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Program Development in a Community Setting

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Two surveys highlight the components and complexities of community-based cancer risk assessment and genetic testing.

In 1985 the California Cancer Medical Center, with our involvement, initiated a genetic counseling program and risk assessment evaluations for our community oncology center. This effort pre-dated the ability to test for most individual gene mutations; however, with the knowledge that most syndromes are autosomal dominant with reduced penetrance, our geneticist was able to identify high-risk families and quantify risk. Here we share our experiences in the development of community-based risk assessment and gene testing programs. In addition, we report information obtained through in-depth interviews of twelve genetic counselors in similar programs at other cancer centers.

Historically, our experience began with identifying high-risk families and quantifying risk when there was a clinical need to provide genetic counseling to patients in families with hereditary colon cancer syndromes and hereditary breast cancer syndromes. Lacking a clinical resource for the specialized genetic counseling and risk assessment in the greater Los Angeles geographic area, we teamed a medical oncologist with a board-certified genetic counselor completing a doctorate in human genetics at the University of California at Los Angeles. Our initial community-based risk assessment program was developed as a result of this partnership. The risk assessment program was performed in the clinical practice offices of the oncologist, with data forms and questionnaires developed by both the oncologist and the genetics counselor. In addition, the team relied on the coordinated resources of the Los Angeles Oncologic Institute within St. Vincent's Medical Center, a community tertiary care institution. The Los Angeles Oncologic Institute was funded as a CHOP (Community Hospital Oncology Program) and later as a CCOP.

Gene testing was initially established at the California Cancer Medical Center as a research investigation. The goals have been to establish the frequency of inherited familial risk syndromes in community-based cancer patients residing in the southern California region and to assess the viability and appropriateness of such a program in a community practice. Patients who agreed to genetic testing signed voluntary informed consent documents, which had been approved (in addition to the research protocol) by the investigational review board at St. Vincent's Medical Center. The results of risk assessment, gene testing, and recommendations were kept in the patient's research file to help ensure confidentiality. As our risk assessment program used multiple sites, the genetic counselor maintained the genetics files, and they did not become part of the clinical record.

More recently, staff at a mammography unit in West Los Angeles had become interested in performing risk assessment and gene testing. Patients at that institution were allowed to participate in our study; the genetic counseling and gene testing were performed at the mammography unit for the convenience of patients from that practice. Additionally, clinical sites at other physicians' offices were added later.

Financing of the risk assessment by the patient on a private basis without insurance reimbursement was encouraged, because reimbursement patterns had been poor. Also, there was, and continues to be, inconclusive evidence of protection of these records from discovery and review by insurers and employers. Insurance or employment discrimination is still possible, although legislation, both state and federal, is developing to protect people who elect to undergo genetic testing. The Americans with Disabilities Act (ADA) has been applied to patients with cancer, and by extension to people with inherited mutations in cancer susceptibility genes, helping to assure against loss of employment due to illness or predisposition. Medical insurance is also becoming protected at the federal level through such vehicles as the Health Insurance Portability and

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Accountability Act of 1996. Some states have similar legislation to help safeguard medical insurance. However, as of this writing, no current legislation guarantees continuation of health insurance long term, and there are no provisions to safeguard life or disability insurance if a gene abnormality is identified. Even if insurance is continued, the premiums on such policies are not guaranteed to remain low. At particular disadvantage are those individuals who do not have adequate health, life, or disability insurance, and then find they are at increased risk for cancer. Nonetheless, some patients with cancer elected to have the genetic counseling session and, in some cases, even chose to submit claims for gene testing to health insurers for reimbursement.

WHY SOME REFUSE TESTING

To evaluate the barriers in the utilization of risk assessment and genetic counseling, we performed an evaluation of a patient cohort and unaffected relatives eligible for cancer risk assessment based on significant family history, but who did not participate in risk assessment. For most respondents, the costs of testing, the possibility of canceled insurance and discrimination, and perceived lack of preventive and prophylactic options ranked highly among the list of concerns. Many patients and family members without cancer had concerns about the accuracy of genetic testing. Forty-three percent selected accuracy of results as an actual barrier to risk assessment. Results are included in Tables 1 and 2.

These results indicate that the most important issues in accepting cancer risk assessment are trust in the accuracy of results, costs, and insurance coverage. Centers developing cancer risk assessment programs must address these issues, through increased research funding, testing at little or no cost, and family/group acceptance of the financial burden. Genetic testing standards currently under development by the National Institutes of Health should address concerns about the accuracy of testing results.

