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Risk Registry

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FOREWORD

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Introduction

A. Nature of the Problem

The Human Genome Project is an international effort jointly funded by the National Institutes of Health (NIH) and the Department of Energy (DOE) to map the entire human genome and a series of model organisms. Over the next ten years the project has the potential to describe the 4000 genes thought to be responsible for human genetic disease (1). By providing highly sophisticated molecular tools to diagnose genetic susceptibility to cancer, the knowledge gained by the Human Genome Project will have major public health implications in terms of genetic screening policies, patient education, counseling strategies, and health care policy.

The clinical implications of the findings of the Human Genome Project are already becoming evident. Mutations in the BRCA1 gene on chromosome 17q are thought to account for the majority of hereditary breast and ovarian cancers (2). A second breast cancer susceptibility gene, BRCA2, has recently been localized to chromosome 13 and appears to account for a significant proportion of hereditary male and female breast cancer (3). At least four genes associated with hereditary non-polyposis colon cancer (HNPCC) are described and are associated with a broad range of gastrointestinal and genitourinary cancers (4). Altogether, over 12 genetic-cancer syndromes have been localized to a specific gene (5).

These and other advances in the isolation of genes associated with hereditary cancer will help to elucidate the basic mechanisms of carcinogenesis as well as the nature of the complex gene-environment interactions which characterize most sporadic cancers. The characterization of specific mutations within ethnic groups will permit more precise and targeted risk estimations. This work will also provide precise biomarkers of cancer susceptibility for clinical use in assessing an individual's risk for cancer. The incorporation of genetic information into clinical cancer risk assessment paradigms is being proposed as a way to target preventive strategies to the most appropriate individuals and to maximize their effectiveness.

The excitement generated by recent advances in cancer genetics has led to an increased awareness among the public of the risk associated with a family history of cancer. As individuals are becoming more aware of the risks associated with familial cancer and of the complex series of issues such a risk provokes, they are seeking more information and active involvement in efforts to reduce their risk. We and others have documented a significant interest in genetic testing among high risk populations, with as many as 85% of women with a family history of breast cancer indicating that they would seek genetic testing when available (6, 7, 8). As genetic testing for hereditary cancers becomes clinically available, it will be particularly important to optimally prepare individuals for the receipt of genetic risk information and for making the choice of participating in genetic testing a truly informed decision. The American Society of Clinical Oncology (9) has recognized the role of inherited genetic alterations on the development of cancer and has recommended that cancer risk counseling be incorporated into clinical aspects of care. These recommendations include: identification and assessment and communication of cancer risk, educational preparation for addressing genetic counseling issues and informed consent, and medical management of high risk populations. Already, genetic services for the evaluation of familial cancers are being implemented at a number of comprehensive cancer centers. Based on the model of traditional reproductive genetic counseling, these programs include education about the contribution of heredity to cancer risk, evaluation of personal risk status, and guidance in health decisions. They are highly specialized and require extensive resources to deal with all of the medical, psychological, social and ethical issues generated by the communication of genetic risk information. While these sophisticated programs are providing the models for future cancer

prevention, they serve only a fraction of the at-risk population, and are often segregated from the mainstream of medical care. Coincident with this rapid progress in understanding the genetic basis of cancer, the current health care reform movement is seeking to control the escalation of medical costs, and has placed an emphasis on a more generalized approach to care, promoting a shift in clinical research for both new treatment modalities and health promotion from the specialized centers of learning to the community providers of care. In fact, genetic testing services available from commercial laboratories will rely largely on the primary care sector to provide the functions of risk identification and counseling. Many barriers, however, including the lack of time, personnel and resources, impede the full implementation of cancer risk services in the primary care setting. A recent survey of individuals undergoing testing from commercial laboratories for a germline mutation in the adenomatous polyposis coli (APC) gene e.g. revealed that only 18.6% had received genetic counseling prior to being tested (10). The true preventive potential of a genetic approach to cancer control cannot be realized until comprehensive models of risk education and counseling are introduced and a new cadre of professionals are trained to provide these services.

Despite the incredible progress made in cancer genetics in the past decade, the ability to apply this knowledge to better understand human disease is in its infancy. The new molecular genetic tools will be the keys to open doors of knowledge for every aspect of cancer genetics including basic science, clinical implications, genetic epidemiology, psychosocial dimensions, and ethical issues. In addition to continuing to search for new cancer-related genes, we must establish the incidence, prevalence, penetrance and expressivity of known cancer susceptibility genes in different segments of the population. The natural history and clinical course of hereditary cancers must be defined. A whole host of related clinical questions, such as the safety of exogenous hormones among women with *BRCA1/2*-related cancers, remains to be addressed. On a population level, the exploration of gene/environment interactions may provide crucial clues about the etiology of sporadic as well as hereditary cancers. By identifying populations with a defined genetic risk we can also begin to explore the legal and ethical issues surrounding cancer genetic testing, and to lay the groundwork for finding new primary and secondary prevention approaches. Effective strategies for the communication of genetic risk information and for the psychosocial support of individuals who receive this information can be explored and established.

A large computerized data base which includes both genetic and environmental risk information from a racially and ethnically diverse set of patients with familial breast cancer, and from women at increased risk for the disease due to a positive family history, will allow investigators from a wide range of disciplines to address questions of gene-environment interactions, of the relative role of reproductive events in women with a genetic risk for breast cancer, and of the underlying reasons for differences in morbidity and mortality from breast cancer in different age and racial groups. It will further our understanding of the genetic basis of breast cancer by identifying families appropriate for genetic studies. The opportunity to maintain long-term follow-up of the women enrolled in the registry will permit evaluation of the effectiveness of new surveillance and prevention strategies. Moreover, preparing community providers to identify and counsel women at high risk for breast cancer will serve as a model for transferring genetic information into the public health realm.

B. Background of Previous Work

The Family Risk Assessment Program (FRAP) was established at Fox Chase Cancer Center (FCCC) in 1991 by Dr. Daly to meet several needs: 1) to offer to breast cancer patients and their family members education and information about cancer risk, screening, diagnosis, and treatment; 2) to serve as a research base for ongoing evaluation of the epidemiologic, biologic, genetic and environmental lifestyle factors which influence breast cancer risk; 3) to develop predictive models which will incorporate pedigree data, linkage analysis information

and epidemiologic risk factors to more precisely estimate cancer risk; and 4) to develop models for the communication of breast cancer risk information.

Candidates for FRAP include women with one or more first degree relative with breast and/or ovarian cancer. They are identified through their affected relatives, or are self-referred or referred by their primary care physicians for cancer risk counseling. Since the inception of the program a total of 1200 high risk women have become participants in the program. Their ages range from 21 years to 75 years, with a median of 40 years. The majority (97%) of the participants are Caucasian, while 3% are African American, Hispanic, or Asian.

On the basis of data provided by each participant on both family history and other pertinent risk factors, an individualized risk estimate for breast cancer is calculated. Trained counselors consider not only the occurrence of cancer within the family, but also the patterns of occurrence and the ages of the affected individuals in determining the type of familial pattern observed. Approximately 40% of FRAP participants meet the criteria for putative hereditary breast/ovarian cancer (i.e. three or more affected relatives in two or more generations) (11), and are eligible for genetic testing protocols. Genetic testing is done in collaboration with Dr. Andrew Godwin in his Genetics Research Lab at FCCC.

To date, we have collected blood samples from over 350 families participating in the FRAP and 20 families in the Department of Defense (DOD) High Risk Registry.

This constantly growing database serves as a research base for many ongoing studies spanning the dimensions of basic science, clinical genetics, epidemiology and psychosocial and educational interventions. The resources of the Genetics Research Lab continue to provide material for the identification of novel genes, mutations and cancer family syndromes, including the identification of two candidate tumor suppressor genes associated with hereditary ovarian cancer (12). Dr. Godwin has provided evidence of two distinct lines of transmission for the 185delAG mutation, only one of which has its origins in the Jewish Ashkenazi population (13). Drs. Daly and Godwin are collaborating with Dr. Steven Narod of The Centre for Research in Women's Health in Toronto to identify significant gene-environment interactions within these families (14). We have described a cancer-prone phenotype in ovaries removed for prophylaxis from women with strong family histories of ovarian cancer (15). In collaboration with Drs. Barbara Weber and Tim Rebbeck at the University of Pennsylvania we are prospectively following women who undergo bilateral mastectomy for prophylaxis to determine the beneficial and adverse sequelae of this procedure.

