



# Process Evaluation of **Community-based Cancer Risk Assessment Programs**

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Cancer risk assessment and counseling are services now routinely provided by community cancer centers. These services involve the evaluation of personal, medical, and genetic information to determine individuals' risk for cancer and develop strategies for risk reduction. Several professional organizations, such as the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN), have published guidelines for providing cancer risk counseling, education, genetic testing, and clinical pathways for managing high-risk patients or gene mutation carriers.<sup>1,2,3</sup> However, little literature exists on how to evaluate cancer risk assessment and counseling programs for the rigor of staff training, confidentiality, informed consent, and clinical outcomes. While a survey of 30 NCI-designated cancer centers showed that institutional review boards (IRBs) provided oversight and review for genetic testing protocols, half of the respondents had no well-defined policies to guide IRB reviews of genetic testing protocols and only three institutions had IRB members with sufficient genetic background to assess the appropriateness of genetic protocols.<sup>4</sup>

## **ABOUT OUR PROGRAM**

Fox Chase Cancer Center (FCCC) in Philadelphia, Pa., an NCI-designated Comprehensive Cancer Center, has conducted cancer risk assessment and research since 1991 through its Family Risk Assessment Program (FRAP). FRAP provides education and counseling to women at risk for breast and ovarian cancer based on their family history. Using FRAP as a template, FCCC has developed additional risk assessment programs for prostate cancer (PRAP), gastrointestinal cancer (GI-TRAP), and melanoma (MEL-FRAP).

In addition to providing participants with education, risk counseling, and screening and prevention options, the risk assessment programs serve as a research base for ongoing studies of the biological, genetic, and environmental factors that influence disease risk. Within the risk assessment programs, behavioral and risk counseling interventions are developed and utilized.

In 1994 FCCC began implementing risk assessment programs in community hospitals participating in Fox Chase Network (FCN). Fox Chase Network, a subsidiary corporation of Fox Chase Cancer Center, is an affiliation of 15 community-based hospital systems with a total of 30 hospitals established to develop or enhance community-based oncology programs. Currently, nine FCN hospital sites offer one or more of the risk assessment programs. To date nearly 6,000 individuals have received risk assessment and counseling through these risk assessment programs.

## **EVALUATING FCN'S COMMUNITY-BASED RISK ASSESSMENT PROGRAMS**

As the number of FCN institutions implementing risk assessment programs has increased over the last several years, it became apparent that a standardized mechanism for evaluation was needed. Process evaluation (i.e., an evaluation designed to determine whether a program is delivered as intended to the targeted recipients and to address questions related to how well the program is functioning<sup>5</sup>) was used to assess fidelity and effectiveness of the risk assessment programs at FCN sites. Using this framework, criteria were developed to delineate the program functions and responsibilities of the risk assessment programs at each FCN site. Outlined in the Standard Agreement of Participation (the "Standards"), these criteria form the blueprint for programmatic operations and



A family risk assessment education session at Fox Chase Cancer Center.

evaluation of all risk assessment programs at all FCN sites. These criteria include staffing requirements; staff cancer genetics training; program functions such as marketing; medical management; coordinator responsibilities; and quality assurance. Quality assurance includes, but is not limited to, IRB certifications of staff, documentation of participant education and risk counseling, storage of files, FCN site nurse coordinator attendance at quarterly in-service programs, and chart review.

Using the Standards as a guide, FCN designed an audit tool for the risk assessment programs at the individual FCN sites. The audit tool identifies six major areas of operational effectiveness, each with numerous performance indicators:

- *Staff competency* ascertains staff training and ongoing mechanisms for education and feedback on cancer genetics skills and practice.
- *Contractual agreements* establish the presence of a written agreement between FCCC and the FCN site outlining oversight by an onsite physician.
- *Documentation* assesses the completeness and quality of patient records per the documentation criteria. At each site, five participant charts per risk assessment program were randomly selected for auditing.
- *Regulatory issues* appraise IRB files for staff certification, documentation, and appropriate amendments to protocols and consents; the confidential storage of records; and compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the informed consent process.
- *Marketing efforts* review all materials for appropriate and timely IRB approval.
- *Outcome indicators* compare accrual reports of patient education and counseling, and number undergoing genetic testing at the sites against FCCC accrual numbers.

