



# A MULTIDISCIPLINARY CONSORTIUM TO ADVANCE GENETIC COUNSELING IN ONCOLOGY

## Findings from the Iowa Oncology Society

### INTRODUCTION

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As cancer clinicians develop increasingly complex treatment plans, the results from somatic testing (i.e., testing done on cancerous cells after a person has been diagnosed) and/or germline tests (i.e., testing done on non-cancerous cells to see if a person has a gene mutation known to increase the risk of developing cancer) are guiding personalized treatment decisions. To ensure that cancer clinicians are following the latest clinical recommendations around genetic testing, the Iowa Oncology Society (IOS) leadership started discussions in November 2020 and then launched a multidisciplinary consortium in the spring/summer of 2021 to advance genetic counseling and testing in oncology. This project focused initially on patients diagnosed with cancer who are eligible for genetic counseling and testing. Working with a diverse group of stakeholders, IOS held a focus group to explore the current landscape, conducted three educational Lunch and Learn sessions, produced a podcast, and hosted a working group meeting.

In an era of precision cancer care delivery, the role of germline genetic testing has rapidly increased to identify patients with hereditary cancer syndromes. Today, the term "genetic testing" may refer to somatic testing for targetable gene mutations, or it may refer to identifying germline variants. The term may also refer to pharmacogenomic testing, a study of the ways in which DNA variants influence how individuals metabolize medications. More than ever, it remains crucial to clearly differentiate somatic vs. germline genetic testing. Using terms such as "molecular testing," "genomic profiling," "next-generation sequencing," or "gene testing" may not clearly communicate whether these tests

are being conducted on somatic vs. germline samples. Moreover, patients may be confused by hearing variations in testing terms.

Commonly used terms in this paper:

- "Biomarker testing" will refer to tests performed on malignant tissue or blood to identify somatic genomic alterations.
- "Genetic testing" will refer to germline testing for inherited variants.
- At times, the term "paired testing" may be used when referring to the combination of somatic and germline testing in the same patient.
- Terms like "next-generation sequencing," "molecular testing," and "genomic profiling," describe laboratory techniques that are utilized for germline and somatic tests.
- Alterations in the genome may be called "variant" or "mutation," and these may be found in germline or somatic tissue. While these terms are not technically synonymous, they are often used interchangeably by cancer clinicians to simplify communication with patients. Some examples of other terms found in the literature include chromosome rearrangement, base substitution, gene deletion, gene insertion, point mutation, missense mutation, frameshift mutation, etc.

## Variant vs. Mutation vs. Polymorphism

- Variant:** A change in the DNA or RNA. The term does not imply frequency or causality.
- Mutation:** A change in the DNA or RNA that has been proven to cause disease (e.g., BRCA1 185delAG).
- Polymorphism:** A change in the DNA that is found in at least 5% of the general population and is considered to be frequent.<sup>1</sup>

Historically, genetic testing was largely performed to assess people for cancer susceptibility attributable to hereditary cancer syndromes. Genetic testing also provided important prognostic information that directly impacted cancer treatment decisions (e.g., prophylactic mastectomy among BRCA mutation carriers). Certain genetic test results, such as a transformation-related protein 53 or tumor protein p53 (TP53) pathogenic variant, may indicate that radiation therapy is relatively contraindicated due to the increased risk of developing radiation-induced secondary cancers.

Recently, the landscape of genetic testing has intersected with the rapidly expanding area of predictive biomarker testing to identify patients who may be eligible for targeted anti-cancer therapies. For example, germline BRCA mutations now identify patients who may be eligible for treatment with poly (ADP-ribose) polymerase (PARP) inhibitors. Lynch syndrome screening using microsatellite instability (MSI) or DNA mismatch repair (MMR) testing in patients with colorectal or endometrial cancer may also identify patients who may benefit from immune checkpoint inhibitor therapy. The presence of MSI represents the phenotypic evidence that MMR is not functioning properly and presents opportunities for making different therapeutic decisions for patients with these types of cancers.