The FRAP program also provides a source of accrual for multiple chemoprevention studies, including a leadership role in accrual to the national cooperative group chemoprevention trials, as well as several Phase I chemoprevention. One of our greatest strengths is our research exploring cancer-related health attitudes and behavior, screening and prevention strategies, quality of life concerns, and the psychosocial dynamics generated by a cancer susceptibility diagnosis. In collaboration with Dr. Caryn Lerman of Georgetown Medical Center and Dr. Barbara Rimer of Duke University, we have conducted a randomized trial to evaluate the psychological and behavioral impact of individualized breast cancer risk counseling and breast self exam (BSE) training among women with a family history of breast cancer. Of interest was the finding at baseline that adherence to mammography among this population was not related to the presence of standard risk factors, including family history (16). Three months after the breast cancer risk counseling and BSE skills training intervention, adherence to correct BSE frequency was significantly improved (17). Furthermore, the counseling intervention had small but significant positive effects on comprehension of personal risk of breast cancer and on decreased breast cancer-specific distress. However, in both groups a significant proportion of women continue to

overestimate their lifetime risk for breast cancer after the counseling session, indicating the need for additional strategies to optimize risk comprehension (18).

1. The Transfer of Cancer Control Strategies to the Community

Fox Chase has also been a leader in extending state-of-the-art cancer knowledge, therapeutics and prevention to health care professionals and to the community. With a long tradition of professional education, including pre- and post-doctoral programs, oncology training at the nursing, medical student, resident and fellow level, and continuing medical education for health care providers, Fox Chase recognizes its responsibility to also disseminate its expertise in cancer prevention and control to the community, as reflected in its many provider outreach efforts.

- *Genetic Risk Education*, an interactive multimedia program on breast and ovarian cancer genetics and cancer risk education. The program uses compact disk interactive (CD-i) technology and offers a variety of media, including text, narration, still graphics, animation and full motion video. It provides multiple self-guided pathways of learning to enable users to process information at their own pace and to take an active role in their learning process. The CD-i is programmed to test a user's knowledge regarding the genetics of breast and ovarian cancer before and after viewing, and to record time spent and the number of content pieces chosen by the user.
- *Training Family Practice Residents in Cancer Risk Counseling*, a four-part physician training program to provide primary care practitioners a background in cancer genetics, and the skills to incorporate genetic risk counseling into their practices. The residents who participated in the pilot presentation of this course will be followed prospectively to measure actual skills practice as they move through their careers. The course is being integrated into family practice residency training programs and serves as a model for putting state-of-the-art information into the hands of primary care providers. (19).
- *Familial Cancer Risk Counseling: A Training Program for Nurses*, a three day nurses training program to provide nurses with the skills to identify individuals with potential hereditary cancer profiles, assess genetic cancer risk, and guide individuals to counseling and testing services. This course has been successfully offered to over 160 nurses from all over the US, with documented improvements in knowledge and skills (20). We are now in the process of developing an advanced course for nurses and genetic counselors to offer more intensive and skills-based training in cancer risk assessment and communication, and more in-depth experience with the genetic testing situation.
- *Train the Counselor*, an ongoing training program for Cancer Information Service (CIS) staff to keep them updated on new developments in cancer genetics and new research opportunities in the tri-state region.
- The FRAP home page (www.fccc.edu/clinical_research/familyriskassessment/frap.htm), which provides information about the Risk Assessment programs available at FCCC and its Network affiliates, and which directs users to appropriate referral sources.

Providing an overarching community framework to all of these outreach efforts is the Fox Chase Network, a unique cooperative relationship between FCCC and 14 Network institutes and health systems representing 20 community hospitals in Pennsylvania and New Jersey which was established in 1986 with a mission to enhance the quality of cancer care in the community. The extension of the FRAP program to the Fox Chase Network is one of

many examples of our commitment to bring state-of-the-art cancer services to the community. In addition, the FCCC Community and Physician Awareness Program targets primary care practitioners and members of the community to make them aware of the FCCC-affiliated cancer programs in their communities and the range of cancer services available to them. Through the Physicians Services Program, physicians in the tri-state area are visited by a physicians' services coordinator who, using an academic detailing approach, provides information about current protocols and clinical programs, including cancer prevention and control initiatives available at the Center.

C. Purpose of the Present Work

The establishment of a registry of high risk families is an ideal way to further our understanding of the mechanisms of breast carcinogenesis, and to learn the best ways to provide information and counsel both to women at increased risk for breast cancer and to their primary care practitioners. A large computerized data base which includes both genetic and environmental risk information from a racially and ethnically diverse population will allow investigators to address questions of gene-environment interactions, of the relative role of reproductive events in women with a genetic risk for breast cancer, and of the underlying reasons for differences in morbidity and mortality from breast cancer in different age and racial groups. It will further our understanding of the genetic basis of breast cancer by identifying families appropriate for linkage analysis studies. The inclusion of a High Risk Specimen Bank in the design of this registry allows investigators to identify and quantify early premalignant markers of breast cancer risk and to estimate the true prevalence of breast cancer gene(s) in the population. Despite widespread public interest in breast cancer, many first degree relatives of breast cancer patients know very little about their true risk status. The establishment of this registry gives us the opportunity to test different counseling strategies so that we can best meet the needs and demands for information which will accompany the eventual identification of breast cancer susceptibility genes. Long-term follow-up of women enrolled in the registry permits evaluation of the effectiveness of surveillance and prevention strategies. Finally, this registry serves as a catalyst for the development of educational materials directed towards community-based health care professionals. In the past, genetic counseling has been the exclusive domain of medical geneticists and medical genetics counselors. However, to be successful, the transfer of information generated by the Human Genome Project to the public health realm of cancer control must be put in the hands of the primary care practitioner, both physician and nurse. Essential to the successful development of a community-based Breast Cancer Risk Registry is the ability of primary care practitioners to target breast cancer screening and prophylaxis towards truly high risk individuals, and the dissemination of genetic information back to the primary health care team in the community. The educational tools developed to complement the establishment of a high risk registry serves as a model for bringing primary care practitioners to the forefront of cancer control and prevention.

D. Methods of the Approach

The methods of accomplishing the proposed goals were set out in the grant proposal in eight specific aims (see Figure 1.)

Program implementation began with collaborative meetings with the Medical Director of each Network Oncology Program. This approach begun in Year One has continued to be the method for assessing interest in participation in the program as well as determine training, education and administrative needs. Those institutions interested in participation have been guided through an implementation process that included 1) the development of an administrative and implementation plan; 2) training and preparation of nursing staff to coordinate and conduct the program; 3) training in all protocols and procedures, and 4) on-

going mentoring and monitoring in cancer risk assessment and counseling. The protocols developed for recruitment (Aim #1) have included community outreach and education or physician referral. These protocols were developed in Year One and initiated in Year Two. During the third year of the program, accrual of high risk women continued. Methods for the accrual into the registry have included the completion of a Health History Questionnaire (HHQ), a health attitudes survey, and having attended an education session on breast cancer risk. The HHQ collected the following information: demographics, family history, medical history, and epidemiologic risk factors. The health attitudes survey items included information on self-perceived risk for cancer and previous screening behavior. These data were entered into the Risk Registry and family pedigrees were developed. Each pedigree has been reviewed by a multidisciplinary team for assignment of family risk (Aim #3). The selection criteria, based on the assigned pattern of cancer, was designated and documented for the Network institutions. With this information, the nurse counselor met individually with high risk individuals to ascertain clinical history and provide cancer risk information and eligibility for genetic studies.