Over a 16-month period, all nine participating FCN hospitals with active risk assessment programs participated in an onsite audit performed by two FCCC/FCN project managers. Using the audit tool, the six areas of operational effectiveness and program components were documented for compliance. Following the audit, the project managers developed a formal report of strengths and deficiencies for each site.

## RISK ASSESSMENT PROGRAM AUDIT RESULTS

Overall, the nine hospitals were compliant in three domains of operations: staff competency, regulatory issues, and contractual agreement. Deficiencies in the domains of marketing, documentation, and outcome indicators were more common. Details of specific criteria for the domains of staff competency, documentation, and regulatory issues are shown in Table 1 (page 35). Items in staff competency and regulatory areas are reported in terms of institutions, with the exception of obtaining informed consent (regulatory), which is reported as number of charts. Items in documentation are reported for the total number of charts reviewed for all hospitals combined.

■ *Staff competency.* The American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) have issued position statements on Cancer Risk Assessment and Counseling.<sup>1,3</sup> These statements support basic and ongoing continuing education in cancer genetics. ASCO's position statement states that "oncologists and other health care providers in varying systems of health care delivery around the world require specialized education in molecular genetics, pedigree construction and interpretation, quantitative cancer risk assessment, and cancer risk management as well as in the psychological, ethical, and legal complexities of genetic testing."<sup>1</sup> However, guidelines for meeting this specialized education requirement remained vague.

FCCC sought to identify the baseline staff competency and required documentation of the type and amount of cancer genetic education. Although not required in the first year of the audit, acceptable education included ASCO's annual conference sessions in cancer genetics; ASCO's Cancer Genetics and Cancer Predisposition Testing tutorial<sup>6</sup>; the American Medical Association's continuing education publications for breast and ovarian cancer and hereditary colorectal cancer syndromes<sup>7,8</sup>; a preceptorship at FCCC; or other validated continuing education programs.

Eleven principal investigators (PIs) were designated to oversee the risk assessment programs at the nine sites. As noted in Table 1, most PIs had some form of education in cancer genetics as required by the Standards. Five PIs met educational requirements through web-based self-study programs, seven attended an FCCC preceptorship in Genetic Education, and three used a combination of self-study and FCCC preceptorship. Two PIs did not have documentation of training in cancer genetics.

All nine institutions had a nurse coordinator trained in familial cancer risk assessment and counseling with the majority having attended a basic genetics course at

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FCCC. Eight of nine nurse coordinators had attended the FCCC Advanced Training for Nurses in Genetics and Risk Counseling course. The healthcare professional involved in cancer genetics at the FCN sites is responsible for keeping abreast of new knowledge related to the field in order to best serve the patients. FCCC requires that nurse coordinators from the FCN sites participate in quarterly educational meetings at FCCC and during this audit four of nine nurse coordinators attended FCCC quarterly programs on a regular basis.

■ **Contractual Agreement for Program Oversight.** As part of the contractual agreement with Fox Chase Network, sites are required to have a physician responsible for directing each of the risk assessment programs at their institution. The physician's responsibility includes supervision of the risk assessment program nurse coordinator and the FCCC genetic counselor assigned to provide counseling services at that site, and supervision of pedigree review and medical management issues for program participants. Eight of nine institutions had contractual agreements for physician oversight in place at the time of the audit.

■ **Documentation.** The Standards require documentation of the cancer risk assessment process. Documentation styles varied among institutions and included the use of checklists, progress notes, and formal reports. Those sites that used multiple methods of documentation demonstrated the cancer risk assessment process more thoroughly compared to those using the checklist method. For example, all expanded pedigrees (i.e., family history information collected on three generations) are required to be reviewed at a formal pedigree review meeting at FCCC. The formal pedigree review process is an opportunity to discuss the pattern of cancer in the family and recommend a course of medical management, such as increased frequency of screening, with the site coordinator and physician. Although nearly all charts had an expanded, three-generation pedigree for each participant, the review process for many of them was either incomplete or not thoroughly documented. The FCCC genetic counselor and FCCC risk assessment program physician were available for consultation especially for pedigrees with extensive family history of cancer; however, many sites did not document the use of these resources for such consultations.