A SURVEY OF PROGRAMS

To compare our experience with other programs in existence in 1998, a pilot survey was conducted of a sample of cancer risk assessment programs across the country. Twelve genetic counselors responded. Follow-up information was obtained via direct interviews with the counselors. Our data reveal that the typical genetic risk assessment programs experience about 200 inquiries about the service from clients per year. Depending on the program, 5 to 35 percent of those callers actually schedule an appointment. Of clients seen, only 2 to 7 percent are actually tested for a genetic mutation.

As a result of our study, we found that most start-up to full-time programs provide detailed cancer risk assessment information and counseling to forty-five to sixty people each year. Most of these programs employ a full-time counselor specializing in cancer risk assessment to perform the services listed in Table 3. He or she must also keep up to date on all literature and research findings, provide follow-up to patients, maintain records, supply information to phone queries from potential clients, make presentations to community and professional groups, and often many other duties involved in advertising and maintaining a program and servicing clients. Many of these activities are necessary, but not billable.

Cancer risk assessment programs vary in selectivity for accepting referrals. Some centers will counsel all those who inquire, but offer testing only to those with high family risk. Others screen callers and limit counseling to those with potentially inherited syndromes. In programs that counsel all who inquire, a low percentage are at high enough risk to warrant gene testing. In programs that limit counseling to those at apparent high risk (as in our program), a greater percentage are then likely to carry a mutation and thus consider gene testing. However, many of those offered genetic testing decline.

One program reported providing free counseling; still only approximately 35 percent follow through with an appointment. Of those who make an appointment, less than half have had probable cancer family syndromes and only one had consented to genetic testing. In our experience, the counseling appointment is often delayed, but the decision about testing is usually immediate, perhaps because there is so much precounseling and information given over the phone by the genetic counselor. Thus, in our program only those who both desire testing

and are likely to be eligible follow through with counseling. While some centers will test anyone after extensive counseling, most of our patients take advantage of the free testing offered as part of research studies. However, to be eligible, they must be reasonably likely to harbor a mutation.

Based on this pilot study, a questionnaire has been designed and disseminated via the Familial Cancer Risk Assessment SIG of the National Society of Genetic Counselors. Results of this follow-up study have yet to be analyzed.

STANDARDS FOR QUALITY PROGRAMS

The quality of risk assessment programs varies with the personnel, budget, and logistics of each center. However, through our study we have identified several parameters to be followed in determining the quality of any program, existing or planned.

Participation of a trained geneticist or genetic counselor. Such a person should be capable of collecting and interpreting complex family history data, in addition to communicating complex information and providing counseling for patients and their families. He or she must understand when empiric risk tables may be appropriate and when a genetic evaluation should be undertaken. This position should be responsible for:

- collecting the most recent information on surveillance, chemoprevention, prophylactic surgery, and prevention
- knowledge of the latest available genetic tests, their availability at both research and commercial laboratories and how their techniques may differ. (In addition, counselors

Table 1. Reasons for Refusing an Appointment for Cancer Risk Assessment

Variables/General Concerns	Very Important	Somewhat Important	Not Very Important	Not Important
Concern for accuracy of results	32%	28%	17%	23%
Cost of testing	46%	22%	8%	24%
Insurance concerns	56%	12%	4%	28%
Fear of job loss	21%	4%	15%	60%
No perceived benefit	19%	23%	19%	38%
Concern for loss of privacy	28%	24%	4%	45%
Fear of result	18%	14%	14%	53%
Concern for current health	19%	10%	13%	58%
No available action	40%	17%	21%	21%

Note: Figures have been rounded to nearest percent. Rows may not total 100%.

Table 2. Rating the Most Significant Barriers

Most Significant Barrier		One of the Three Most Important	
Concern for accuracy of results	43%	Concern for accuracy of results	23%
Cost of testing	14%	Insurance concerns	20%
Insurance concerns	10%	Cost of testing	18%
Concern for current health	10%	Concern for current health	11%
Fear of result	8%	No available action	9%
No available action	6%	Fear of result	9%
No perceived benefit	6%	Concern for loss of privacy	5%
Concern for loss of privacy	4%	No perceived benefit	3%
Fear of job loss	0%	Fear of job loss	1%

should be able to access testing for unusual syndromes.)
- awareness of new genetic syndromes as they are discovered.

Physician commitment. The physician should contribute expertise on prevention, screening, lifestyle modification, and new technologies.