Figure 1. Specific Aims of the Breast Cancer Risk Registry

1. To establish a protocol for identifying and recruiting women with one or more first degree relatives with breast cancer into a regional FCCC Network-wide registry of high risk individuals.
 2. To establish a computerized data base system of comprehensive information including family history, personal medical history, lifestyle and environmental factors, health practices and beliefs, and psychological status which will serve as a resource for a spectrum of research activities.
 3. To develop protocols for the selection of individuals and families for closer genetic investigation and genetic counseling.
 4. To expand the FCCC/Network Breast Cancer Tissue Registry to include specimens of benign breast lesions as well as serum and DNA from women in the high risk registry.
 5. To develop educational tools for primary care physicians at the community level to prepare them to take a leading role in the identification of women with a family history of breast cancer, in the interpretation of genetic test data, and in its relevance and application to clinical medicine.
 6. To develop workshops for training nurses at the community level to provide breast cancer risk information, risk assessment, tailored preventive recommendations, and psychosocial support to high risk women and their families.
 7. To develop and test behavioral interventions which are sensitive to cultural, ethnic and racial differences which will promote positive outcomes to breast cancer risk information, including the results of genetic testing.
 8. To form a Breast Cancer Risk Advisory Panel to provide guidance and counsel regarding the social, legal and ethical aspects of genetic testing for breast cancer.
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The data management system for the Breast Cancer Risk Registry has utilized the methods and operations of FCCC Family Risk Assessment Program system (Aim #2). Data entry, storage, and retrieval is achieved through the relational database management system (RDBMS) ORACLE. The program uses a relational structure which permits substantial flexibility in ad hoc query formulation. Relatively straightforward procedures, such as SQL*FORMS, were used to generate forms which provide a visually attractive user interface for data entry. In addition, these forms are used for editing and simple database queries. For more demanding data management, ORACLE provides a complete implementation of the structured query language (SQL).

The software system runs on a UNIX-based distributed computing system consisting of multiple DecStation 5000 and Digital Alpha RISC processors managed and operated by the Research Computer Services group at FCCC. The existing software system is capable of generating multigenerational pedigrees. The data which feeds pedigree generation is easily updated to include deaths or new cancers reported for previously listed family members, as well as new births. The software is also capable of creating the union of family histories provided by two or more distinct study subjects in the same family in order to create an "extended" pedigree. In order to preserve the privacy of the human subjects, a series of security procedures have been implemented. Only numeric identifiers are stored with study results. Lists of names and addresses are retained by the investigators in a secure location.

Protocols used at FCCC for the collection, transportation and processing of blood samples for genetic testing have been utilized as the model for the Network Hospitals (Aim #4). Dr. Jose Russo, Director of Experimental Pathology at FCCC, agreed to guide the expansion of a High Risk Breast Specimen Bank. Detailed procedures for the protocols were developed and compiled in a procedures manual to assist Network staff. Procedures were described and appended in Year Two. Quality control measures established to ensure that OSHA standards for the handling of human biologic materials have been followed by all specimen bank and laboratory personnel.

Essential to the success of the Registry has been the development of programs to train both nurses and physicians at each Network hospital for their expanded role in cancer risk identification and counseling (Aim #5, #6). The education methods for nurses have included the continuation of the formal three-day training and one-day practicum and quarterly inservice updates in cancer risk assessment and genetic counseling issues as reported in Year Two. The methods for physicians included regional updates through the physicians services program, grand rounds, one formal symposium (**Appendix A - Toward 2000 brochure**) and a pilot training in cancer risk assessment. Dr. Daly, in conjunction with the faculty of the Hunterdon Medical Center Family Practice Residency Program, developed an educational program in Familial Cancer Risk Counseling designed to prepare community-based primary care physicians to take an active role, along with the nursing staff, in the identification and assessment of familial cancer syndromes. The curriculum was adapted from the Nurses' Training, and was based on the Medical School Core Curriculum in Genetics (19). The curriculum was organized into four three-hour modules plus a clinical practicum. The modules were a mix of didactic and interactive teaching covering the following topics: fundamentals of cancer genetics; cancer inheritance patterns; risk assessment and notification; genetic testing and counseling; and cancer prevention and control options.

To assess the impact of the Nurses' Training, evaluation methods described in Year Two have continued to be utilized. To evaluate the impact of the residents' training, the following methods were used: (1) pretest/posttest measure of knowledge; (2) subjective evaluation of course objectives for each session and total program; (3) baseline and six-month follow-up survey items were included in the pre/posttest to assess self-reported practice and

confidence as well as facilitators and barriers to implementing Cancer Risk Counseling (CRC) in community practice. (**Appendix B - Residents' Evaluation**)

In the evaluation phase, descriptive analysis was used to measure the subjective responses to program objectives. Univariate analysis was conducted to compare pre- to posttest measure of knowledge using a t-test. Univariate analysis will be used to measure change over time from baseline to six months post-training on taking cancer family histories, practicing cancer risk counseling and confidence in skills in cancer risk counseling.

During Year Three, the Breast Cancer Risk Advisory Panel work has helped to develop counseling interventions for receipt of genetic test results (Aim #7), including predisclosure, disclosure and follow-up interventions (**Appendix C - protocols**). The predisclosure session utilizes presentation of information, counseling and role play to help prepare individuals for genetic test results. A multi-disciplinary team conducts the disclosure session designed to provide genetic test results, to address adjustment to the information and to develop a plan for medical management and follow-up. Follow-up is conducted via phone at one and 12 months post-disclosure to evaluate the impact of genetic test results and provide information for resources or referrals if necessary.

The Breast Cancer Risk Advisory Panel has brought together health care professionals, both at FCCC and the Fox Chase Network, community representatives, as well as lay consumers. This group has the mandate to provide information, counsel and advice to the staff of the Breast Cancer Risk Registry (Aim #8). The approach to the work has been an annual meeting by the entire panel of experts. The panel has identified pertinent issues that have been addressed by the group as a whole and by sub-committee working groups.

The work of the FCCC Network Breast Cancer Risk Registry is providing the opportunity to develop and evaluate educational and psychological strategies to optimize breast cancer risk counseling in the community setting. It is also providing important information on relevant issues to transferring genetic knowledge into community-based practice. This information will guide future research on the optimal way of delivering breast cancer risk information, and the true impact of counseling programs on participants' risk comprehension, psychological adaptation, and adoption of recommended health practices.

Body

The overall goal of the third year of the Breast Cancer High Risk Registry was to continue accrual to expand the research base regarding the epidemiologic and biologic knowledge about modifiable causes of breast cancer. Therefore, the tasks for this year were to: 1) continue implementation and accrual; 2) continue nurse and physician training in cancer risk counseling; 3) develop protocols for predisclosure and disclosure counseling, and 4) monitor the programs at each of the participating institutions. The following describes the process and tasks that were accomplished in Year Three.

1. Implementation and Accrual

To date, contact with Medical Directors has been made in all but three Network institutions. Nursing staff have been trained in twelve facilities; of these, eight have assigned a nurse as the program coordinator. The education and program resources have been provided to nine hospitals. Seven sites have begun the breast cancer risk education through community education and have been accruing participants for the Risk Registry. Two sites are projecting to begin accrual in October 1997. Table 1 outlines the status of the individual Network facilities and their participation status.

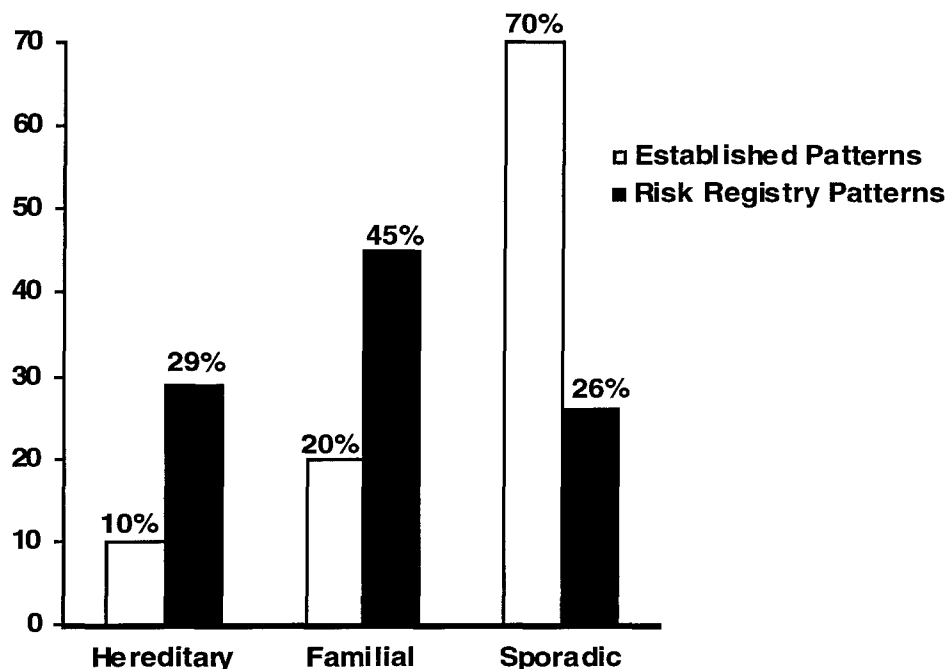
Table 1. Network Participation in the Risk Registry Program

