The NCCCP Cancer Genetic Counseling Assessment Tool

How to assess your program and improve performance

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Today genetics and personalized medicine are core components of multidisciplinary cancer care. Genetic counseling is a key factor along the entire cancer care continuum from prevention to screening to treatment and into survivorship.[1] It provides education to patients and family members on hereditary and familial causes of cancer, and aims to empower individuals to make informed decisions about cancer prevention, screening, and treatment. Genetic counseling evaluations are vital for identifying those at high risk to develop cancer and recommending appropriate strategies for cancer surveillance and risk reduction. Numerous professional organizations, including the National Society of Genetic Counselors (NSGC), have identified core components of a cancer genetic counseling and risk-assessment program.[2] Essential elements often include the following:[3]

- Documentation of an individual's family, reproductive, medical, and surgical histories to aid in risk assessment.
- Collection of a three to four generation pedigree analysis and use of currently available risk-assessment models to determine an individual's risk for developing cancer and chance of having a hereditary cancer syndrome.
- Education regarding cancer genetics, hereditary cancer syndromes, and inheritance patterns.
- Genetic testing as indicated by evidence-based guidelines.
- Discussion of the risks, benefits, and limitations of genetic testing, including issues related to genetic discrimination.
- Informed consent prior to specimen collection.
- A pre-test assessment of the patient's ideas about cancer risk and etiology, as well as a psychosocial assessment.
- Post-test result counseling and re-assessment.

While it is critical for institutions to assess the strengths and weaknesses of their cancer genetic services to identify areas in need of improvement, few resources and/or tools exist to help in these efforts. To help meet this need, the National Cancer Institute Community Cancer Centers Program (NCCCP) developed a self-assessment tool to assist cancer centers in assessing their programs and developing quality improvement plans. (For more on the NCCCP and its role in improving cancer genetic services, see box on page 41).

Developing the CGCAT

NCCCP sites developed the Cancer Genetic Counseling Assessment Tool (CGCAT) to address the goal of providing enhanced genetic and molecular testing at NCCCP community cancer centers. In 2008 the Quality of Care Subcommittee formed a Genetics Working Group; the group consisted of 10 individuals from 8 of the NCCCP sites that either had existing cancer genetic services or were interested in developing an oncology genetic counseling program. Those participants with genetics programs described a variety of different methodologies for providing genetic counseling services, including:

- Onsite genetic counseling
- Referral to outside services
- Contracted genetic counselors
- Telehealth and telemedicine.

Genetic counseling services at these NCCCP sites were provided by a combination of genetic counselors, oncologists, and nurse practitioners.

With so much variety, the NCCCP Genetics Working Group recognized the need for a tool to help programs set internal goals and growth measurements. The first step in the tool development process was an extensive literature review to identify benchmarks, guidelines, and position statements. This literature review did not reveal any models for systematically evaluating a cancer genetics program.

Next, to establish key components to include in the CGCAT, the NCCCP Genetics Working Group reviewed professional position statements and guidelines regarding cancer genetic counseling and testing from several organizations, including the American Society of Clinical Oncology (ASCO), NSGC, the U.S. Preventive Services Task Force (USPSTF), the American Society of Human Genetics (ASHG), and the Oncology Nursing Society (ONS).[4-8] All position statements recommended that:

- Cancer genetic counseling and testing to be performed by a qualified healthcare provider, including certified genetic counselors as well as oncologists and advanced practice oncology nurses with specialized education in hereditary cancer genetics.

With so much variety, the NCCCP Genetics Working Group recognized the need for a tool to help programs set internal goals and growth measurements.

- Patients at risk to have a cancer-predisposing mutation are to be appropriately identified.
- Genetic testing is performed only subsequent to pre-test counseling and in conjunction with post-test counseling.

By consensus, the NCCCP Genetics Working Group selected seven clinical and programmatic components as "essential" to a successful cancer genetics program:

1. Patient Identification
2. Physician Referrals
3. Services Provided
4. Pre-Test Counseling
5. Post-Test Counseling
6. Documentation of the Cancer Genetics Consult in the Patient's Medical Record
7. Financial (billing).

As a numerical measurement, the NCCCP Genetics Working Group modeled the CGCAT after the NCCCP Multidisciplinary Care Assessment Tool. The CGCAT uses a five-level measurement system ranging from Level 1 (having few to none of the elements for a given component) to Level 5 (having all the elements for a given component).

