The Commission on Cancer Genetics Standard: Risk Assessment and Genetic Counseling

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The Commission on Cancer (CoC) of the American College of Surgeons is a consortium of professional organizations with the mission to improve survival and quality of life for patients with cancer through standard setting, prevention, research, education, and the monitoring of comprehensive quality cancer care.1 Earlier this year, the CoC released a revised set of standards (www.facs.org/cancer/coc/cocprogramstandards2012.pdf) with improvements focusing on the enhancement of patient-centered functions, as well as the provision of performance criteria in quality measurement and outcomes.[1]

Some examples of patient-centered areas addressed by the updated standards include navigation programs, psychosocial distress screening and intervention, palliative care services, the development of survivorship plans, and genetic risk assessment and counseling services for patients at risk of hereditary cancer syndromes.

The goal of this article is to review CoC Standard 2.3, Risk Assessment and Genetic Counseling, as well as to discuss resources for implementation and to review the benefits of meeting this standard.

The New Genetics Standard

CoC Standard 2.3 necessitates that cancer risk assessment, genetic counseling, and genetic testing services be provided to patients, either on site or by referral, by a qualified genetics professional.[1] The standard emphasizes that these services are to be performed by a cancer genetics professional who has extensive experience and educational background in cancer genetics and counseling to provide patients with an accurate risk assessment, as well as pretest and posttest genetic counseling to discuss the risks, benefits, and limitations of genetic testing.

The standard outlines the various healthcare professionals who are qualified to provide these services, including:

1. An American Board of Genetic Counseling or American Board of Medical Genetics board-certified or board-eligible genetic counselor
2. An American College of Medical Genetics physician who is board certified in medical genetics

3. A Genetics Clinical Nurse or an Advanced Practice Nurse in Genetics who is credentialed through the Genetics Nursing Credentialing Commission
4. An advanced practice oncology nurse who is prepared at the graduate level, with specialized education in cancer genetics and hereditary cancer predisposition syndromes (educational seminars offered by commercial laboratories about how to perform genetic testing are not considered adequate training for cancer risk assessment and genetic counseling); certification by the Oncology Nursing Certification Corporation is preferred
5. A board-certified physician with experience in cancer genetics, providing cancer risk assessment on a regular basis.

In addition, the standard outlines the various components of pretest and posttest counseling required to be provided to patients receiving genetic risk assessment and genetic counseling.

The components of the pretest genetic counseling are:

1. A 3- to 4-generation pedigree on maternal and paternal families, including ancestry or ethnicity
2. An assessment of the patient's risk to carry a heritable cancer susceptibility gene mutation, as well as the patient's absolute risks to develop various types of cancer, given that patient's family history
3. Psychosocial assessment and counseling
4. Education of the patient regarding the suspected hereditary cancer syndrome (eg, inheritance, penetrance), and the implications of having genetic testing
5. Informed consent before obtaining a sample for genetic testing.

The components of posttest genetic counseling are:

1. Disclosure of the genetic test results
2. Significance of the test results with regard to cancer risk
3. Medical management options, based on the estimated cancer risk
4. Implications of the test results for family members
5. Identification of resources for psychosocial support and future decision-making related to medical management.

Why Was the Genetics Standard Developed?

Genetic testing for inherited cancer susceptibility syndromes has become a routine component of cancer care. This testing allows for the identification of patients and families who are at increased risk to develop future malignancy, with the hope of tailoring management to promote early detection and, at times, cancer prevention.

Various national cancer organizations have outlined when to offer genetic testing, as well as the need for pretest and posttest genetic counseling. For example, the American Society of Clinical

Oncology (ASCO) has published policy statements on genetic testing, recommending that genetic testing be offered when (1) the individual being tested has a personal or family history suggestive of genetic cancer susceptibility, (2) the genetic test can be adequately interpreted, and (3) the test results have accept-ed clinical utility.[2,3] In addition, ASCO's policy statement recommends that genetic testing be conducted only in the setting of pretest and posttest genetic counseling; the policy statement outlines the important components of genetic counseling, as well as proper informed consent, in the setting of genetic testing for cancer susceptibility.[2,3]

The US Preventive Services Task Force has similar recommendations, emphasizing the importance of appropriate genetic counseling by healthcare providers with appropriate training.[4] To assist providers in the identification of patients eligible for risk assessment and genetic counseling, the National Comprehensive Cancer Network has published guidelines that include personal and family history criteria that warrant referral.[5]

Given the widespread recognition of the importance of cancer risk assessment, it is fitting that the CoC would develop a standard to address the appropriate delivery of genetics services at CoC-accredited sites, particularly because the CoC has taken on a patient-focused model.

The CoC genetics standard is designed to ensure that risk assessment and genetic counseling or testing services are available, and to ensure that professionals with genetics expertise are providing these services.

