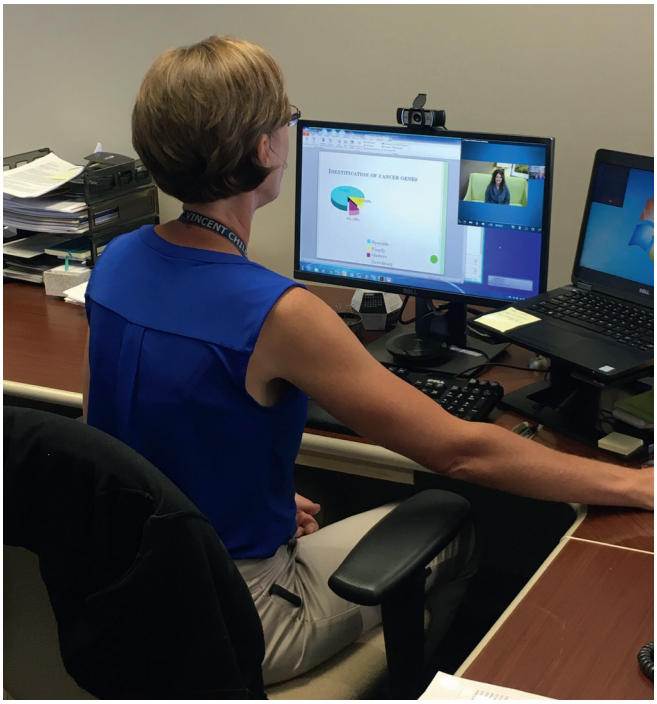
Increasing Usage with Telegenetics

Our program's collaborative process for increasing access to genetic counseling has been facilitated by the integration of telegenetics, which provide patients in remote sites genetic counseling by board-certified genetic counselors. Before implementing telegenetics, we traveled to clinics once a month to bring board-certified genetic counseling services to satellite locations. This process limited the number of patients who could access genetic counseling to that one day per month. With the addition of telegenetics services, board-certified genetic counselors are available to patients five days a week. This is particularly helpful for patients who are coming to a cancer center for treatment, as they can schedule same-day appointments, avoiding an extra trip. At St. Vincent Kokomo and St. Vincent Anderson, the number of patients who received cancer genetics risk assessment services doubled with the addition of telegenetics in 2017. We have also significantly reduced patient wait times; the average wait time for all patients (in person and via telegenetics) is now approximately 8 business days, whereas in the past, patients at remote sites frequently had to wait 30 days or longer.

Evaluating, Modifying, and Sustaining a Collaborative Program

Documenting our program's performance requires tracking patient volumes and metrics, such as wait times. We created a REDCap database to track the status of a patient (e.g., test result pending, test result complete), outcome of test results, research participation, and changes in management (breast MRI, more frequent colonoscopy, etc.). This information allows us to provide long-term follow up as necessary. For example, when new tests become available, we can identify and contact appropriate patients. Having this information has enabled us to help our organization meet National Accreditation Program for Breast Centers (NAPBC) and Commission on Cancer (CoC) requirements with reporting metrics, identifying possible quality improvement studies and tracking research participants.

The number of patients who receive risk assessment and genetic counseling at St. Vincent Evansville has steadily increased since April 2017, when the program began at this site. In the first year of the collaborative program, we saw an average of 11 patients per month, in the second year we saw an average of 15 patients per month, and in 2019 so far we have increased to an average of 18 patients per month. Genetic counselor extenders have seen 60 percent more patients than the certified genetic counselors at the Evansville site, demonstrating our success in triaging patients with complex needs for evaluation by a board-certified genetic counselor.



Provider view of a telegenetics appointment.