	Contact- Med. Dir	Nurse trained	Nurse coord.	Education resources	Education initiated	Accrual begun
Bonsecours	-	-	-	-	-	-
St. Luke's	X	X	X	X	X	X
Reading	X	X	-	-	-	-
Pinnacle	X	X	X	X	X	X
Burlington (Mem.)	X	X	X	X	-	-
St. Francis	X	X	X	X	-	-
Montgomery	X	X	X	X	X	X
North Penn	-	-	-	-	-	-
St. Mary's	-	X	-	-	-	-
Paoli	X	X	X	X	X	X
Riverview	X	-	-	-	-	-
Hunterdon	X	X	X	X	X	X
Delaware County	X	X	X	X	X	X
South Jersey	X	X	-	-	-	-
Community Med.	X	X	X	X	X	X

The breast cancer risk education sessions were marketed in two ways: through the medical oncologist contact with breast cancer patients and through community education. In the former, the medical oncologist alerted breast cancer patients about the program. The patients in turn contacted their relatives. Five of the Network hospitals have done general media announcements about the breast cancer education sessions and three programs have developed brochures to market the program (**Appendix D - Selected marketing and brochures**). A description of the Risk Registry Program is given at the education session with the option for participation. To date, there were a total of 32 education sessions with 463 women attending. Of those, 121 women from 80 families chose to participate in the Risk Registry program. These women all have had their family history information reviewed by the Pedigree Review Committee at FCCC. The purpose of the review is to assign a preliminary diagnosis of the cancer family pattern, and identify appropriate individuals for further genetic evaluation and collection of blood or tissue samples. Each family receives a diagnosis for both the maternal and paternal side of the family by cancer type and by pattern. The patterns include: sporadic, family or putative hereditary. Family cancer patterns for the 80 families in the Risk Registry have shown 26% sporadic, 45% familial and 29% putative hereditary. Figure 2 shows the breakdown of the cancer family patterns in the High Risk Registry as compared to expected patterns of cancer for the general population. It has been established that 5 to 10% of breast cancers are attributed to hereditary cancer syndromes, 70% attributed as sporadic and the remaining 20% falling into a familial category (21). Since hereditary cancer is expected to account for 5 to 10% of breast cancers, these figures show that the Risk Registry program is appropriately recruiting individuals that carry a higher degree of risk for breast cancer than the general population.

Of the 80 families recruited into the registry, 23 families with a hereditary pattern of cancer were approached for participation in genetic studies. Thirty individuals from 20 families have participated in genetic research studies. Protocols used at FCCC for the collection, transportation and processing of blood samples for genetic testing have been utilized as the model for the Network hospitals. Blood collection procedures developed and compiled in a procedures manual were utilized to assist the Network staff in procuring and mailing samples. The procedures description and manual were provided in Year Two.

Figure 2. Percent of Risk Registry Cancer Patterns Compared to Established Cancer Patterns



2. Nurses & Physicians Training

The third year of the Risk Registry program allowed us to continue preparing community-based providers with the knowledge and the skills to make familial cancer counseling available. Three additional nurses from Network institutions attended the Familial Cancer Risk Counseling Training for Nurses. To date, 18 Network nurses have attended the three-day training. A total of 164 nurses nationwide have participated in the training, and of those, 62 attended the optional one-day practicum.

Eighty-two participants have completed evaluation measures, i.e. pretest/posttest measures of knowledge, and baseline and six-month follow-up of self-reported practice and confidence in Cancer Risk Counseling (CRC) skills. Of the 82, 43 (52%) attended the three-day training, and 39 (48%) attended both the training and the one-day practicum. There was a statistically significant improvement in knowledge scores from pre- to posttest, with a mean of 18 correct items out of 28 at pretest compared to 23 at posttest ($p < 0.01$, Wilcoxon signed rank test). There were no significant knowledge differences between the practicum and training only groups at both baseline and follow-up.

In order to evaluate the impact of the practicum on attainment of confidence in skills, bivariate analysis was conducted on self-report of confidence from the 60 participants who had practiced CRC at least once since the training. Those who had attended the practicum were more active in counseling than those who attended the training only (mean of 5 vs 3 individuals counseled/month respectively). Statistically significant differences were found at six months between groups in levels of confidence in all of the cancer risk assessment skills (Fisher's Exact Test). The practicum group reported more confidence in all skills, with the

greatest improvement in taking and assessing family history. Overall, the lowest levels of confidence were reported for the more complex skills of communicating risk information and making recommendations for follow-up. Qualitative six month data showed that those practicing CRC worked as a team with a medical oncologist; and the most important facilitators to practicing skills were having a genetic resource person, access to on-going genetic information, and clear performance guidelines for nursing (20).

The results of this work in training nurses suggest that knowledge alone does not predict skill performance. After the three-day training, the total group showed improvement in knowledge scores, but the majority reported needing more observation and practice time. A significant proportion (27%) were not practicing their skills at all. Other reported needs included clearly defined nursing performance guidelines and access to team members. The findings and the significant differences in confidence levels between those who attended the practicum and those who did not supports the role of hands-on-training opportunities and supervision as the means to improve skills utilization.

In order to assist the Network nurses in skills development, an ongoing mentoring process continued from Year Two into Year Three. This process has included observation and supervision by FCCC staff of the breast cancer risk education session and the individual cancer risk counseling session. All Network nurses had the opportunity to observe in the FRAP program. Their observations included attending pedigree review and the individual pedigree evaluation session. Feedback on pedigrees was given prior to each individual session. For the initial individual counseling session at the Network hospital, the nursing coordinator observed FCCC staff conduct an individual risk assessment session. Afterwards, FCCC staff supervised the nurse coordinator conduct two sessions. A monthly mailing of current literature has continued in Year Three to address the advances in genetic information and issues related to the counseling and testing process. A quarterly inservice training has also continued. These four hour trainings consist of peer updates regarding individual Network hospital progress in the Risk Registry, review of administrative concerns or issues, and two hours of educational inservice. Additional monitoring of the program is provided by telephone conferencing and site visit.

The process of training and preparing nurses to assume the role of providing cancer risk information has underscored the need to bring physicians into the loop of a genetic based approach of cancer prevention. During the Risk Registry program, the nurse coordinators have the opportunity to obtain information from the research project team. As CRC becomes part of community practice, information needs will be better addressed by the practice team. Physicians in the Network hospitals were offered ongoing updates regarding the advances in genetics via the Network's Physician Services. This service organizes regional inservice updates and grand rounds. Cancer risk assessment and genetic updates were presented at two regional meetings and four grand rounds at Network institutions. Dr. Mary Daly in cooperation with the FCCC Continuing Medical Education Department will provide an offering for physicians in the genetic advances in cancer control. (**Appendix A, Toward 2000 brochure**). This one-day symposium will address breast cancer genetics and prevention.

As part of FCCC's effort to educate physicians, the needs of practicing physicians regarding the identification of genetic risk for disease and the options available for high risk families became more apparent. Following from the work of the Risk Registry grant, FCCC was awarded funds from the National Cancer Institute to pilot an education program for family practice residents. This program called: "Training Family Practice Residents in Familial Cancer Risk Counseling," was designed with the faculty of one of the participating Risk Registry institutions. The design was unique in that the faculty of the Hunterdon Medical Center Family Practice Residency Program participated in both the development and teaching

sessions on familial cancer risk assessment and counseling. A clinical practicum provided the residents with an opportunity, in a supervised setting, to take a thorough family history and develop a family pedigree, assess the information obtained for familial cancer risk and communicate risk information and recommendations to a patient. The practicum interview was videotaped to allow review and feedback.