## Project Elements

This project included the following elements:

**Focus Group**  
(Jul 2021)

**Lunch  
and Learn  
Series**  
(Aug - Oct 2021)

**Working  
Group  
Meeting**  
(Nov 2021)

**Podcast**  
(Nov 2021)

**White Paper**  
(Jun 2022)

## Lunch and Learn Series and Podcast

For this project, IOS hosted and recorded a series of three virtual Lunch and Learn sessions. These sessions were designed to spark conversations with local providers and stakeholders about challenges and solutions around genetic testing, counseling, and screening for patients diagnosed with cancer and their family members. Those sessions were titled:

- Tips and Tricks to Optimize Genetic Testing at Your Cancer Program

- Genetic Testing Approaches to Improve the Identification of Hereditary Cancer Syndromes
- Genetic Counseling and Testing in Community Cancer Centers: Perspectives, Challenges, and Opportunities.

A mini-podcast was also recorded to cover policy changes that can help ensure access to genetic counseling across diverse patient populations. These recorded resources may be found on the project webpage of the IOS website: [acc-cancer.org/iowa-genetic-counseling](http://acc-cancer.org/iowa-genetic-counseling).

## Genetic Counseling and Testing Referrals

Many patients with cancer who meet criteria for genetic testing are not referred for pre-test genetic counseling and testing. During the IOS focus group held in July 2021, participants discussed some of the key reasons eligible patients with cancer may not be receiving genetic counseling or testing in a timely manner:

- **Perceived “shortage” of genetic counselors.** Some oncologists may falsely perceive that there is a shortage of genetic counselors in Iowa and may be reluctant to refer patients. In reality, the genetic counselor workforce in Iowa is very strong, but oncologists in private practice may lack partnerships with these individuals since most genetic counselors work for hospitals or health systems.
- **Difficulty finding genetic counselors.** Oncologists may not be sure how to find a licensed certified genetic counselor or may not know that certain telehealth companies offer genetic counseling services.
- **Misunderstanding about the role of genetic counselors.** Members of the cancer care team may not understand the role of the genetic counselor. They may not be aware of the professional credentialing requirements and scope of practice laws that affect licensed genetic counselors.
- **Confusion around genetic testing criteria.** Recent updates in clinical practice guidelines have expanded the criteria around which patients with cancer should undergo genetic testing. However, guidelines do not always provide the same recommendations, and this may confuse clinicians. For example, the American Society of Breast Surgeons recommends genetic testing for all patients with breast cancer. In contrast, the National Comprehensive Cancer Network (NCCN) Guidelines<sup>®</sup> provide specific criteria for testing based on the patient’s age, ancestry, family history, and type of cancer.<sup>2</sup> The lack of guideline concordance may make it difficult for cancer centers to standardize their approach around referrals for genetic counseling and testing.
- **Patients are not discussed at tumor boards.** Multidisciplinary meetings (e.g., tumor boards) are often where patient risk factors are evaluated and discussed. During these meetings, clinicians determine who should be referred for genetic counseling and testing. However, many patients with cancer are not discussed at a tumor board and may not be identified as candidates for genetic counseling and testing.
- **Suboptimal coordination around genetic test ordering.** Different medical specialists, such as general surgeons, urologists, and gastroenterologists, are often the ones making the initial diagnosis of cancer. Some of these specialists will also initiate a genetic testing referral, but others may assume that medical oncologists will handle this task. Breakdowns in communication and coordination across different medical specialists may cause some patients to miss an opportunity for genetic testing.
- **Patients may perceive that genetic testing is cost-prohibitive.** Patients may think that genetic testing is expensive, or they may be confused by direct-to-consumer testing options.

- **Patients may think that genetic testing does not apply to them.** Some patients may think that certain tests, such as BRCA 1/2 genetic testing, are only relevant for female family members like daughters and aunts.