After multiple revisions, the NCCCP Genetics Working Group finalized the CGCAT in 2009; it was subsequently approved by the NCCCP Quality of Care and Executive Subcommittees. In 2010 the NCCCP employed the CGCAT to establish a retrospective baseline at the NCCCP sites, and then to prospectively assess current program status, set goals, and identify desired program enhancements.

In 2011 the NCCCP formed a second working group to revise the CGCAT to capture incremental growth and observe effective strategies for program enhancement, which was not available in the previous tool. The updated 2011 CGCAT included the same seven component areas of performance as the 2009 version. Updates were made to the component areas of "physician referrals" and "services provided" (see specific core element below), while the other five component areas were not amended. The 2011 CGCAT can be found on pages 38-39.

The NCCCP CGCAT is intended to be used to assess individual genetics programs within the context of the unique qualities and challenges that any given institution may face. The tool can be used to look at the program as a whole or to look at specific areas (e.g., only colon cancer referrals). Additionally, cancer programs should select the core elements to include in the assessment based on their unique needs and quality improvement efforts. The goal is for cancer programs to identify areas of opportunity and to use the self-assessment tool to provide measurable outcomes based on their own strategic plan.

Component 1: Patient Identification

This component quantitatively assesses the percentage of patients for a given disease site who are referred for a genetic counseling consultation. Approximately 20 percent of cancers develop from hereditary or familial causes.[4,9] Based on this statistic, the Genetics Working Group set a 20 percent increment for appropriate referrals per disease site (primarily breast and colon) as the highest target goal. Thus, if a community cancer center were to refer 10 percent of its breast cancer patients appropriate for genetic counseling, this site would have reached 50 percent of the target goal (Level 3). A site that referred 20 percent of its appropriate breast cancer patients would have reached 100 percent of the target goal (Level 5).

The patient identification component may be used for any type of cancer for which a significant proportion of the cancer results from hereditary or familial causes. Flexibility is built into the component such that programs can choose to assess a patient population of interest or in greatest need of improvement. Additionally, there is no set time frame for analyzing the "patient identification" component. For example, if a program identifies a paucity of referrals for breast cancer and decides to implement an improvement plan over a one-year time frame, it can track the number of referrals for breast cancer using the patient identification component on a monthly basis for that year.

In addition, this component may also be used to track referrals for unaffected individuals. For example, if a program identifies a dearth of referrals for a family history of breast cancer and decides to improve on this over a one-year time frame, the program may assess the percentage of individuals seen for screening mammography that are referred for genetic counseling services using the patient identification component on a monthly basis over the course of that year. Such analysis will aid a program in determining if intervention strategies for improving patient identification and referrals are effective.

Component 2: Physician Referrals

This component quantitatively assesses what percentage of genetic counseling referrals come from a given type of healthcare provider. The percentage is analyzed by summing the number of referrals received from one type of physician specialty, such as medical oncology, and dividing this number by the total number of referrals received for genetic counseling. The physician referrals component uses a tiered system:

- Tier one: physicians who refer the most often for cancer genetic counseling services
- Tier two: physicians who refer often or occasionally
- Tier three: physicians who rarely refer.

For example, if 100 referrals are received for genetic counseling

and 75 of the referrals are made by oncologists, 20 referrals from primary care physicians, and 5 referrals from other healthcare specialties, this would correspond to Level 3 on the CGCAT.

The NCCCP Genetics Working Group determined the percentage for each tier by using the collective performance of the NCCCP sites as a reasonable standard. This tiered system allows programs to identify the most common referral source provider type and the provider that refers less frequently. This data allows programs to focus the target of their marketing efforts.

Over time, the Genetics Working Group amended the physician referrals component of the CGCAT. The 2009 CGCAT version defined the provider types for physician referrals as front line "cancer" clinicians (i.e., medical oncologists, radiation oncologists, and surgical oncologists), primary care clinicians, and specialists. Use of the CGCAT before 2011 revealed a greater diversity of front line referring providers at NCCCP cancer genetic counseling sites than previously thought. For example, one NCCCP site reported that dermatologists were a primary type of referring physician. To make the CGCAT more robust, the definition for "physician referrals" was revised in 2011 to remove specific provider types. Additionally, the 2011 revision added two more rating levels, the 2009 CGCAT had allotted only three levels by which sites could score their performance. The inclusion of five levels allows programs to more closely monitor their progress.