The course has been successfully administered to 12 first and third year residents. Evaluation of the training has included a pre/posttest measure of knowledge and confidence, subjective written evaluations and group debriefings after each of the four sessions and practicum. The pre/posttest questionnaire was developed to measure change over time in knowledge and confidence in CRC. In addition to a statistically significant improvement in knowledge ($p=.01$, t test), the residents reported greater confidence in recognizing patients at risk, and in using the family and medical history to construct and assess a pedigree. The greatest improvement in confidence was in referring appropriate patients for genetic testing services. All the residents rated the practicum as the most helpful component for building confidence and skill attainment, and the best way to incorporate cancer risk assessment into their practice. The residents will be followed longitudinally to measure actual skills practice as they move through their careers.

These findings suggest that the role of risk assessment and identification of appropriate candidates for genetic testing services is within the scope of community primary care. Furthermore, the work of the Advisory Panel, in conjunction with Network physicians, has suggested that community-based physicians with training will become essential team members in the disclosure process.

3. Development of Protocols for Predisclosure and Disclosure Counseling

The main goal of the Breast Cancer Risk Advisory Panel was to provide guidance and expertise on issues and concerns that could arise with establishing a high risk registry, providing familial cancer risk assessment and genetic information. The Breast Cancer Risk Advisory Panel with representatives from multiple disciplines and expertise was expanded in Year Three (**Appendix E - Advisory Panel List**). These members included consumers, risk registry participants, experts in the area of oncology nursing, genetics, genetic counseling, medical testing, marketing, psychology, the law, health insurance, primary care, and ethics. The entire panel met twice in Year Three and a special working group addressed the development of disclosure counseling interventions.

The counseling intervention sub-group met to discuss issues related to preparation, receipt and follow-up of genetic test results. Advisory sub-group members interviewed Network representatives and discussed the range of issues related to disclosure counseling including training, staffing, documentation, privacy, and medical management. Working in conjunction with the FCCC staff who provide genetic test results, the group members then reviewed the predisclosure, disclosure, and follow-up counseling process and compiled protocols that provided details on 1) the purpose of the session; 2) format; 3) staffing considerations; 4) counseling process, and 5) options for implementing the counseling process (**Appendix C**). The protocols were reviewed by the participating Network staff who identified key issues for their institutions. These issues were discussed with the medical directors, administrative and nursing staff from the participating Network hospitals along with the full Advisory Panel. Recommendations for implementing the disclosure process included:

- Network hospitals utilize a multi-disciplinary approach for both predisclosure and disclosure counseling;

- Develop training for both nurses and physicians with specific focus on genetic test results;
- Develop guidelines for documentation of test results.

Working groups were appointed to provide guidance with the above recommendations. The working group to address training has conducted preliminary interviews with physicians and media companies to explore video or computer learning modules for physicians. FCCC is in the process of developing an advanced course for nurses to offer more intensive and skills-based training with genetic testing and disclosure counseling.

4. Monitoring

Contact with the Medical Directors at two additional Network institutions allowed for assessing interest in participation in the program as well as determine training, education and administrative needs. These institutions are being guided through an implementation process that includes training and preparation of nursing staff to coordinate and conduct the program. Once a nursing site coordinator is assigned, administrative and procedural components of the program are addressed. The project manager has been working individually with the sites to develop an implementation plan tailored for the individual Network facility. The components of the plan include: recruitment strategies, marketing, administrative requirements, such as Institutional Review Board approval, educational resources, documentation and security for records, strategies for counseling and for collection of blood samples. A Procedure Manual described and appended in Year Two, along with all forms and letter have been provided on disk and hard copy to facilitate the necessary adaptation for the individual hospital.

For sites that have already implemented the program, an ongoing monitoring process has continued with periodic observation and supervision of the breast cancer risk education session and the individual cancer risk counseling session. Ongoing mentoring and monitoring of the programs are provided by telephone conferencing, site visits, and quarterly inservice education. This process is discussed in the training section.

Conclusions

Work in Year Three in the High Risk Registry program has accomplished an increase in the number of participating institutions and overall accrual. Eleven of the 14 Network institutions have entered into participation agreements with seven sites accruing high risk participants and two additional sites scheduled to begin accrual in the Fall of 1997. The number of education sessions and women accrued has doubled over this year with the nurse coordinators taking the lead in community education and individual counseling. These activities have enabled local hospitals to provide community-based CRC.

The development of counseling protocols for disclosure of genetic test results was completed with the guidance of the Advisory Panel. The Panel's work with the medical and administrative staff to identify issues in the disclosure process underscored the need to bring physicians into a multi-disciplinary approach for delivery of genetic results. The Advisory Panel will continue to offer direction regarding training for both nurses and physicians in the delivery of test results and documentation of genetic information.

As genetic test results become available, it is apparent that creative education strategies for nurses and physicians are needed. An advanced nurses course will provide a skill building approach to provide experiential learning in the area of genetic testing. Quarterly inservice training for the Network nurses will continue. The Network nurses will begin taking a more

active role at the quarterly meetings by leading case presentations and journal reviews. The Advisory Panel and project staff are exploring video and computer-based learning methods to creatively address the learning needs of physicians.

Recruitment and collection of blood and tissue samples will continue. Project efforts will be made to integrate counseling interventions for delivery of genetic test results as part of community-based practice. Network staff will receive training and supervision for conducting disclosure sessions. Options for supervision and consultation will also be developed. This next step will increase the number of skilled providers who can appropriately communicate and counsel individuals regarding genetic information.

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**Department of Defense Infrastructure Grant
Breast Cancer High Risk Registry
September 15, 1996 to September 14, 1997**

Appendices

Appendix A	Toward 2000 Brochure
Appendix B	Residents' Training Evaluation
Appendix C	Counseling Protocols
Appendix D	Selected Marketing Brochures
Appendix E	Advisory Panel

Appendix A



FOX CHASE
CANCER CENTER

The Thirteenth Annual Toward 2000

Symposium

The Clinical Spectrum of Breast Cancer

October 17, 1997

Sponsored by

FOX CHASE
CANCER CENTER

Philadelphia, PA

Location:
Auditorium

Fox Chase Cancer Center
7701 Burholme Avenue
Philadelphia, PA

Supported by an unrestricted educational grant from Bristol-Myers Squibb Oncology

TRANSPORTATION

Directions to Fox Chase Cancer Center and to the Park Hyatt Philadelphia at the Bellevue will be forwarded upon receipt of the Registration Form.

Airport to Park Hyatt Philadelphia at the Bellevue: Taxi fare from the Airport to the hotel is \$20 per carload. Airport shuttle service is available from 6:30 AM until 10:00 PM for \$8 per person plus gratuity. Proceed to the Ground Transportation Desk in the Airport Baggage Claim area to request the Airport Shuttle which is provided by a number of companies (Lady Liberty, Super Shuttle, etc.)

30th Street Train Station to Park Hyatt Philadelphia at the Bellevue: Taxi service is available from 30th Street Train Station to the hotel at a cost of approximately \$10 per carload.

ACCOMMODATIONS

Park Hyatt Philadelphia at the Bellevue, Broad and Walnut Streets, Philadelphia, PA 19102

Make hotel reservations directly by calling 215-893-1776.

Rate: Single \$165 Double \$190
(Rate does not include 13% guest room tax.)

Group Name: Fox Chase Cancer Center.

Hotel Registration Deadline: September 16, 1997

STATEMENT OF THE FOX CHASE CANCER CENTER DISCLOSURE POLICY

It is the policy of Fox Chase Cancer Center (FCCC) to insure that all sponsored continuing medical education activities are independently designed and produced, relative to content and quality, and that all presentations maintain scientific integrity, and are objective, balanced, and free of commercial bias. Fox Chase Cancer Center policy requires that each faculty member be asked to provide appropriate disclosure information prior to an educational activity. Fox Chase Cancer Center requires disclosure to program participants of any financial interest or other relationship a faculty member or Fox Chase Cancer Center, as the sponsor of the activity, has with (1) the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in an educational presentation and (2) any commercial supporters of the activity.