We closely monitor time spent by board-certified genetic counselors on efforts related to the collaborative program so that we can make sure we do not overextend our ability to serve patients onsite and to demonstrate need for additional staff. During the first 17 months of our collaboration with St. Vincent Evansville, our 3 board-certified genetic counselors spent an average of 17.6 hours per month on all activities related to the extender program, meaning that each board-certified genetic counselor spent about one day per month on collaborative activities. The amount of time certified genetic counselors spent meeting with and supporting the genetic counselor extenders was initially high, but it decreased over time as the genetic counselor extenders became more comfortable with their role. We are currently collecting metrics on genetic counselor extender time, which will help us determine staffing needs and identify areas for improved efficiency. We have been enrolling patients in an IRB-approved study to compare in-person and telegenetics genetic counseling by board-certified genetic counselors with in-person risk assessment with a genetic counselor extender. Initial satisfaction data indicates similar and high satisfaction across all measures, regardless of who or how the service was delivered.

At first, this collaborative approach was a stop-gap measure to help meet CoC requirements, but stakeholders quickly realized the value of the program. We have a contract for services provided by the board-certified genetic counselors, paid by each collaborative site. This contract includes a set monthly fee that covers board-certified genetic counselors' time supporting the site. Additionally, we charge a fee per patient, by the amount of time spent on a telegenetics session. Each site can bill a facility fee and/or blood draw fee if they choose. When this program was established, we could not bill for telegenetics appointments according to Indiana Medicaid rules. The law has changed recently, such that it is no longer a barrier. The logistics of billing through the EHR at each site are being resolved, and we are in the process of implementing direct patient insurance billing with a professional fee by the board-certified genetic counselor and a facility fee at the patient site. We are exploring the options for billing genetic counselor extender appointments, with one possible solution proposed to bill with a nursing charge.

We have been able to document downstream revenue to help justify our risk assessment program. Individuals identified at increased risk based on gene mutation status or family history may undergo additional surveillance as recommended by NCCN guidelines. This surveillance may include breast MRI, more frequent (and/or earlier) colonoscopy, and completion of prophylactic surgery such as oophorectomy, all of which brings in additional revenue. Additionally, by identifying individuals at risk, lives saved can be estimated, due to cancers avoided with prophylactic surgeries and earlier detection of cancers.[21] Finally, offering risk assessment services onsite may reduce patient flight to other systems.

Last Words

Along the way, we have remained flexible in our approach to the collaborative process. This flexibility has allowed for a natural evolution of our program to fit the changing times, needs, and resources available. There are many possible solutions to improve access to risk assessment services and genetic testing, and every cancer center will have different resources, needs, and goals. While many other healthcare providers are well suited to identifying appropriate patients and ordering testing, without a coordinated approach, method of follow up, and the expertise to handle the inevitable non-routine cases, a program is not likely to grow, thrive, and provide high-quality care. Therefore, we would argue strongly that any service involving genetic testing should include at least one board-certified genetic counselor. At St. Vincent Indiana, the collaboration between board-certified genetic counselors and trained genetic counselor extenders has worked well to improve access to high-quality cancer genetic services. This program will continue to evolve as we strive to improve its efficiency and maintain high-quality patient care. OI

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First-Person Perspective: Touching Lives, Changing Outcomes

One of the things I enjoy most about my role as a genetic counselor extender is seeing the significant impact access to genetic testing services can have on a patient's life and long-term health. For example, one young woman in her 30s was referred to our facility for breast imaging and evaluation after a breast lump was discovered. She was flagged as a patient who should be offered a hereditary cancer risk assessment. Luckily, her breast lump evaluation was negative. She followed through with our web-based hereditary cancer risk assessment survey and made an appointment with me.

During our encounter, I saw that the woman was very worried about developing breast cancer, and she was not sure what to do. Her affected family members were either no longer living or had no interest in pursuing genetic testing. She was appreciative of the opportunity to sit down and discuss her strong family history of breast cancer and learn more about hereditary cancer.

The woman decided to proceed with genetic testing, and when the results came back, she was identified as having a pathogenic variant in BRCA1. After consulting with a certified genetic counselor via telegenetics, meeting with a breast surgeon and oncologist, and receiving local support from myself, she was able to make a well-informed decision about how to manage the increased risk to her long-term health.

Ultimately, the woman chose to undergo risk-reducing surgeries. She has shared with me more than once that coming to our facility changed her life, and, in her words, gave her the chance to make sure she is around to raise her children. I can't think of anything more empowering for a patient or any better reason to do everything we can to make these services available to everyone.