Our understanding of the genetic basis of cancer is ever-changing with the continual discovery of new cancer susceptibility genes, making cancer risk assessment a complex science. In addition, genetic testing technology is quickly evolving, more so now than ever before.

In light of these complexities, the CoC recognized the importance of involving specialized genetics professionals in the genetic risk assessment and counseling process to ensure that patients are receiving accurate risk assessment, undergoing testing in a cost-effective manner that includes ensuring that the correct genetic test is being ordered, and receiving accurate interpretation of genetic test results so that medical management can be individually tailored using genetic test results and/or family history information.

Meeting the Standard: How to Implement Genetic Services at Your Institution

Healthcare professionals trained in genetics are skilled at providing risk assessment and genetic counseling and, ideally, are the type of professionals your institution should strive to have on staff or refer to.

If your institution already has a genetics professional (as defined by the standard), it is important that you contact this individual to make sure that he/she is meeting the minimum essential elements outlined in the new CoC genetics standard and is involved with your cancer committee and cancer conferences.

If your institution does not currently meet the standard, several options are available to make your institution compliant. One strategy would be to hire a genetics professional. Recognizing the budgetary pressure that many organizations face, genetics and genomic medicine are quickly making their way into routine care in many areas of medicine beyond oncology, and it is possible that a genetics professional can be a “shared cost” across multiple departments, such as cardiology, neurology, pediatrics, and prenatal obstetrics and gynecology. Specifically, most medical geneticists or genetic counselors receive multifaceted training and can provide genetic risk assessment across specialties.

Once hired, most genetics professionals have the skill set to initiate a cancer risk assessment program; this skill set generally includes:

1. Working with hospital administrators and physician leads in determining the logistics for where to see patients (eg, in a shared multidisciplinary clinic with other oncology staff or a separate clinic specifically dedicated to genetics), depending on the institution’s space availability and workflow
2. Developing billing and reimbursement protocols with hospital administrators and finance staff
3. Setting up meetings with staff from different oncology subdivisions (eg, breast, gastroenterology, gynecology, and endocrine) to discuss strategies for referral and communication before and after consultations; if house staff are not familiar with what a genetics professional has to offer or who to refer for a cancer risk assessment, the genetics professional may provide educational in-services for the staff
4. Developing documentation (eg, pedigree, consult notes) protocols, which in turn may require communicating with the medical records and/or the legal department to determine whether there are specific statutes in state genetics legislation that have certain requirements for the documentation or the release of genetic information; for institutions with an electronic medical record, a meeting with information technology staff may be needed
5. Establishing relationships with physicians who refer to your cancer center to promote the cancer genetic risk assessment program
6. Meeting with public relations staff to assess how to best promote the program to the community, which would likely require the genetics professional going into the community to give talks to a lay audience about cancer genetics
7. Working with the laboratory administration to develop genetic testing protocols that facilitate efficiency in ordering testing, while minimizing costs to the institution
8. Instituting a database of patients seen that may be able to be completed in conjunction with current registries.

If hiring a genetics professional is not feasible, consider the option to contract with another local institution that has a genetics professional on site. With this model, either your institution could refer patients to the contracted site and, in turn, the genetics professional would send back formal documentation with the risk assessment and/or the genetic test results, with follow-up recommendations to your institution, or the genetics professional from the outside institution could come to your institution (eg, 1 or 2 days weekly) and provide the risk assessment and counseling on

site, which would also allow the input of documentation directly into your own medical record system. The expense of this second approach would be lower than the expense associated with hiring a full-time genetics professional and may be a more feasible option for institutions with budgetary restrictions.

A third choice for implementing the genetics standard is to refer patients to a third-party over-the-phone genetic counseling company. This option may be ideal for centers that cannot afford to hire a genetics professional or that are in a rural area in which either recruiting a genetics professional is difficult or a truly local (eg, a drive less than 60-90 minutes) professional referral is not available.

Currently, there are 2 companies—DNADirect (www.dnadirect.com/dnaweb/home.html) and Informed Medical Decisions (www.informeddna.com)—that employ certified and/or licensed genetic counselors who provide cancer risk assessment over the telephone.

If genetic testing is indicated, the company will coordinate sample collection with the referring provider. Once complete, the company will send the patient and referring provider a summary of the consultation, which generally includes a pedigree, the consult notes, and genetic test results (if performed), which can be added to the patient's chart. These companies often work directly with a patient's insurer on the billing associated with the consultation and testing.