Focus group members also discussed some of the challenges associated with the fact that gene variants are constantly being reclassified. A patient who underwent genetic testing many years ago may have been told that their test result included a “variant of unknown significance.” However, that variant may now be classified as “likely pathogenic,” but the patient may not know this information if they lose contact with the provider who ordered their genetic test. Additionally, the field is constantly finding new hereditary cancer conditions and improving technology. People who underwent genetic testing many years ago may not know that updated testing is available to them. Some clinical guidelines also recommend retesting patients who received genetic testing prior to a certain year. For example, genetic testing prior to 2014 most likely would not have included *PALB2* or other relevant genes.<sup>3</sup>

## How Are Variants Classified?

The American College of Medical Genetics (ACMG) recommends a five-tier classification system for classifying variants:<sup>4</sup>

- Pathogenic
- Likely pathogenic
- Uncertain significance
- Likely benign
- Benign

A VUS, or “variant of unknown significance,” is a variation in a genetic sequence for which the association with disease risk is unclear.<sup>5</sup>

## Certified Genetic Counselors

### What is a Certified Genetic Counselor?

The American Board of Genetic Counseling (ABGC) Certified Genetic Counselor (CGC®) credential is an internationally recognized professional credential for the specialty. Professionals who have been awarded the CGC credential have completed a rigorous academic program, including supervised clinical experience, and have passed the ABGC national certification exam. Individuals who have earned the CGC credential have also met established standards of knowledge, skills, and practice for their profession. These individuals have demonstrated a commitment to excellence by meeting the standards required to achieve and maintain their professional credential.

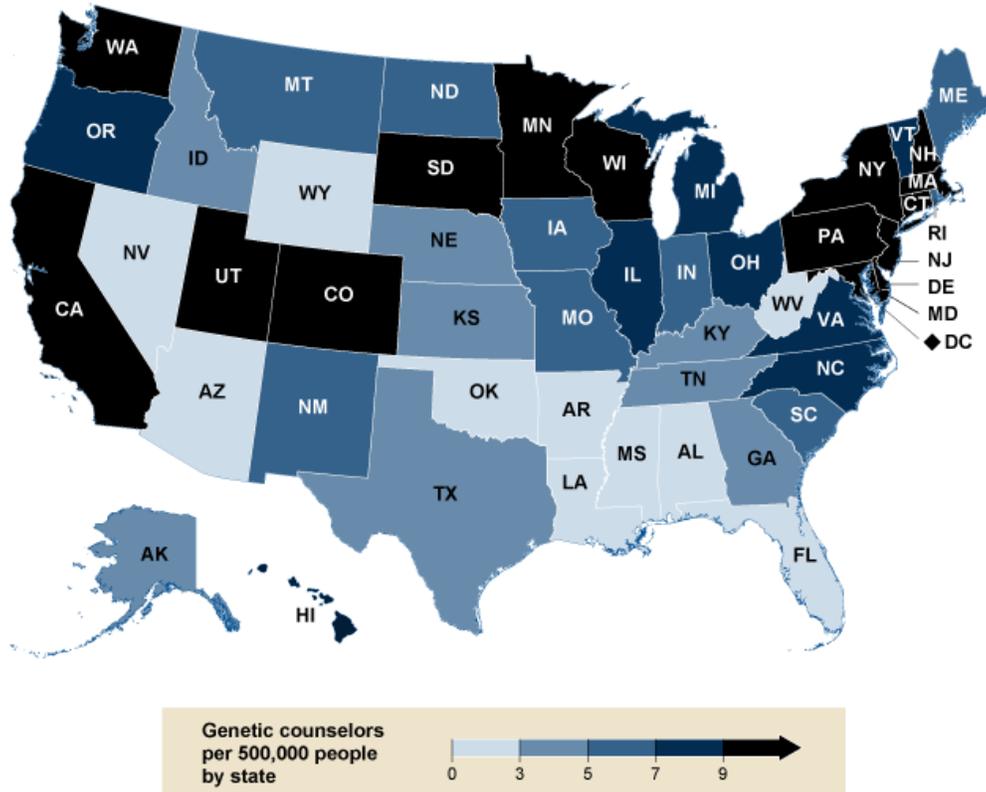
When the Government Accountability Office (GAO) did a workforce study in 2019, it found that Iowa had 34 genetic counselors for its population of 3,155,070, resulting in a ratio of 5.388 genetic counselors per 500,000 people.<sup>7</sup> The National Society of Genetic Counselors (NSGC) reports that there are 5,629 CGCs in the United States as of April 2021.<sup>8</sup>