■ **Regulatory Issues.** Eight of nine sites were in compliance with the regulatory criteria shown in Table 1; one site failed to store participant charts in a secured location. One area identified for improvement was the timely distribu-

tion of protocol addenda and amendments from the parent institution (FCCC) to the FCN sites. In order to comply with Food and Drug Administration regulations, FCN sites are required to submit all addenda and amendments to their IRB upon receiving them from FCCC. All FCN sites were found to be in HIPAA compliance in a manner congruent with National Institutes of Health Guidelines.

■ **Marketing.** All marketing materials were required to be submitted to the respective site's IRB for approval before utilization. Seven sites had IRB-approved marketing materials.

■ **Outcomes.** FCN sites send monthly statistics to FCCC. These statistics document recruitment, accrual, and other program indicators, such as community outreach efforts; provide an understanding of program status; and develop and allow for increased support from FCCC. Submission of monthly reports and the congruency of statistics varied between sites according to the length of time the RAP was open to accrual. Newer programs working from the Standards established in 2000 were found to be more compliant and accurate in this area.

## LESSONS LEARNED

The first year of the audit process was used as an educational exercise for both FCCC and its FCN risk assessment program sites. Using the process evaluation framework, an auditing procedure was developed to assess quality assurance information about the FCN risk assessment program sites. (FCCC's Risk Assessment Program Audit Tool is available online at [www.accc-cancer.org/publications/audittool.pdf](http://www.accc-cancer.org/publications/audittool.pdf)).

From the results of the audits and formal reports, we found that several sites had implemented the risk assessment programs as intended and were operating up to the established standards. We were also able to identify the types of program deficiencies and found they were a result of implementation failure (i.e., the intended services were not provided so the expected benefits could not have occurred) and not theory failure (i.e., the program was implemented as intended but failed to produce expected effects).

A comprehensive report describing overall findings and necessary remediation for each risk assessment program at each site was an essential part of the evaluation process. These reports were distributed for review to both the FCCC and FCN principal investigators, the FCCC genetic counselor and risk assessment program project manager, the FCN risk assessment program site nurse coordinator and oncology program manager, and appropriate staff and administration within the FCCC-FCN

**Table 1: Combined Scores of Specific Criteria for the Risk Assessment Programs for Families (FRAP), Prostate Cancer (PRAP), and Gastrointestinal Cancer (GI-TRAP)**

<b>Selected Domains</b>	<b>FRAP Score*</b>	<b>PRAP Score*</b>	<b>GI-TRAP Score*</b>
<b>Staff Competencies</b>			
Supervising physician	8/8	3/3	3/3
Physician education in cancer genetics	6/8	3/3	3/3
Nurse education in cancer genetics	8/8	3/3	3/3
<b>Documentation</b>			
Screening/medical history	26/34	13/13	9/10
Expanded pedigree (3 generation history)	33/34	11/13	9/10
Risk estimate for cancer	25/34	6/13	10/10
Genetic counseling prior to genetic testing	11/18	N/A	7/10
Documentation of physician recommendations	12/14	9/13	6/8
Follow-up plan for those receiving genetic testing	12/16	N/A	5/8
<b>Regulatory Issues</b>			
All staff IRB certified	8/8	3/3	3/3
All files kept in confidential and secure manner	8/8	2/3	3/3
Informed consent has been obtained and filed in chart	33/34	13/13	3/3
HIPAA compliance	8/8	3/3	3/3

\*Number of institutions evaluated for each program. FRAP: N=8; PRAP: N=8; GI-TRAP: N=3

subsidiary. Several risk assessment program sites went one step further and responded to their audit report by developing short- and long-term action plans to correct deficiencies. For example, physicians who did not meet educational requirements for cancer genetics were advised that further education and training within the next six months was required in order to meet FCCC standards and participate in the risk assessment program. The provision of a full-time nurse coordinator dedicated to the RAPs was a key element of one site's long-term action plan. The audit results and accrual statistics clearly showed that the most successful FCN RAPs had a full-time nurse coordinator responsible for all aspects of the risk assessment program's daily functions.

As the results indicate, the majority of RAP staff at the FCN sites met the staff competency requirements and had contractual agreements for oversight in place and all sites were diligent in their regulatory indicators. An important issue that resulted from the documentation indicators was the need for more specific requirements in the Standards for how and where to document the risk assessment process. Specifically, the Standards need to address how and where to document contact with the participant, consultations with FCCC staff regarding the pedigree or medical recommendations, and the informed consent process.