A focus on research. The program should conduct studies related to outcomes of the risk assessment program, its effect on cancer prevention and screening measures, and performance evaluations of the overall program.

A network of consultative/support personnel. Dietitians and therapists can be enlisted to offer assistance with exercise introduction and lifestyle modification, psychologists for psychological reactions, surgeons for prophylactic surgery, radiologists for advanced scanning and screening, and gastroenterologists for colonoscopy programs.

Communication with community physicians. Primary care physicians and other oncologists should be consulted regularly to ease referral.

Risk assessment programs are generally not cost-effective as measured by profit on counseling sessions. However, the value of a program to a cancer center or institution may extend beyond such a narrow analysis. Based on the responses to our study, we found that many community risk assessment programs are introduced out of a sense that it is simply "the right thing to do." Patients

Table 3. Task List of a Cancer Risk Assessment Session

1.	Discuss individuals' wants, needs, concerns, desires, and fears.
2.	Collect and verify the family history, particularly regarding cancer.
3.	Collect personal, hormonal, and lifestyle information.
4.	Educate about sporadic vs. inherited cancers.
5.	Educate about genes, inheritance, autosomal dominance, reduced penetrance, and explain genetic syndromes.
6.	Evaluate the family history and assess risk, using all available information.
7.	If, and only if, the risk is not high, empiric risk tables may be used with caution.*
8.	If the pedigree indicates high risk, use Mendelian analyses.
9.	Counsel about the risk, the impact on the person, and family dynamics.
10.	Discuss gene testing, what is available, and what is appropriate.
11.	Explain the necessity, in most cases, of starting testing with a relative who has a diagnosed cancer.
12.	Present the alternatives, clinical vs. research testing, and partial (select mutations) vs. more complete testing (sequencing).
13.	Discuss the pros of testing (knowledge, ability to use risk information to increase or decrease surveillance, and to consider chemoprevention or prophylactic surgery).
14.	Discuss the cons of testing, including discrimination (health, employment), self-image, family dynamics.
15.	Discuss the efficacy of interventions.
16.	Evaluate the likelihood of finding a mutation, given the apparent syndrome and state of testing.
17.	If testing is appropriate, identify the best relative for testing. Counsel and obtain informed consent for testing.

* Gail MH, Brinton LA, Byar DP et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 81:1879-1886, 1989.

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Table 4. Opportunities for Reimbursement	
Oncology consult with physician	Standard insurance
Genetic counseling evaluation	Private pay Insurance if individual is a patient or wishes to bill his/her insurance Funding from other sources
Gene testing	Private pay Insurance Research testing (no test fee)
Intervention by physician	Standard insurance
Increased screening	Standard insurance
Prophylactic surgery	Standard insurance Private pay

have come to expect such services from a state-of-the-art facility. As such, the program can enhance an institution's image and identity in the community. The output of funds to cover a risk assessment program often leads to increases in charitable gifts and grant opportunities. There can also be rewards from the increased use of cancer detection services as a result of the program as well as an increase in clients who self-refer to the institution for counseling, then remain loyal to the center for any subsequent screening, diagnosis, or treatment.

CONCLUSIONS

Reimbursement continues to be a problem in our program as well as in others. We suggest a general guideline for sources of available payment, which may reduce reluctance to participate in these programs. (See Table 4.) In addition, risk assessment programs require resources for development and expansion. Sources for funding include fees for services rendered, grants, gifts, and institutional support.

As our studies have shown, the introduction of risk assessment counseling and genetic testing in a community setting is feasible, and these services are often desirable to both medical professionals and the lay community. Soon, it may become the standard of care to advise family members of their risk. Guidelines for screening have been established, and recommendations for follow-up for individuals with inherited predisposition for cancer also have been published.[1,2,3] The expectations of patients regarding those who provide genetic counseling and testing have also been studied,[4] indicating the need for both genetic counseling and oncologists. Recent studies have suggested very high efficacy (90 percent) for prophylactic surgery at certain sites.[5] Information is accruing on chemoprevention in high-risk, but nonaffected, individuals.

Cancer risk assessment counseling is very time intensive, both in keeping abreast of a rapidly evolving field and providing service to patients. The bonus is that patients can receive important information and use prevention and surveillance strategies that are proving to be life enhancing while increasing longevity and disease-free years. Our experience suggests a very high rate of satisfaction with people who use our service. We recommend consideration of this service to other community-based oncology programs.

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