Component 3: Services Provided

This component assesses the diversity of the indications for which patients are referred for a genetic counseling consultation. Reasons for referral for genetic counseling are varied, but often include:[10]

- Cancer diagnosed at an unusually young age (e.g., breast or colon cancer before age 50).
- Multiple close family members with either the same type of cancer or related cancers (e.g., breast and ovarian cancer; colon and uterine cancer).
- Two or more primary cancer diagnoses in the same individual (e.g., breast cancer in both breasts, ovarian and breast cancer, colon and uterine cancer).
- Certain rare cancers or tumors (e.g., medullary thyroid cancer, male breast cancer, adrenocortical carcinoma, pheochromocytoma).
- Other features associated with a hereditary cancer syndrome (e.g., multiple colon polyps).

This component is analyzed by summing the number of referrals received for a particular indication, such as breast cancer, and dividing this number by the total number of referrals received for genetic counseling. For example, if 100 referrals are received for genetic counseling and 60 of the referrals are for a personal and/or family history of breast cancer, 30 referrals are for colon cancer, and 10 referrals are for other types of cancer this would correspond to a Level 5 on the CGCAT.

The services provided component allows programs to identify which type of cancer is the primary indication for referral. As with physician referrals, the percentage for each tier was based on what the Genetics Working Group believed was a reasonable standard, using the collective performance of the NCCCP sites with existing genetic counseling services as a guide. This component allows programs to identify if there are certain disease sites for which referrals are rarely made so that strategies may be implemented to improve these referrals.

Component 4: Pre-Test Counseling

This component assesses information from a patient's personal and family history, as well as the information that is provided to a patient. The following four elements are a critical part of quality genetic counseling:[2,3,5]

1. Ascertainment and documentation of a three to four generation family pedigree.
2. Evaluation of the personal and family history for the purpose of determining what, if any, genetic testing is appropriate.
3. Calculation of risk assessment via computer-based risk assessment models (as appropriate).
4. For patients pursuing genetic testing, discussion of all elements of ASCO-informed consent.[5]

Component 5: Post-Test Counseling

This component assesses the information provided to a patient after the initial risk assessment and evaluation of the genetic counseling session. The following six elements are essential to quality genetic counseling:[2,3,5]

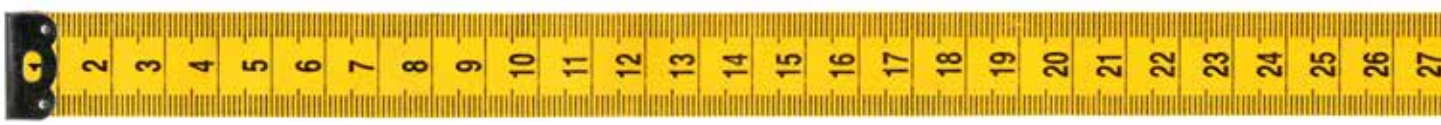
1. Cancer risk estimation based on genetic test result (if applicable) or empiric data.
2. Recommendations for cancer screening and prevention.
3. Discussion of risk-reduction surgeries, if appropriate.
4. Provision of educational resources and referrals, as needed.
5. Disclosure and interpretation of genetic test results within the context of personal and family history (if applicable).
6. Discussion of additional genetic testing options (if applicable).

Component 6: Documentation of the Cancer Genetics Consult in the Patient's Medical Record

The Genetics Working Group identified the following elements as essential components for documentation within a patient's medical record:[5]

- Personal history
- Family history

(continued on page 39)