Toward 2000
The Clinical Spectrum of Breast Cancer

WORKSHOPS—October 17, 1997

Please check the workshop of your choice for each session. Selections will be accommodated on a first-come, first-served basis.

- 1:30 p.m. W-1 Genetic Testing and Counseling
3:00 p.m. W-2 Current Controversies in the Diagnosis and Treatment of Early Stage Breast Cancer
- 3:15 p.m. W-3 Guidelines and Pathways—Tools to Improve Cancer Care
4:45 p.m. W-4 Patient Attitudes Regarding Breast Cancer and Breast Cancer Risk

SPECIAL NEEDS

Physically Challenged—Fox Chase Cancer Center is accessible to participants who are physically challenged. FCCC wants to ensure that no individual with a disability is excluded, denied services, segregated, or otherwise treated differently than other individuals because of the absence of auxiliary aids or service. If you require auxiliary aids or services as identified in the Americans with Disabilities Act, please note your needs below.

- Auxiliary aids or services required (Specify) _____

Dietary Requirements—Please note any special dietary requirements that you may have.

- Kosher Vegetarian
 Other (Specify) _____

Shuttle Service—If you will require transportation between the hotel and Fox Chase Cancer Center, please note.

- Shuttle service required

Name _____

PROGRAM DESCRIPTION

For the thirteenth year, Fox Chase Cancer Center offers the annual Toward 2000 symposium. Since the initiation of Toward 2000 in 1985, the symposium has provided a forum for presentation of the latest issues in clinical and basic research in oncology. This year's symposium will focus on the clinical spectrum of breast cancer, taking advantage of the explosion of information regarding breast cancer genetics, biology and management. The symposium is designed to provide information about prevention, screening, diagnosis and treatment options for breast cancer to oncologists, primary care physicians, nurses, and allied health professionals.

Lectures will be presented by leaders in the field of breast cancer. Workshops will focus on genetic testing and counseling, patient attitudes and local management of early breast cancer, as well as guidelines and pathways to improve cancer care. Adequate time for questions and answers has been allotted throughout the program.

New this year is the "Ask the Experts" session that will be held during the luncheon. This will provide an opportunity for informal interaction with the faculty. Participants will have the opportunity to bring up challenging cases for discussion by the program faculty.

TARGET AUDIENCE

Medical, surgical, and radiation oncologists, general practitioners, family practitioners, internists, hematologists, gynecologists, surgeons, radiologists, nurses, and allied health personnel involved in the treatment of cancer patients.

ACCREDITATION STATEMENT

Fox Chase Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

DESIGNATION STATEMENT

The Fox Chase Cancer Center designates this educational activity for a maximum of 8 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

COVER

Fox Chase Cancer Center would like to express appreciation to The Art Institute of Chicago for granting the rights to use the artwork that appears on the cover of the brochure. Alsbott Handerson Thayer, American, 1849-1921, Winged Figure, oil, 1889, 51 1/2 x 37 3/4 in., Simeon B. Williams Fund, 1947-32. Photograph © 1996 The Art Institute of Chicago. (Detail)

PROGRAM - Friday, October 17, 1997

7:15 a.m. Shuttle Leaves Park Hyatt Philadelphia at the Bellevue for Fox Chase Cancer Center

7:30 a.m. REGISTRATION AND CONTINENTAL BREAKFAST

8:00 a.m. **Welcome and Overview**
Louis M. Weiner, M.D.

8:15 a.m. **Breast Cancer Risk Assessment and Management**
The presentation should enable the participant to recognize the genetic mutations which enhance the risk of breast cancer; describe the mechanisms for assessing risks for development of breast cancer; and review contemporary approaches to the prevention of breast cancer.
Mary B. Daly, M.D., Ph.D.

9:00 a.m. **Contemporary Approaches to the Systemic Therapy of Breast Cancer**
The presentation should enable the participant to review the anti-tumor properties of systemic chemotherapy agents on breast cancer; review theoretical and practical considerations related to chemotherapy dosing and scheduling; and define the role of chemotherapy in patients with metastatic cancer.
Larry Norton, M.D.

9:45 a.m. **BREAK**

10:00 a.m. **Alteration of the HER-2/neu Gene in Human Breast Cancer: Diagnostic and Therapeutic Implications**
The presentation should enable the participant to identify oncogenes and other proteins, the expression of which leads to altered growth characteristics in breast cancer; determine the role of HER-2/neu in determining breast cancer prognosis; and discuss the emerging role of antibodies directed against HER-2/neu in the management of women with breast cancer.
Dennis J. Slamon, M.D., Ph.D.

10:45 a.m. **Update on Mammography**
The presentation should enable the participant to recognize the sensitivity and specificity of mammograms as a screening tool for breast cancer; determine the role of screening mammograms in conjunction with other screening modalities to improve the diagnosis of early breast cancer; and discuss current recommendations for screening mammograms in women under the age of 50.
Stephen A. Feig, M.D.

**TOWARD 2000
REGISTRATION FORM**

(Print or Type) _____
Name _____ Degree _____
Medical Specialty (Physicians) _____
Institution _____
Mailing Address _____
City _____ State _____ Zip _____
Daytime Number _____ Fax Number _____

REGISTRATION AND PAYMENT
Toward 2000 Registration Fee: \$100 (\$50 for Fellows, Residents, Students)

Two-Day Registration Fee: \$175—A reduced registration fee is offered to participants who want to attend "Oncology Nursing: New Directions in Cancer Treatment" on October 16 (Announcement enclosed) in addition to the October 17 symposium, "Toward 2000: The Clinical Spectrum of Breast Cancer." If you are attending only the October 16 nursing conference, please complete the registration form in the enclosed announcement.

Registration and Payment—Please send your Registration Form with check (payable to **Fox Chase Cancer Center**) in the enclosed envelope to:

Kathy Smith, Room C-400, Office of Continuing Medical Education,
Fox Chase Cancer Center, 7701 Burholme Avenue, Philadelphia,
PA 19111 (Telephone: 215-728-5358; FAX: 215-214-8908)

Check the Appropriate Box **Amount Enclosed**

Toward 2000 The Clinical Spectrum of Breast Cancer (October 17 only) \$ _____

Oncology Nursing: New Directions in Cancer Treatment (October 16) and Toward 2000: The Clinical Spectrum of Breast Cancer (October 17) \$ _____

(If you are attending only the October 16 nursing conference, please complete the registration form in the enclosed announcement.)

(Select Workshops on Other Side)

REGISTRATION

Registration Fee: \$100 (\$50 for Fellows, Residents, Students)

Includes program materials, continental breakfast, luncheon, breaks, and shuttle transportation.

Two-Day Registration Fee: \$175

A reduced registration fee is offered to participants who want to attend "Oncology Nursing: New Directions in Cancer Treatment" on October 16 (Announcement enclosed) in addition to the October 17 symposium, "Toward 2000: The Clinical Spectrum of Breast Cancer."

Registration Deadline: October 10, 1997

Supported by an unrestricted educational grant from Bristol-Myers Squibb Oncology.

CANCELLATIONS

Cancellations received prior to October 10, 1997 will be refunded minus an administrative fee of \$15.

INQUIRIES

If you would like additional information about Toward 2000, please contact:

Kathy Smith or Louise Blasick
Room C-400
Office of Continuing Medical Education
Fox Chase Cancer Center
7701 Burholme Avenue
Philadelphia, PA 19111
(Telephone: 215-728-5358; FAX: 215-214-8908)

11:30 a.m. LUNCHEON and ASK THE EXPERTS

The "Ask the Experts" session during the luncheon will provide an opportunity for informal interaction with the faculty. Participants will have the opportunity to bring up challenging cases for discussion by the program faculty. The session should enable the participant to discuss specific case management problems related to breast cancer and clarify points raised during the morning lectures.

Lori J. Goldstein, M.D., Moderator

12:30 p.m. Update on the Adjuvant Therapy of Breast Cancer

The presentation should enable the participant to review the history of adjuvant therapy for breast cancer; determine the indications for adjuvant chemotherapy for the major program groups of breast cancer patients; and identify the contemporary clinical trials in breast cancer and the specific themes being addressed in those trials.

