Genetic Testing
Challenges and changes in testing for hereditary cancer syndromes

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BACKGROUND: The practice of genetic testing for hereditary cancer syndromes has changed dramatically in recent years, and patients often approach oncology nurses requesting information about genetic testing.

OBJECTIVES: This article aims to explore changes in cancer genetics, the role of genetics professionals in providing comprehensive genetic care, and the implications of these new developments in genetics for oncology nurses.

METHODS: A literature review was conducted and focused on articles about the updating of genetic tests with panel testing, insurance changes, alternative genetic counseling strategies, and direct-to-consumer genetic testing.

FINDINGS: Oncology nurses play an important role in identifying and referring patients, including those who have tested negative for hereditary susceptibility genes, to genetics professionals. Genetics professionals can assist with insurance issues, interpretation of test results, clarification when a variant of unknown clinical significance is detected, and recommendations for care based on personal and family history and testing results. Oncology nurses can assist families with understanding the limitations of direct-to-consumer genetic testing.

KEYWORDS
hereditary breast cancer; genetic testing; direct-to-consumer genetic testing

DIGITAL OBJECT IDENTIFIER
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TESTING FOR HEREDITARY CANCER SYNDROMES HAS CHANGED significantly since 2013 because of legal decisions and technological advances in genetic science. Hereditary cancer syndromes account for about 10% of all malignancies, and the identification of individuals in families who have a genetic predisposition for developing cancer can guide decisions about cancer prevention and early detection, including the use of prophylactic surgery (Weitzel, Blazer, MacDonald, Culver, & Offit, 2011). The evolution of genetic testing for hereditary cancer syndromes has progressed rapidly (see Figure 1).

The implications of genetic science in clinical oncology practice have become complicated; the simple days of oncologists ordering BRCA testing for their patients with breast cancer is over. Multiple genes associated with varying degrees of risk for developing breast and other cancers have been identified. Individuals who tested negative for the common BRCA mutations in the past, for instance, may harbor a less common hereditary susceptibility gene (Daly et al., 2017; Rich, Woodson, Litton, & Arun, 2015). The availability of testing for multiple genes using a panel of genes has led to more families discovering a susceptibility gene, but expanded panel testing has also created new challenges (Marcus et al., 2015). For example, many variants of unknown clinical significance are detected, and insurance requirements for coverage of panel testing are complicated. The interpretation of expanded panel testing is similarly complex and is best managed by a credentialed genetics professional; however, the shortage of credentialed genetics professionals has necessitated the use of alternative counseling strategies. In addition, direct-to-consumer testing has increased, and oncology nurses are often confronted with patient questions about it. Taken as a whole, these developments have made understanding cancer genetics more challenging for patients and healthcare providers.

Updating Genetic Testing
With the advent of panel testing, patients who previously underwent BRCA or other genetic testing with negative results should be offered more extensive testing (Graffeo et al., 2016). New panel testing includes testing for high penetrance breast and colon cancer genes (e.g., TP53, PTEN) and moderate penetrance genes (e.g., ATM, CHEK2, PALB2) (Castellanos et al., 2017; Economopoulou, Dimitriadis, & Psychou, 2015). The National Comprehensive Cancer Network (2016) provides recommendations for risk management for high and moderate risk genes that are associated with hereditary breast and ovarian cancer syndromes. About 9% of patients with breast cancer who had tested negative for BRCA mutations and later underwent panel testing were found to have a pathogenic mutation in a breast cancer susceptibility gene (Moran et al., 2017).
Contacting Patients About Genetic Testing