Cancer Genetic Counseling Assessment Tool

COMPONENTS	ELEMENTS/DEFINITION	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Patient Identification	Potential patient numbers based on 20% of applicable yearly analytic cases having hereditary and/or familial predisposition for: • Breast, breast/ovarian • Colon, colon/uterine • Other ▲ Genodermatoses ▲ Thyroid ▲ Renal/neuroendocrine ▲ Pediatric	0–20% of appropriate patients identified	21–40% of appropriate patients identified	41–60% of appropriate patients identified	61–80% of appropriate patients identified	81–100% of appropriate patients identified
Physician Referrals	Subtypes of clinicians: • Tier one top referring physician subtype (e.g., medical oncology)—always to often refers • Tier two—refers occasionally to often • Tier three—rare to few referrals	Majority (>90%) of referrals from tier one	85% tier one 15% tier two	75% tier one 20% tier two 5% tier three	70% tier one 25% tier two 5% tier three	60% tier one 30% tier two 10% tier three
Services Provided	Cancer Genetics Service Lines: • Breast, breast/ovarian • Colon, colon/uterine • Other ▲ Genodermatoses ▲ Thyroid ▲ Renal/neuroendocrine ▲ Pediatric	Majority (>90%) of cancer genetics consultations occur for one service line	85% for one service line with at least 15% occurring for a second service line	75% for one service line with at least 20% occurring for a second service line and 5% from a third service line	70% for one service line with at least 25% occurring for a second service line and 5% from a third service line	60% for one service line with at least 30% occurring for a second service line and 10% from third service line
Pre-Test Counseling	• 3-4 generation pedigree • Evaluation of the personal and family history to determine what, if any, genetic testing is appropriate • Run risk-assessment models as appropriate • Provide all elements for ASCO informed consent	0–1 components of pre-test counseling provided	2 components of pre-test counseling provided and/or components provided episodically	3 components of pre-test counseling provided routinely	All components of pre-test counseling routinely provided	Level 4 plus utilization of computer applications for pedigree drawing risk calculation
Post-Test Counseling	• Genetic test results disclosure and interpretation in the context of the personal and family history • Cancer risk estimates based on genetic test results or empiric data • Recommendations for cancer screening and prevention • Discuss risk-reduction surgeries, if appropriate • Educational resources and referrals given as needed • Discuss additional genetic testing options	0–1 components of post-test counseling provided	2–3 components of post-test counseling provided and/or components provided episodically	4–5 components of post-test counseling provided routinely	All components of pre-test counseling routinely provided with utilization of computer applications for risk calculation when available	Level 4 plus at least one of the following: • Patient is referred to long term follow-up program • Research options are reviewed • Resources are provided to assist without dissemination of information to family members

Cancer Genetic Counseling Assessment Tool (cont.)

COMPONENTS	ELEMENTS/DEFINITION	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Documentation of the Cancer Genetics Consult in the Patient's Medical Record	• Personal history • Family history • Initial impression • Genetic testing recommendations • Test result • Result interpretation • Cancer risk estimates • Summary management recommendations	Limited to no documentation in the patient's medical record	N/A	Applicable elements documented in the patient's medical record	N/A	Level 3 plus copies distributed to the patient and his/her physicians
Financial		No billing occurs for pre- or post-test counseling sessions	N/A	Billing for pre- and post-test counseling session is episodic (e.g., only when MD is present)	N/A	Global billing for pre- and post-test counseling session

- Initial impression
- Genetic testing recommendations
- Test result(s)
- Result interpretation
- Cancer-risk estimates
- Summary of the medical management recommendations.

Both for the initial, as well as the revised version of the CGCAT, the NCCCP Genetics Working Group defined only three levels of assessment.

Note: this component does not specify whether documentation occurs in a hand-written chart or an electronic medical record. A genetic counseling program's ability to document services in an electronic medical record depends, in large part, on the ability of clerical support staff and technical support, as well as rules and regulations stipulated by state laws to protect against genetic discrimination. The Genetics Working Group felt that it was critical not to impose requirements such as documentation within a medical record so that a program's ability to score at a high level was not impacted by factors that are often not within the scope of control of a genetic counselor.

Programs should also be aware of any privacy laws on protection of genetic information and the ability to protect information in electronic medical records as some systems may not be HIPPA compliant.

Component 7: Financial

Billing for genetic counseling services is essential to a program's financial solvency. Historically, genetic counseling services have been poorly reimbursed; although there are various ways to bill for services, most have become outdated with the changes in healthcare billing policy. Reimbursement challenges may restrict the potential growth of an oncology genetic counseling program. The Genetics Working Group included the financial component in the CGCAT in order to encourage NCCCP sites to work toward billing for services to promote the sustainability of genetic counseling programs. The financial component qualitatively measures the frequency with which billing occurs for genetic counseling services on three levels (Level 1, Level 3, and Level 5).

Genetic counselors can bill using Current Procedural Terminology® (CPT) Evaluation and Management (E&M) codes 99201-99205 or 99241-99245 linked to a physician within the hospital or use CPT code 96040 for "Medical Genetics and Genetic Counseling Services." However, a 2010 survey of genetic counselors revealed that only one-third of cancer genetic counselors reported billing under the 96040 code.[11] Of the 24 respondents who participated in the survey for CPT code 96040, five (8 percent) said their facility received 10 to 30 percent of the amount they billed, ten (16 percent) received 31 to 50 percent, six (9 percent) received 51 to 70 percent, and three (5 percent) received 71 percent or more.[11] Clearly billing and reimbursement continue to be areas in need of improvement for genetic services and should be included for future assessments.