Table 1

Table 1 Options for Implementing the Genetics Standard

On-site genetics services	Referral to outside genetics services
Advantages	
Provide comprehensive services to patients in-house	Potentially no additional costs to start a program
Have genetics involvement with cancer committees and tumor boards	Foster relationships with other institutions or companies
Increase opportunities for internal genetics educational seminars for staff	If referrals are local, may be able to have genetics representation at cancer committees and tumor boards
Can use the genetics services providers from other departments (eg, cardiology, prenatal)	For over-the-phone genetic counseling companies, can provide patient services on nights and weekends, as well as to the patient's home for a patient who lives a long distance from the institution
Reduce risk of losing patients to competitors	Do not need additional space for the program
May be able to generate additional revenue with both billing for genetics service and downstream revenue from additional tests or procedures	
Genetics professional can represent your institution at the local and national level	
May decrease referral laboratory costs for genetic testing	
Disadvantages	
Costs associated with genetics professional and additional personnel (ie, administrative support), if needed	Referring patients out increases risk of losing patients to competitors
Need space to house personnel and program	May not have genetics representation on cancer committees and tumor boards
	Potentially do not have genetics personnel to interact and educate in-house staff
	May lose out on additional revenue
	Referring out may suggest to patients that the institution is not a comprehensive cancer center

There are varied benefits and limitations to each of these options (**Table 1**), all of which should be considered when your cancer center is making its plan for how to meet the CoC genetics standard.

The Benefits of Meeting the Genetics Standard

The most important point in trying to meet the CoC genetics standard is to understand that the standard promotes cancer risk assessment and genetic counseling, not necessarily genetic testing. By following the elements outlined in the standard and having a trained genetics professional provide a risk assessment, your cancer center can pride itself on the identification of patients who face an elevated risk of a future cancer. Once high-risk patients are identified, cancer surveillance and risk reduction options can be offered, which have been shown to lead to reduction of cancer-related morbidity and mortality.

Furthermore, patients will have an understanding of the benefits, risks, and limitations of genetic testing, allowing them to make an informed choice about whether they or their family want the information that genetic testing can provide.

Ultimately, your center will provide the high level of care that is consistent with a multitude of medical societies' and organizations' professional guidelines.

In addition to improving patient care and allowing patients to be fully informed of the implications of genetic testing, the CoC genetics standard can help minimize inappropriate genetic testing. Historically, commercial laboratories have provided assistance to nonspecialized healthcare professionals on how to order genetic testing. However, this can lead to "one-size-fits-all" testing, absent a true cancer risk assessment, where patients are all offered the same genetic test for only 1 cancer syndrome.

Although this type of testing may identify some individuals with a hereditary cancer syndrome, patients who have a pattern of cancer that fits a different syndrome may never be tested for the correct syndrome. As a result, patients will not know what cancers they and their families may be at risk for, leading to improper medical management, and the ordering physician may be at risk of being accused of malpractice if the true cancer syndrome would have been obvious to a genetics specialist. Another result of a nongenetics professional ordering testing is that inappropriate individuals may be offered unnecessary (and expensive) tests, putting further financial strain on the healthcare system.

Genetic Counseling Resources

Table 2

Table 2 Resources for Genetics Counselors

Organization	Functions
National Society of Genetic Counselors (NSGC) www.nsgc.org	Find a local genetic counselor Post an employment opportunity via NSGC's job connection services Review NSGC practice guidelines and position statements
American College of Medical Genetics (ACMG) www.acmg.net	Find a local medical geneticist Post an employment opportunity via ACMG's employment resource center Review ACMG practice guidelines and policy statements
Genetic Nursing Credentialing Commission (GNCC) www.geneticnurse.org	Find information on the credentialing process for a nurse to become a Genetics Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APNG)
International Society of Nurses in Genetics (ISONG) www.isong.org	Review ISONG's practice standards and position statements Learn more about nursing master's and doctorate programs that involve a genetics specialization

Table 2 lists a number of organizations that can provide assistance when you are looking to identify a local genetics professional who can assist your institution in meeting the CoC genetics standard. These resources can be valuable when looking to hire for a new position, when locating a nearby provider who may accept referrals, or in researching the process of credentialing a professional you may already have on staff.

References

1. American College of Surgeons Commission on Cancer. Cancer program standards 2012: ensuring patient-centered care. www.facs.org/cancer/coc/cocprogramstandards2012.pdf. Accessed August 27, 2012.
2. Robson ME, Storm CD, Weitzel J, et al. American Society of Clinical Oncology policy statement update: genetic and genomic testing for cancer susceptibility. *J Clin Oncol*. 2010;28:893-901.
3. 3. American Society of Clinical Oncology. American Society of Clinical Oncology policy statement update: genetic testing for cancer susceptibility. *J Clin Oncol*. 2003;21:2397-2406.

4. 4. US Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Ann Intern Med*. 2005;143:355-361.
5. 5. National Comprehensive Cancer Network (NCCN). NCCN guidelines. NCCN Website. www.nccn.org/professionals/physician_gls/f_guidelines.asp#detection. Accessed August 27, 2012.

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