No consensus exists regarding how to best contact patients who need updated genetic testing (Carrieri et al., 2016). Studies suggest that most patients would like to be recontacted and that they place this responsibility solely on genetics professionals (Carrieri et al., 2016; Otten et al., 2015). Genetics professionals also believe that patients should be recontacted, but they find the process to be difficult and think that patients should share the responsibility.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>1994</td>
<td>BRCA1 gene is identified; Myriad Genetic Laboratories files patent.</td>
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<tr>
<td>1995</td>
<td>The full sequence of the BRCA2 gene is identified by Myriad, which files BRCA2 patent.</td>
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<tr>
<td>1996</td>
<td>BRCA2 gene is identified; Myriad Genetic Laboratories files patent.</td>
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<tr>
<td>2003</td>
<td>Myriad announces BRCA large rearrangement testing (deletion/duplication testing), which is available on a limited basis to patients with a greater than 30% chance of having a BRCA mutation.</td>
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<td>2007</td>
<td>Medicare approves coverage for BRCA large rearrangement testing, most private insurers follow. Genetics professionals are confronted with how or whether to recontact patients who have not yet undergone such testing.</td>
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<td>2008</td>
<td>Multigene panel testing becomes readily available from multiple laboratories.</td>
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<td>2012</td>
<td>Angelina Jolie reveals she has a genetic predisposition for breast and ovarian cancer and has undergone prophylactic surgery, raising awareness about the impact and importance of genetic testing in risk management.</td>
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<tr>
<td>2013</td>
<td>United Healthcare requires patients undergoing genetic testing to be evaluated by a genetics professional.</td>
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*Such testing does not use comprehensive sequencing technology but rather evaluation of single nucleotide polymorphisms (variations in a single base pair). It allows consumers to pay with a credit card to evaluate their genetic material without the assistance of a healthcare provider.*

*A parallel Myriad campaign targeting primary care providers and gynecologists emphasizes the ease and simplicity of ordering BRCA testing, and the sales force provides training on how to assess for hereditary risk and order testing.*

**Note.** Based on information from Graffeo et al., 2016; Matloff & Caplan, 2008; So & Joly, 2013; Stanislaw et al., 2016; Wang et al., 2011; Weitzel et al., 2011.
(Carrieri et al., 2016; Otten et al., 2015). Challenges include tracking data, deciding when or if to recontact, lacking resources (e.g., time, money, staff), scheduling an overwhelming number of patients who have received a recontact letter, and not having patients’ current contact information (Hampel, 2009; Otten et al., 2015). Many professional associations of legal experts and ethicists believe that recontacting patients should be a legal obligation, but there are no legal precedents to support this (Otten et al., 2015).

Most genetics professionals recommend that the patient regularly recontact the office where the genetic testing was done to update family history and contact information and to check for new genetic developments (Otten et al., 2015). The majority of genetics professionals report that they do recontact patients, but this tends to be only if a new event prompts chart review for a particular patient; recontacting is not conducted in any standardized fashion (Carrieri et al., 2016).

Many patients have undergone testing for one syndrome (e.g., BRCA only) and may erroneously conclude that they do not carry a pathogenic mutation in a cancer susceptibility gene (Stanislaw, Xue, & Wilcox, 2016). Oncology nurses play an important role in identifying and educating these patients about the availability of expanded and updated panel testing. For those families in which updated panel testing identifies a mutation, appropriate evidence-based recommendations for care can be provided, and nonaffected (those without a diagnosis of cancer) family members will have the opportunity to undergo genetic testing to better clarify their risk (Desmond et al., 2015).

Although many genetics professionals do not have a specific system in place to recontact patients (and, in fact, no agreement exists on this matter), nurses can help to bridge this gap by assessing what testing has been done, to date, at regular patient follow-up visits; educating patients regarding the need and availability of additional testing; and encouraging patients to contact their genetics professional for more information (Otten et al., 2015). The practice of reviewing previous genetic testing results should be a routine assessment when patients return for follow-up.

**Genetic Testing Coverage and Referrals**

Changes in major insurers’ policies for the coverage of genetic testing have affected genetic testing practices. The estimated cost of genetic testing to a third-party insurance payer ranges from $2,760–$4,100 for a panel of 20–30 genes associated with a hereditary cancer syndrome (Foote et al., 2017). Citing concerns for quality and the expenses associated with genetic testing, some insurance companies now require pre- and post-test genetic counseling by a credentialed genetics professional and submission of a three-generation pedigree (Wang, Beattie, Ponce, & Phillips, 2011). The American Society of Clinical Oncology (2016) released a statement strongly opposing the new insurance requirements, noting that oncology providers are well qualified to provide pre- and post-test genetic counseling to their patients and that this policy will restrict access to care.