CGCAT Case Study

One NCCCP site identified a disparity in cancer genetic counseling and risk assessment in the minority population for an area that encompasses a large proportion of Hispanics and African Americans. The NCCCP site used the CGCAT to assess the healthcare system, and the initial score was Level 1 across the majority of components. It became clear that the genetics services were being underutilized. Education was needed, as well as tools to identify and refer patients.

These findings led the NCCCP site to create a pocket guide, key indicators for referral, and fax referral forms that were provided to the physician offices.

After disseminating the education materials, the NCCCP site saw an increase in the number of referrals. However, there was a high rate of patient no-shows to the appointments.

Additional research into the high rate of no-shows revealed transportation challenges, lack of health insurance, and language as the major barriers to attendance for genetic counseling. The NCCCP site partnered with the state's federally-qualified healthcare centers (FQHC) to bring genetic counseling services to the patients and the targeted community.

In addition, the NCCCP site developed a cancer questionnaire in English and Spanish and made it available to patients to help identify if they might be at increased risk for a hereditary cancer syndrome. Genetic counselors reviewed the questionnaire and contacted patients who met the referral criteria.

The NCCCP site used the CGCAT to re-assess progress monthly. Over the two-year project, the site's CGCAT scores went from Level 1 to Level 4. Referrals increased from a total of 12 annually to 9 referrals per month in the second year. This exceeded the site's goal of 8 new referrals a month for year two. The NCCCP site saw the biggest increase in the number of referrals in the second half of year two, which had an average of 14 new referrals per month. This data is primarily attributed to addressing transportation barriers and bringing the service to the FQHCs, which are in walking distance of the residents.

The cancer questionnaire allowed the NCCCP site to identify families with a variety of cancer diagnoses. Developing education for healthcare providers, fax referral forms, and the pocket guide also helped to identify patients and increase physician referrals.

Discussion & Future Implications

Community cancer centers can use the CGCAT to focus on specific core elements and develop targeted quality improvement strategies. They may also want to establish their own time frames for when to re-assess their programs with the CGCAT to help with needs assessment, goal setting, and improvement planning.

Community cancer centers should not expect to score a Level 5 in all core elements; the objective is to use the CGCAT to determine performance improvement targets and strategies to reach the level that is most realistic for each individual organization.

For NCCCP sites, use of the tool enabled progress and promoted creative strategies for quality improvement in cancer genetics programs. Some NCCCP sites are working with survivorship teams and nurse navigators to attend community events. Other sites are instituting telegenetics, chart reviews, or a tracking system.

Additionally, by using the CGCAT, the NCCCP sites were well positioned for compliance with the 2012 American College of Surgeons Commission on Cancer (CoC) Risk Assessment and Genetic Counseling Standard, which was only a draft at the time of the tool's design.[12] The CGCAT specifically addresses key competencies for a genetic counseling program as outlined by CoC, such as the need for identification of patients with indications for hereditary cancer conditions. By using the CGCAT for analysis of cancer genetic counseling services, NCCCP sites are not only able to monitor the performance of their genetic counseling services but are able to determine whether those services are in compliance with CoC standards.

Genetic counseling services for oncology play an integral role in identifying patients at high risk for developing cancer and additional primary cancer. Such identification may lead to appropriate cancer surveillance and early intervention, thereby helping individuals to prevent and/or detect cancer at earlier stages when treatment will be most effective. A comprehensive metric tool is essential to providing the necessary genetic counseling services for a site's at-risk oncology patient population. NCCCP sites designed the CGCAT to address the gap in quantifiable metrics for evaluating a cancer genetics

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program. While the CGCAT has yet to be validated, NCCCP sites have used it extensively for self-assessment and program planning. The CGCAT is the first of its kind and provides community cancer centers with a tool for assessing specific cancer genetics programs.

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ABOUT NCCCP

The National Cancer Institute Community Cancer Centers Program is a network of community hospital-based centers collaborating to improve quality, enhance access to cancer care, and expand cancer research. Launched in 2007 as a pilot program with 16 community hospitals and expanded in 2010 with the addition of 14 more hospitals, the program currently has 21 participating community hospitals. One of the NCCCP's goals is to bring services typically only provided by large academic centers to the community setting. Genetic counseling is one such service and over the past six years the NCCCP community cancer centers have worked toward establishing or enhancing infrastructures for genetic and molecular testing services either onsite or through referrals. Program deliverables which focus on enhancing or improving genetic counseling services have been in place since the inception of the program and remain in place today.