Bernard Fisher, M.D.

1:30-3:00 p.m. WORKSHOPS

W-1 Genetic Testing and Counseling

The presentation should enable the participant to evaluate current methods for detecting genetic mutations related to cancer; consider counseling issues in managing high-risk families; and assess the role of prophylactic mastectomy in medical management.

Mary B. Daly, M.D., Ph.D., Moderator, Josephine Costalas, M.Sc., Andrew K. Godwin, Ph.D., Elin Sigurdson, M.D., Ph.D.

W-2 Current Controversies in the Diagnosis and Treatment of Early Stage Breast Cancer

The workshop will consist of a series of case presentations which will focus on issues related to the diagnosis, surgical approach, mammographic evaluation and treatment of early stage breast cancer. The presentation should enable the participant to describe the role of the core biopsy (Abbi) in the diagnosis of breast cancer; recognize the significance of resection margin status and its impact on treatment options; recognize the role of post-biopsy mammograms in patients presenting with calcifications; and discuss the appropriate follow-up of the patient treated with breast conservation.

Barbara L. Fouuble, M.D., Moderator, Marcia Boraas, M.D., Howard B. Kessler, M.D., Arthur S. Patchefsky, M.D.

3:00-3:15 p.m. BREAK

- W-3 Guidelines and Pathways—Tools to Improve Cancer Care**
The presentation should enable the participant to discuss the impact of guidelines and pathways on quality cancer care.
Ginny Martin, RN, MSN, AOCN, Moderator,
Gwen A. Bednarz, RN, MSN, OCN, Karin G. Hoffmann, RN, CCM,
Richard Kostrowski, MD, Carolyn Weaver, RN, MSN, OCN
- W-4 Patient Attitudes Regarding Breast Cancer and Breast Cancer Risk**
The presentation should enable the participant to describe how patient attitudes affect decision making; describe how patients' attitudes and beliefs affect response to information; and determine what health professionals can do to enhance delivery of the information to the patients and improve patient outcomes.
Suzanne Miller, Ph.D., Moderator, Michael A. Diefenbach, Ph.D.,
Carolyn Y. Fang, Ph.D., Linda G. Fleisher, M.P.H., C.H.E.S.

4:45 p.m. Shuttle to Park Hyatt Philadelphia at the Bellevue

FACULTY

- Gwen A. Bednarz, RN, MSN, OCN**
 Clinical Manager
 Fox Chase Cancer Center
 Philadelphia, PA
- Marcia Boraas, M.D.**
 Breast Surgeon
 Fox Chase Cancer Center
 Philadelphia, PA
- Josephine Costalas, M.Sc.**
 Cancer Genetics Counselor, Margaret
 Dyson Family Risk Assessment Program
 Fox Chase Cancer Center
 Philadelphia, PA
- Mary B. Daly, M.D., Ph.D.**
 Associate Director, Cancer Control
 Science Program
 Fox Chase Cancer Center
 Philadelphia, PA
- Michael A. Diefenbach, Ph.D.**
 Assistant Member
 Fox Chase Cancer Center
 Philadelphia, PA
- Linda G. Fleisher, M.P.H., C.H.E.S.**
 Director, Cancer Information Service
 and Outreach Program
 Fox Chase Cancer Center
 Philadelphia, PA
- Bernard Fisher, M.D.**
 Scientific Director
 National Surgical Adjuvant Breast and
 Bowel Project
 University of Pittsburgh School
 of Medicine
 Pittsburgh, PA
- Stephen A. Feig, M.D.**
 Professor of Radiology
 Jefferson Medical College
 Director, Breast Imaging Center
 Thomas Jefferson University Hospital
 Philadelphia, PA
- Carolyn Y. Fang, Ph.D.**
 Assistant Member
 Fox Chase Cancer Center
 Philadelphia, PA
- Richard Kostrowski, M.D.**
 Medical Director,
 North Penn Cancer Program
 North Penn Hospital
 Lansdale, PA
- Ginny Martin, RN, MSN, AOCN**
 Clinical Director, Ambulatory Care
 Fox Chase Cancer Center
 Philadelphia, PA
- Suzanne Miller, Ph.D.**
 Senior Member and Director,
 Psychosocial and Behavioral
 Medicine Program
 Fox Chase Cancer Center
 Philadelphia, PA
- Howard B. Kessler, M.D.**
 Chief, Breast Imaging; Co-Director,
 Cross-Sectional Imaging
 Fox Chase Cancer Center
 Philadelphia, PA
- Karin G. Hoffmann, R.N., C.C.M.**
 Clinical Standards Coordinator
 Fox Chase Cancer Center
 Philadelphia, PA
- Lori J. Goldstein, M.D.**
 Director, Breast Evaluation Center
 Fox Chase Cancer Center
 Philadelphia, PA
- Andrew K. Godwin, Ph.D.**
 Associate Member
 Fox Chase Cancer Center
 Philadelphia, PA
- Barbara L. Fowble, M.D.**
 Associate Director,
 Breast Cancer Program
 Fox Chase Cancer Center
 Philadelphia, PA
- Barbara L. Fowble, M.D.**
 Chief, Breast Cancer Medicine Service
 Noma S. Sarofim Chair of
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- Professor of Medicine**
 Cornell University Medical College
 New York, NY
- Arthur S. Patchefsky, M.D.**
 Chairman, Department of Pathology
 Fox Chase Cancer Center
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- Elin Sigurdson, M.D., Ph.D.**
 Head of Surgical Research
 Fox Chase Cancer Center
 Philadelphia, PA
- Dennis J. Slamon, M.D., Ph.D.**
 Professor of Medicine
 UCLA School of Medicine
 Chief, Division of
 Hematology/Oncology
 Director of Clinical/Translational
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 Jonsson Comprehensive
 Cancer Center
 Los Angeles, CA
- Carolyn Weaver, RN, MSN, OCN**
 Patient Education Coordinator and
 Staff Development Instructor
 Fox Chase Cancer Center
 Philadelphia, PA
- Louis M. Weiner, M.D.**
 Chairman, Department of
 Medical Oncology
 Fox Chase Cancer Center
 Philadelphia, PA

Appendix B

Pre-Test
Hunterdon Family Practice Residents
Genetics in Oncology Course

1. Which of the following characteristics is associated with hereditary cancer?
 - a. late stage at diagnosis
 - b. early age at onset
 - c. poor response to treatment
 - d. obesity

answer _____

2. Which of the following reasons suggest that colon cancers in a family are sporadic rather than hereditary?
 - a. late age at onset
 - b. cancer history on paternal side of the family
 - c. shared environment
 - d. left-sided cancer

answer _____

3. Which of the following syndromes is not associated with hereditary cancer?
 - a. Li Fraumeni syndrome
 - b. MEN syndrome
 - c. Fragile X syndrome
 - d. Lynch syndrome

answer _____

4. Which non-malignant genetic condition is associated with hereditary cancer?
 - a. cystic fibrosis
 - b. adenomatous polyp
 - c. fibrocystic breast disease
 - d. Huntington's chorea

answer _____

5. Which of the following statements best applies to the FUNCTION of a gene?
 - a. is made of DNA base pairs
 - b. is part of a chromosome
 - c. codes for a protein
 - d. humans have 23 pairs

a n s w e r _____

6. Choose the statement which best describes the effect of a DNA change on a protein coded by a gene.
 - a. DNA changes can have no effect, can alter the function, or can destroy the function of a protein
 - b. DNA changes either alter or destroy the function of a protein
 - c. DNA changes destroy the function of a protein
 - d. DNA changes have no effect or destroy the function of a protein

a n s w e r _____

7. Which of the following statements is false?

- a. An autosomal dominant cancer generally shows a vertical pattern of inheritance.
- b. An autosomal dominant pattern of cancer cannot be caused by the inheritance of a recessive mutation.
- c. An autosomal recessive cancer generally shows a horizontal pattern of inheritance.
- d. An autosomal recessive pattern for cancer cannot be caused by the inheritance of a dominant mutation.

answer _____

8. For BRCA1 and breast cancer, which of the following statements is true?

- a. women who inherit one mutant allele will develop cancer
- b. women who inherit two normal alleles will not develop cancer
- c. both a and b are true
- d. both a and b are false

answer _____

9. Which of the following would not be included as a purpose for obtaining a cancer family history?

- a. to help determine risk for an inheritable cancer
- b. to change the patient's perception of risk
- c. to provide a basis for cancer screening guidelines

answer _____

10. Ideally, data on how many generations should be included in the cancer family history?

- a. one
- b. two
- c. three

answer _____

11. In the current genetic literature what percentage of reported ovarian cancers are inaccurate?

- a. twenty percent
- b. thirty percent
- c. forty percent

answer _____

12. A risk estimate that provides an estimation of cancer risk for each subsequent decade of life based on specific variables is called:

- a. relative risk
- b. lifetime risk
- c. cumulative risk
- d. absolute risk

answer _____

13. The Claus model allows for estimation of risk for individuals with a family history of which cancer:

- a. breast
- b. ovarian
- c. colon

answer _____

14. Which risk model would provide the most appropriate estimate of risk for a woman undergoing regular screening for breast cancer and having a sporadic family pattern of breast cancer?