Genetic counseling, correct test selection, and acquisition of informed consent have become increasingly complex with the advent of panel testing (Fecteau, Vogel, Hanson, & Morrill-Cornelius, 2014; Marcus et al., 2015). Panel testing has resulted in the identification of more mutations, but, for some genes, few evidence-based guidelines regarding prevention and early detection exist (Stanislaw et al., 2016). For example, AXIN2, SDHD, and BAP1 are genes that may be found on various pancreatic cancer panels without clear management guidelines regarding types of screening, ages to begin screening, or frequency of screening, particularly in the area of pancreatic screening. Explaining the implications of a less common gene or a moderate risk gene is challenging and time-consuming. Challenges cited by genetics professionals (see Figure 2) include ensuring participant understanding of testing and its implications, as well as working through complicated social family situations (e.g., misattributed heritage, confusion regarding paternity, pressure from family members) (Tomlinson et al., 2016). Because of significant concerns about patient safety and the possibility of medical errors, studies have evaluated strategies to provide support, education, and assistance to healthcare providers who do not specialize in genetics (Korngiebel, Fullerton, & Burke, 2016). Overall, several studies show that providers who undergo additional genetics training have an increase in knowledge; however, these studies did not really evaluate practice behavior, so determining whether patients are actually receiving better care is difficult to ascertain (Bonadies et al., 2014; Douma, Smet, & Allain, 2016; Korngiebel et al., 2016).

Appropriate referrals for hereditary cancer evaluation to credentialed genetics professionals continue to be low. A study by Febbraro et al. (2015) showed that only 34% of patients with breast cancer, 13% of patients with uterine cancer, and 15% of patients with ovarian cancer who met guidelines for genetic testing were referred by their healthcare providers. In addition, just 70% of referred patients will ultimately meet with a genetics professional (Febbraro et al., 2015). Healthcare providers fail to make referrals for many reasons, including a lack of knowledge of genetics referral procedures and a dearth of genetics professionals in their area (Delikurt, Williamson, Anastasiadou, ...

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“Hereditary cancer syndromes account for about 10% of all malignancies.”
& Skirton, 2015). Healthcare providers, such as gynecologists, primary care physicians, and oncologists, often order genetic testing and see this as an opportunity to provide an important service to patients who may not have easy access to testing. Studies have shown that healthcare providers who do not specialize in genetics feel confident in their knowledge and counseling ability; however, when asked questions about basic genetic concepts, these same providers often scored poorly on surveys measuring hereditary cancer knowledge (Douma et al., 2016). Figure 3 provides an outline of the benefits of having genetics professionals manage counseling, testing, and follow-up for at-risk families.

Clinical Navigation

Oncology care is complex and requires multiple disciplines, such as radiation therapy, surgery, medical oncology, nutrition, rehabilitative services, and psychosocial services. Genetic counseling and testing is another treatment modality service. Genetics professionals can advocate for the most appropriate genetic test or panel of tests and coordinate care for the entire family. Nurses can ensure that patients and their families access appropriate testing by referring them to a credentialed genetics professional.

Conducting and facilitating genetic testing is time-consuming. Genetics professionals spend an average of 84 minutes on the initial visit and 74 minutes on the follow-up visit (Mahon, 2013a). In addition, as previously noted, many insurance companies now require documented pre- and post-test counseling; busy oncologists often are not able to provide this time-consuming service. The three-generation pedigree, which is another requirement of some insurance companies, involves ancestry information, additional paperwork, and clinical notes detailing the specifics of the counseling session; this is not typically performed by healthcare providers who do not specialize in genetics. Without a three-generation pedigree, the risk of the wrong testing being ordered is greater (Mahon, 2016b).

When testing is done outside of a consultation with a genetics professional, the risk of errors is greater (e.g., wrong test is ordered, results are interpreted incorrectly) (Bonadies et al., 2014; Brierley et al., 2012; Mahon, 2013b; Trepanier & Allain, 2014). Many insurance plans will not pay for multiple rounds of testing (Wang et al., 2011), and if a clinician does not order the correct test, the patient may not be able to afford the correct test later. Interpretation of the results also presents a challenge to healthcare providers who do not specialize in genetics because it is not always straightforward, particularly with new panel testing (Fecteau et al., 2014; Marcus et al., 2015).