### How Do I Find a Genetic Counselor?

The Find a Genetic Counselor directory offers access to over 3,300 genetic counselors (in the U.S. and Canada). Find a local or tele-health certified genetic counselor at: [findageneticcounselor.nsgc.org](https://findageneticcounselor.nsgc.org).<sup>6</sup>

Currently, 29 states require CGCs to be licensed to practice. In Iowa, CGCs are licensed by the Iowa Board of Medicine, and their scope of practice includes, but is not limited to, the ability to “identify, order, and coordinate genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment of a patient.”<sup>9</sup>

**Distribution of Genetic Counselors per 500,000 People by State, 2019<sup>7</sup>**



## Who Is Eligible for Licensure to Practice Genetic Counseling in Iowa?

To be eligible for licensure to practice genetic counseling in Iowa, an applicant must hold and maintain active certification as a genetic counselor by the American Board of Genetic Counseling, as a genetic counselor by the American Board of Medical Genetics and Genomics, as a medical geneticist by the American Board of Medical Genetics and Genomics, or the successor to any of the aforementioned organizations.

A genetic counselor licensed under Iowa Code chapter 148H may use the words “genetic counselor,” “licensed genetic counselor,” or the corresponding abbreviation “LGC” after the person’s name. Persons who possess a provisional license should add the designation “provisional licensed genetic counselor” after their name.<sup>9</sup>

Most CGCs work in academic medical centers or other hospital settings, but some work in group practices or are employed by companies that offer genetics services. Since many CGCs also provide services via telehealth, it is easier than ever before for patients to receive genetic

counseling. While the COVID-19 pandemic has led to an increased adoption of telehealth across the United States, many people living in rural areas still struggle with limited access to video-based devices or the lack of broadband internet.<sup>10</sup>

## Access to Genetic Counselor Services Act of 2021

As more patients with cancer are referred to CGCs for counseling and testing, the current healthcare system struggles with the fact that CGCs are not recognized as healthcare providers by Medicare. As such, Medicare does not reimburse CGCs for the services they provide to Medicare beneficiaries. In March 2021, the Access to Genetic Counselor Services Act of 2021 bill (H.R.2144) was introduced in the House of Representatives.<sup>11</sup> A similar bill, S.1450, was introduced in the Senate in April 2021.<sup>12</sup> Prior versions of these bills were introduced in 2018 (H.R.7083) and 2019 (H.R.3235). Under these

proposed bills, Medicare would recognize CGCs as healthcare providers and enable these professionals to provide telehealth services. As previously stated, CGCs do not have provider status under Medicare, even though genetic counseling is a covered benefit.

The NSGC continues ongoing advocacy efforts and encourages stakeholders to send endorsement letters to congressional representatives in support of the Access to Genetic Counselor Services Act. Federal advocacy resources are available on the NSGC website ([nsgc.org](https://nsgc.org)).

## Cascade Testing

Genetic testing has the potential to identify high-risk individuals before they develop cancer. While the scope of the IOS 2021 project did not specifically address ways to screen and identify people before they develop hereditary cancer syndromes, there are numerous opportunities to promote cascade testing once a patient is diagnosed with cancer. Cascade testing involves counseling and testing biological relatives once a patient is diagnosed with a pathogenic variant. In an ideal healthcare system, every at-risk biological relative would be informed and referred to a genetic counselor. Currently, the burden of contacting at-risk biological relatives often falls on the patient, and many relatives may not be informed about their potential risk of harboring a pathogenic mutation.

Research has suggested that a peer support model may improve cascade testing by providing role models for addressing emotional concerns as family members contact their blood relatives to speak with them about genetic testing.<sup>13</sup>

By improving the uptake of genetic screening in people at high-risk for cancer, clinicians may help prevent certain cancers or provide early treatment. Several large research projects are currently underway to inform evidence-based strategies to identify those at risk for inherited cancer syndromes and implement appropriate clinical management.