The provision of adequate information is essential for individuals to give informed consent to participate in programs that gather and evaluate genetic information that

can have broad implications with respect to screening, disease susceptibility, and medical management. Informed consent has been referred to as the foundation of the genetic testing process.<sup>9</sup> During the informed consent process for genetic testing, the following points should be addressed: the benefits and risks of genetic testing, management and treatment options, and the type of answers obtained from genetic testing.<sup>9</sup> Although not all the risk assessment programs use genetic testing, each can benefit from more specific guidelines on documenting the informed consent process and participant understanding.

The FCCC-FCN risk assessment programs have evolved over the last 10 to 12 years, as have the expectations for statistical data collection. Outcome indicators for education and counseling were interpreted differently at several sites and therefore documentation in monthly reports did not match FCCC data on accrual to programs. Obtaining accurate information related to program growth is essential in order to provide necessary support and guidance to the principal investigator and nurse coordinator at the FCN site. Therefore, statistical reporting has been revised to a universal, one-page monthly report to capture all areas of recruitment, education, counseling, marketing and any remediation issues found during the audit. These reports allow staff to monitor program growth in shorter time increments and to identify and resolve program issues at an earlier stage.

The audits of community hospitals offering risk assessment programs show the need for well-defined cri-

Each risk assessment program has a **procedural manual**

**that is regularly updated** to keep all FCN programs

*in compliance with protocol and regulatory changes.*


teria or guidelines to implement programs and to serve as a mechanism for oversight. In this report, a parent institution (FCCC) provided the criteria for implementation and oversight. Many hospitals establishing RAPs rely on internal mechanisms, such as local IRBs or specialized task forces to evaluate programs.

As a result of the audit process, FCCC has developed tools to facilitate program procedures and processes. Each risk assessment program has a procedural manual that is regularly updated to keep all FCN programs in compliance with protocol and regulatory changes. FCCC has also provided tools for program development, comprehensive documentation, and statistical reporting. Template charts that include all major components of documentation with sample forms have been provided. A universal intake form for the risk assessment programs has been developed, and we are now focusing efforts on a web-based documentation and reporting process. Recommendations were made to the FCN risk assessment program sites to use the audit tool for periodic internal review of their program. For instance, monitoring performance data on a continuous basis, including monthly reports and yearly audits, provides a way for FCCC program managers to ensure that operations are conducted appropriately and efficiently. The end result is that FCCC program managers can properly administer the risk assessment program. The audit process also provides a tool for documenting the operational effectiveness, justifying ways in which staff are deployed, requesting further support, and defending the program's performance. Reporting performance information makes the program accountable and provides evidence of what was actually accomplished.

### **AUDIT PROCESS: YEAR TWO**

The second year of the audit process will reinforce program strengths, support compliance for the Standards of Participation, and implement a structured remediation plan for deficiencies. The Standards will serve as criteria to maintain active risk assessment programs. In addition to the Standards, an annual accrual goal will be established requiring 10 participants per year/per risk assessment program. Deficiencies noted in the second audit will be addressed in an Action Plan to be completed by the FCN risk assessment program site within 30 days after the audit. FCN risk assessment program sites will document and report monthly on Action Plan outcomes, progress and barriers.

The work described here demonstrates that community-based hospitals, with the support of education and quality control measures, can successfully provide cancer genetic risk assessment and counseling in the community setting. Community-based hospitals are critical to expand-

ing cancer control activities to a wide range of populations. These efforts are contributing to further identify individuals and families at risk for cancer and to optimize chemoprevention, surveillance, and risk-reduction strategies that will decrease cancer morbidity and mortality. 

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### **ACKNOWLEDGEMENT**

Authors would like to thank institutions that participated in this audit process: Community Medical Center, Toms River, N.J.; Delaware County Memorial Hospital, Drexel Hill, Pa.; Hunterdon Medical Center, Flemington, N.J.; Jennersville Regional Hospital, West Grove, Pa.; Paoli Hospital, Paoli, Pa.; Pinnacle Health System, Harrisburg, Pa.; The Reading Hospital and Medical Center, Reading, Pa.; Riverview Medical Center, Red Bank, N.J.; Fox Chase Virtua Health Cancer Program, Voorhees, N.J.

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