Genetic Counseling Delivery: Other Options

Genetics professionals have typically provided in-person pre- and post-test counseling for patients undergoing cancer genetic testing. Given the limited number of credentialed genetics professionals, this has presented a burden for many patients (Cohen et al., 2013). More studies are needed that evaluate different mechanisms for pre- and post-test genetic counseling to ease this burden and to increase access to testing in consultation with a credentialed genetics professional (Trepanier & Allain, 2014).

Most genetics professionals (92%–96%) use the traditional face-to-face genetic counseling model, and concern exists that moving away from this model may affect quality of care (Cohen et al., 2013; Hilgart, Hayward, Coles, & Iredale, 2012; Trepanier & Allain, 2014). Telephone counseling employs widely available technology but is used by just 8%–17% of genetics professionals (Cohen et al., 2013; Otten, Birnie, Lucassen, Ranchor, & Van Langen, 2016). Videoconferencing is available to 24% of European genetics professionals, but only 9% use the technology (Otten et al., 2016).

However, patients are more receptive to alternative counseling models, and patient satisfaction scores are similar among videoconferencing, telephone counseling, and in-person counseling (Bradbury et al., 2016; Buchanan et al., 2015; Hilgart et al., 2012; Patrick-Miller et al., 2014). Patients reported many benefits of telephone and videoconference counseling, including lower travel burden and increased convenience (Bradbury et al., 2016; Patrick-
Miller et al., 2014). Patients who had genetic counseling via videoconference experienced an increase in knowledge, as well as a decrease in anxiety and depression (Bradbury et al., 2016; Kinney et al., 2016). In a study by Surphee et al. (2016), as many as 66% of patients reported that they would not have undergone genetic counseling if they had had to present to a clinic for the counseling. This number is likely somewhat inflated because this particular study did not include patients with cancer and included only patients who had previously consented to participation in a telephone counseling study. Patients with cancer and patients who may have preferred in-person counseling were, therefore, excluded from this study.

Multiple studies have compared genetic counseling outcomes among patients who had in-person counseling versus telegenetic counseling (counseling via video or telephone) (Kinney et al., 2016; Patrick-Miller et al., 2013; Schwartz et al., 2014). In the areas of anxiety, knowledge, quality of life, and decision-making outcomes, telephone counseling was not inferior to in-person counseling (Kinney et al., 2016; Patrick-Miller et al., 2013). Patients undergoing telephone pretest counseling were less likely than patients undergoing in-person pretest counseling to undergo genetic testing (28% versus 37%, respectively); in addition, patients undergoing telephone pretest counseling were less likely to attend their scheduled visits after the telephone pretest counseling (79% versus 89% of in-person counseling visits) (Buchanan et al., 2015; Kinney et al., 2016). Although reasons for this lower rate of completion of testing are unclear, Kinney et al. (2016) speculated that the wait time between telephone counseling and actual testing may reduce enthusiasm for testing. In addition, because most of the test results were negative, determining whether these patients experienced psychological harm and followed risk management guidelines based on their personal and family history, similar to the experiences noted by patients who tested positive for BRCA, was difficult (Kinney et al., 2016).

Traditionally, in-person pre- and post-test counseling has been the standard of care, but many advantages exist with genetic counseling via telephone or videoconference. Patients have reported appreciating the convenience of telegenetic counseling, and studies suggest that patients’ understanding of the information received in pre- and post-test counseling visits is similar to that of patients receiving in-person counseling versus using alternative methods of counseling (Cohen et al., 2013). Figure 4 provides an overview of the strengths and limitations of telemedicine. Oncology nurses need to emphasize to patients that undergoing counseling with an expert in genetics has known benefits, assist the patient in accessing a genetics professional, and note that multiple effective
approaches to genetic counseling exist (Berliner, Fay, Cummings, Burnett, & Tillmanns, 2013; Bradbury et al., 2016; Buchanan et al., 2015; Castellanos et al., 2017; Cohen et al., 2013; Kinney et al., 2016; Mahon et al., 2013a; Otten et al., 2016).

**Variants of Unknown Clinical Significance**

When the human genome was sequenced in June 2003, it was representative of only a few individuals (Genome News Network, 2003). Although humans are 99.9% genetically identical, variations exist within the DNA sequence that contribute to making each person unique. The human genome consists of more than 22,000 genes, and an average person has 3.5 million variants within his or her genome (Evans, Burke, & Jarvik, 2015).