### Ongoing Debates: Genetic Testing in Patients with Breast Cancer

The debate continues about optimal genetic testing criteria for identifying patients with high-risk breast cancer genes. According to one study, the criteria outlined by the NCCN Guidelines may miss about half of people with a genetic variant.<sup>14</sup> In a 2021 editorial published in the *Journal of Clinical Oncology*, Tung and Desai wrote whether we should be shifting the paradigm from “whom to test” to “whom not to test” since there is much clinical value in identifying a high-risk breast cancer gene mutation among the 3 percent of patients with breast cancer who have a pathogenic or likely pathogenic variant in a high-risk breast cancer gene.<sup>15</sup> One potential approach the article’s authors suggest is to test all patients diagnosed by age 60 or 65 years and those with triple-negative breast cancer at any age.<sup>16</sup>

## Opportunities to Improve Cancer Genetic Testing in Iowa

Based on multi-stakeholder input throughout this project, members of the consortium made the following ideas and recommendations:

- **Support the Access to Genetic Counselor Services Act by sending endorsement letters to congressional representatives.** Advocacy resources are available on the NSGC website. The passage of this act will enable certified genetic counselors to be recognized as healthcare providers under Medicare. To learn more, listen to the ACCC mini-podcast “Ep 72: Genetic Counseling Advocacy” at [accc-cancer.org/genetic-counseling-advocacy](http://accc-cancer.org/genetic-counseling-advocacy).
- **Organize a process for collecting family history that includes information about first-, second-, and third-degree blood relatives.** Examples of family history collection strategies and tools are covered in the Lunch and Learn session: “Tips and Tricks to Optimize Genetic Testing at Your Cancer Program” at [accc-cancer.org/iowa-lunch-and-learn](http://accc-cancer.org/iowa-lunch-and-learn).
- **Develop processes and procedures to track genetic counseling referrals in patients with cancer.** Based on this information, conduct a quality improvement (QI) project aimed at increasing genetic testing in eligible patients with a specific type of cancer (e.g., prostate). Engage all members of the multidisciplinary team to ensure that referrals for genetic counseling are coordinated at the time of diagnosis. Ensure there is someone on the team to champion this effort.
  - ◆ Identify gaps in genetic testing rates by performing audit/feedback and discussing these findings with members of the multidisciplinary cancer care team.
  - ◆ Develop a map of the referral process to determine why eligible patients are not being referred or tested.
  - ◆ Review and update universal genetic testing policies for specific types of cancers (e.g., all patients with exocrine pancreatic cancer should receive germline testing).
- **Refer patients to genetic counselors who can provide clear information about insurance coverage for genetic testing.** This can help clear up any misconceptions patients may have about insurance coverage and out-of-pocket costs for genetic testing. Remember that some health insurance companies may require pre-test genetic counseling prior to testing.
- **When referring patients to genetic counselors, provide them with education materials like handouts or pamphlets that clearly explain the importance of genetic counseling and testing for patients with cancer.** Examples of resources include the MD Anderson “Genetic Counseling” handout in English ([mdanderson.org/patient-education/Genetics/Genetic-Counseling.pdf](http://mdanderson.org/patient-education/Genetics/Genetic-Counseling.pdf)) and Spanish ([mdanderson.org/patient-education/Genetics/Genetic-Counseling-\(Spanish\).pdf](http://mdanderson.org/patient-education/Genetics/Genetic-Counseling-(Spanish).pdf)) and NSGC’s About Genetic Counselors webpage at: [aboutgeneticcounselors.org](http://aboutgeneticcounselors.org).
- **Develop partnerships with local or regional genetic counselors or telehealth genetic counseling companies and streamline the referral process.** Every member of the multidisciplinary cancer care team should know how to refer patients to these genetic counselors. Examples of different genetic service delivery models were covered in the Lunch and Learn session: “Genetic Testing Approaches to Improve the Identification of Hereditary Cancer Syndromes” at [accc-cancer.org/iowa-lunch-and-learn](http://accc-cancer.org/iowa-lunch-and-learn).
- **Provide continuing education to members of the multidisciplinary team about genetic testing updates.** For example, ensure that urologists who are treating patients with prostate cancer are knowledgeable about germline testing and the role of PARP inhibitors. Also, confirm that gastroenterologists are coordinating MSI/MMR tests in patients who are diagnosed with colorectal cancer.
- **When discussing or documenting test results in the patient’s chart, clearly differentiate whether “molecular” or “genetic” test reports reflect somatic and/or germline test results.** Remember that circulating tumor DNA (ctDNA) tests have the potential to identify somatic and/or germline variants.
- **To reduce confusion about somatic vs. germline testing, consider using consistent terms outlined by the Consistent Testing Terminology Working Group.**<sup>16</sup> “Biomarker testing” refers to somatic test results originating from malignant tissue or blood. “Genetic

testing for an inherited mutation” and “genetic testing for inherited cancer risk” refers to tests that identify germline pathogenic variants.

- **Work with pathology to review abnormal somatic biomarker test results.** Some results may suggest a potential germline finding since pathogenic variants reported in the tumor may be of somatic or germline origin. Somatic pathogenic variants seen in tumor specimens may be more common in genes with germline implications (e.g., *TP53*, *STK11*, *PTEN*, etc.). Remember that the sensitivity of many tumor (somatic) genetic tests is lower than germline tests.
- **Examine the clinical workflow for genetic testing when patients are being considered for targeted therapies (e.g., PARP inhibitor).** Is the process for referral and genetic testing the same as biomarker testing? Specific case examples are covered in the Lunch and Learn session: “Genetic Counseling and Testing in Community Cancer Centers: Perspectives, Challenges, and Opportunities” at [acc-cancer.org/iowa-lunch-and-learn](https://acc-cancer.org/iowa-lunch-and-learn).
- **Explore ways to work with organizations like the Iowa Cancer Consortium to track and improve genetic counseling and testing in patients with cancer.**

### Examples of Universal Genetic Testing in Patients with Cancer:

- NCCN Guidelines recommend genetic risk evaluation and germline and somatic testing for all patients with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.<sup>17</sup>
- NCCN Guidelines for pancreatic adenocarcinoma recommend germline testing for any patient with confirmed exocrine pancreatic cancer.<sup>18</sup>
- NCCN Guidelines for colon cancer recommend universal mismatch repair (MMR) or microsatellite instability (MSI) testing for all patients newly diagnosed with colon cancer.<sup>19</sup>

## CONCLUSION

As the landscape of cancer genetics continues to evolve, the Iowa Oncology Society (IOS) leadership remain committed to providing education and resources to its members and the general public. IOS sponsored this program in 2021 and committed time and resources to this important effort.

IOS is a Chapter Member of the Association of Community Cancer Centers (ACCC), the leading education and advocacy organization for the cancer care community. Additional tools and resources focused on genetic testing and precision medicine may be found on the ACCC website: [acc-cancer.org/precision-medicine](https://acc-cancer.org/precision-medicine).

To access the full compendium of resources that support genetic counseling in Iowa, please visit [acc-cancer.org/iowa-genetic-counseling](https://acc-cancer.org/iowa-genetic-counseling) or scan the QR code.



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## ACKNOWLEDGEMENTS

The Iowa Oncology Society is grateful to the consortium members who graciously contributed their time to this effort.

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A publication from the IOS education project, "A Multidisciplinary Consortium to Advance Genetic Counseling in Oncology." Learn more at [acc-cancer.org/iowa-genetic-counseling](http://acc-cancer.org/iowa-genetic-counseling).

Founded in 1992, the **Iowa Oncology Society** is the largest oncology professional organization in the state. IOS comprises a powerful community of oncologists, nurse practitioners, physician assistants, pharmacists, and other multidisciplinary care providers involved in the treatment of patients with cancer.

IOS is one of 21 State Chapter Members that is managed by—and collaborates with—the Association of Community Cancer Centers (ACCC) and is a State Affiliate of the American Society of Clinical Oncology. IOS members receive valuable educational content and innovative resources designed to keep them ahead of the local and national challenges and trends directly impacting the high-quality care their patients deserve. For more information, visit [ios-iowa.com](http://ios-iowa.com) or call 301.984.9496. Follow us on Twitter @OSSatACCC.

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This publication is a benefit of IOS membership.

This project is sponsored by the Iowa Oncology Society.