Most of these variants have no significant effect on a gene’s function and are classified as benign or likely benign. The American College of Medical Genetics and Genomics and the Association for Molecular Pathology have made recommendations and standards for the classification of genetic variants; accurate classification is critical because management of risk is based on the variant classification (Richards et al., 2015). Benign variants are typically not reported on genetic testing results because these changes likely do not increase cancer risks (90%–99% certainty) (Richards et al., 2015). Variants can also be classified as pathogenic or likely pathogenic. Pathogenic or likely pathogenic variants are changes to the DNA sequence that negatively affect the gene’s function and increase cancer risk (90%–99% certainty) (Richards et al., 2015).

About 19%–20% of patients undergoing hereditary cancer panel testing will have a genetic variant or a change in their DNA of unknown clinical significance (Cragun et al., 2014; Maxwell et al., 2015). A variant of unknown clinical significance is a change in the DNA sequence, but whether the change affects the gene’s function and, therefore, increases cancer risk is unclear. Such a result is challenging because decisions regarding management cannot be based on finding with an ambiguous meaning. Instead, these are based on personal and family history (van Marcke, De Leener, Berlière, Vikkula, & Duhoux, 2016). Patients may be frustrated and disappointed because their risk was not clarified. In addition, testing other family members outside of variant reclassification studies is not recommended because the meaning of the variant of unknown clinical significance is unclear (van Marcke et al., 2016).

Clinical laboratories have entire scientific teams dedicated to determining the classification of variants. These teams take multiple lines of evidence into consideration before categorizing a variant, including population data (how often the variant is seen in the general population), computational or in silico models (computer models that predict the effect of the change on protein function), functional data (laboratory methods that directly analyze the effect of the change on protein function), segregation data (frequency with which a variant tracks with the suspected malignancy), de novo data, allelic data, literature reviews, and established genomic databases (Richards et al., 2015).

If a laboratory cannot say with 90%–99% certainty that a variant is benign or pathogenic, it will be classified as a variant of unknown clinical significance. In some cases, families will be offered the option to participate in a variant reclassification study; testing may then be offered to carefully selected family members to understand how a variant tracks with the malignancy in the family and, ultimately, to contribute to information about the reclassification of the variant of unknown clinical significance (Garrett et al., 2016). As more data become available, a variant of unknown clinical significance will often be reclassified to pathogenic or benign, but this may take many years.

**Follow-Up**

Oncology nurses may encounter patients who have undergone hereditary cancer testing and were found to have one or more variants of unknown clinical significance. Because supporting evidence is unclear regarding a variant of unknown clinical significance, these patients and their families should be managed based on their personal and family history.

The very real possibility of a variant of unknown clinical significance should be discussed in pretest counseling. Patients and families need reassurance that a variant of unknown clinical significance is relatively common but can be confusing and frustrating because it is noninformative in regard to risk clarification.
Because reclassification can take a long time, patients and families should be instructed to recontact the genetics professional on a regular basis to determine if anything more is known about the variant. Nurses can communicate with genetics professionals on the best ways to support patients when a variant of unknown clinical significance is detected, reinforce information about the variant of unknown clinical significance and rationale for recommendations for care, and encourage enrollment in reclassification studies when available.

Direct-to-Consumer Testing
Direct-to-consumer genetic testing is defined as genetic testing that consumers can purchase and interpret without involving healthcare providers. As medicine becomes much more autonomous, the number and type of direct-to-consumer genetic testing options has increased (Javitt, Stanley, & Hudson, 2004; Kaufman, Bollinger, Dvoskin, & Scott, 2012). Although many consumers of direct-to-consumer testing seek out information regarding their ancestry, health-related testing is also available. Interviews with patients who have undergone direct-to-consumer testing note that they hoped to obtain health-related information and to learn about genetic risk factors (Turrini & Prainsack, 2016). Unfortunately, many individuals overestimate what they will learn from direct-to-consumer testing and may be disappointed with the limited clinical significance of the results or their inability to alter risk based on the findings (van der Wouden et al., 2016). Individuals may also be motivated by a desire to provide information to children; however, the research does not make clear whether this is because of perceived clinical utility or social reasons, including the desire to be an early adopter of newer technology (Turrini & Prainsack, 2016).

Supporters of direct-to-consumer genetic testing cite patient empowerment as being the primary reason this testing should be available (Covolo, Rubinelli, Ceretti, & Gelatti, 2015). Consumers of direct-to-consumer genetic testing note that results may prompt patients to adopt a healthier lifestyle. However, studies show that patients who undergo direct-to-consumer testing do not actually make any changes to their lifestyle (e.g., diet, exercise, screening such as mammography or colonoscopy) (Turrini & Prainsack, 2016).

Critics of direct-to-consumer genetic testing argue that laboratories that may perform tests do not have the reliability or the validity to provide clinical useful information on which to base recommendations for cancer prevention and early detection (American College of Genetics and Genomics Board of Directors, 2016; Hudson, Javitt, Burke, & Byers, 2007). For a test to be good quality, the laboratory must be able to detect a specific variant when it is present and not detect a variant when it is absent. The laboratory must also establish that a health condition or risk associated with that particular variant is clinically actionable, which means that the information can change health behavior or management.

The U.S. federal government has limited oversight on direct-to-consumer genetic testing. Direct-to-consumer genetics laboratories must be Clinical Laboratory Improvement Amendment (CLIA) certified (Hudson et al., 2007), which requires that laboratories meet basic quality standards regarding documentations and quality control. However, CLIA does not address the validity or reliability of direct-to-consumer genetics laboratories. The U.S. Food and Drug Administration has required some direct-to-consumer genetics laboratories to limit their offerings. Patients must decide whether a laboratory is reliable and valid, often without having the necessary background knowledge.

Direct-to-consumer genetic testing may include only a very small percentage of disease-causing variants (Turrini & Prainsack, 2016). The limited number of genes typically evaluated in direct-to-consumer testing leads to incomplete and, therefore, inaccurate testing results. Individuals undergoing direct-to-consumer testing need to be informed that such testing is not comprehensive and may not provide useful information to clarify risk for developing a disease (Burke & Trinidad, 2016). In addition, interpreting results of positive or negative genetic testing is a complicated process and one that patients likely cannot do on their own. Patients may be inappropriately reassured by negative direct-to-consumer genetic testing results.

A very real risk of direct-to-consumer genetic testing is psychological distress. Case studies of patients who have undergone direct-to-consumer genetic testing who have been found to have a BRCA mutation show that patients are often completely unprepared for the results and may experience significant fear and anxiety (Dohany, Gustafson, Ducaine, & Zakalik, 2012; Mahon, 2016a).

Counseling and Context
Direct-to-consumer genetic testing is a controversial topic. Patients with cancer may turn to direct-to-consumer genetic testing because they believe that no one is paying attention to their genetic health. Nurses can advise patients that discerning clinical utility from direct-to-consumer genetic tests is difficult, if not impossible. In addition, nurses can explain that interpreting results without pre- and post-test genetic counseling is complex and may, ultimately, lead to psychological distress. If nurses and other healthcare providers take the extra step to connect their patients with genetics professionals, patients may not feel the need

IMPLICATIONS FOR PRACTICE
- Recognize that genetic testing for hereditary cancer syndromes is a complex process in terms of test selection and interpretation that is best carried out with the assistance of a credentialed genetics professional.
- Assess whether a patient has potential genetic risk and may benefit from referral to a genetics professional, particularly for up-to-date testing if previous testing has been negative or for follow-up if a variant of unknown clinical significance has been detected.
- Educate families that direct-to-consumer testing is not necessarily comprehensive and that a negative test does not eliminate the possibility of genetic risk.
to undergo direct-to-consumer genetic testing (Burke & Trinidad, 2016).

**Conclusion**
All oncology nurses should have basic knowledge of hereditary cancer syndromes and their management. The landscape of genetic risk assessment and genetic testing has become increasingly complex within the past several years. More testing options have become available, but with these advances have come more challenges and complexity in interpreting results. Genetics professionals are an important part of the cancer care team and are well suited to manage the complexities of genetic testing for hereditary cancer syndromes. Oncology nurses support patients and families with hereditary risk and can reinforce the importance and value of being evaluated by a credentialed genetics professional. The importance of genetic testing cannot be understated, and oncology nurses should know when and how to refer patients to a genetics professional in their community to provide the best possible care to these patients and their families.

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