- a. Claus model
- b. Gail model
- c. LOD score

answer _____

15. Which of the following types of genetic test for cancer predisposition is the most accurate?

- a. linkage analysis with a large family
- b. linkage analysis with a small family
- c. DNA or protein analysis with a known mutation
- d. DNA or protein analysis with an unknown mutation

answer _____

16. Which of the following statements is false?

- a. Women with a BRCA1 mutation have an 80-85% lifetime risk of breast cancer.
- b. Men with a BRCA1 mutation have no increased risk of cancer.
- c. Mutations in some cancer genes virtually guarantee the development of cancer.
- d. Men with an APC mutation have a 50% risk of passing the gene on to each of their children.

answer _____

17. The National Center for Human Genome Research currently recommends that DNA testing for presymptomatic identification of cancer risk be done only in a research setting.

- a. true
- b. false

answer _____

18. Which of the following is NOT a benefit of genetic testing by linkage analysis?

- a. earliest test available-can be used before exact gene location is known
- b. mutant genes identified are known to cause disease
- c. option when mutation cannot be found with other tests
- d. may not need to test other family members

answer _____

19. Which of the following is NOT a limitation of genetic testing by DNA analysis?

- a. can't always distinguish mutations from polymorphisms
- b. must have large, informative family with available samples
- c. can miss mutations in parts of gene that are not tested
- d. test of first family member is slow and expensive, especially for large genes

answer _____

20. Which of the following is NOT a benefit of genetic testing by protein analysis?

- a. relatively fast and cheap
- b. detects changes more likely to be mutations than polymorphisms
- c. can detect most mutations, regardless of type
- d. works well on any size gene

answer _____

21. Which of the following offer 100% protection against breast cancer?

- a. multiparity
- b. low fat diet
- c. prophylactic mastectomy
- d. none of the above

answer _____

22. Which of the following screening tests are recommended for hereditary colon cancer?

- a. flexible sigmoidoscopy
- b. CEA level
- c. colonoscopy
- d. barium enema

answer _____

23. Which of the following methods are used to screen high risk women for ovarian cancer?

- a. pelvic exam, CEA, ultrasound
- b. pelvic exam, CT scan
- c. pelvic exam, CA-125, ultrasound
- d. pelvic exam, pap smear

answer _____

24. Which of the following offers the best method for secondary prevention of breast cancer in young, high risk women?

- a. birth control pills
- b. breast self-exam
- c. mammography
- d. ultrasonography

answer _____

25. Which strategies have proven efficacy in reducing the incidence of colon cancer?

- a. low fat diet
- b. biannual sigmoidoscopy
- c. annual Hemocult testing
- d. daily aspirin

answer _____

26. BRCA1/2 testing should be offered to which population groups?

- a. all breast cancer patients
- b. all Jewish women
- c. all sisters of breast cancer patients
- d. all of the above
- e. none of the above

answer _____

27. Emotional reactions to cancer risk information include anxiety, fear, embarrassment, and guilt.

- a. True
- b. False

answer _____

28. Genetic information is unique in that it has implications for which of the following?

- a. the patient only
- b. patient and partner
- c. patient and other family members across generations

answer _____

29. Which of the following are considered ethical and/or legal concerns related to predictive testing for cancer susceptibility?

- a. informed consent
- b. privacy and confidentiality
- c. discrimination issues
- d. all of the above

answer _____

30. List four resources providing cancer risk assessment.

31. List four resources providing genetic testing.

32. List four resources providing cancer prevention and control trials.

33. Use the scale below to rate how confident you currently feel about performing each of the skills listed below. *Write the number on the line.*

1 = not confident at all, would definitely not try

2 = some confidence, might try

3 = fairly confident, likely to try

4 = very confident, would definitely try

- _____ a. recognize patients whose medical or family history may put them at increased risk for cancer
- _____ b. use a basic knowledge of molecular genetics to help understand genetic testing, and the inheritance and development of cancer
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- _____ e. inform patients of available genetic tests and their risks and benefits
- _____ f. provide medical management for high risk patients
- _____ g. provide counseling for patients in the areas of risk notification and informed consent for genetic testing and cancer prevention/control strategies
- _____ h. refer patients to available resources providing cancer risk assessment, genetic testing, and cancer prevention and control trials

34. As family practitioners, you see patients for a wide variety of reasons. List several situations where you think it would be appropriate to bring up the topic of inherited cancer risk.

Post-Test
Hunterdon Family Practice Residents
Genetics in Oncology Course

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- _____ e. inform patients of available genetic tests and their risks and benefits
- _____ f. provide medical management for high risk patients
- _____ g. provide counseling for patients in the areas of risk notification and informed consent for genetic testing and cancer prevention/control strategies
- _____ h. refer patients to available resources providing cancer risk assessment, genetic testing, and cancer prevention and control trials

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Class One: Identifying Families at Risk

I. Recognizing Familial Cancer: Dr. Mary Daly

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all

II. Molecular Genetics of Cancer: Dr. Cindy Keleher

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all

III. Obtaining a Family History and Pedigree Construction: Agnes Masny

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all

IV. Workshop: Patient Identification, Family History, and Pedigree Construction

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all
3. Please describe on the back of the page what you liked or found most useful in the whole class.
4. Please describe on the back of the page how the class could be improved.

Class Two: Risk Estimation

I. Risk Estimation: Traditional: Agnes Masny

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How could we improve the clarity of the presentation?
3. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all
4. How could we make the material more useable in your current practice?

II. Cancer Genetic Testing: Dr. Cindy Keleher

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How could we improve the clarity of the presentation?
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 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all
4. How could we make the material more useable in your current practice?

III. Risk Estimation Based on Genetic Testing: Dr. Cindy Keleher

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little

2. How could we improve the clarity of the presentation?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all

4. How could we make the material more useable in your current practice?

IV. Workshop: Risk Estimation

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little

2. How could we improve the clarity of the presentation?

3. How useful do you feel the material will be to you in your practice?
 - extremely useful
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 - somewhat useful
 - not useful at all

4. How could we make the material more useable in your current practice?

5. Please describe on the back of the page what you liked or found most useful in the whole class.

6. Please describe on the back of the page how the class could be improved.

Class Three: Counseling

I.

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How could we improve the clarity of the presentation?
3. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all
4. How could we make the material more usable in your current practice?

II.

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How could we improve the clarity of the presentation?
3. How useful do you feel the material will be to you in your practice?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all
4. How could we make the material more usable in your current practice?

III.

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little

2. How could we improve the clarity of the presentation?
 - extremely useful
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 - somewhat useful
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IV. Workshop: Counseling

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 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little

2. How could we improve the clarity of the presentation?

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 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all

4. How could we make the material more usable in your current practice?

5. Please describe on the back of the page what you liked or found most useful in the whole class.

6. Please describe on the back of the page how the class could be improved.

Class Four: Future and Review

I. Practical Considerations (first three speakers)

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little
2. How could we improve the clarity of the presentation?
3. How useful do you feel the material will be to you in your practice?
 - extremely useful
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4. How could we make the material more usable in your current practice?

II. Genes and Common Cancers: Cynthia Keleher

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
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 - not clear, I understood very little
2. How could we improve the clarity of the presentation?
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4. How could we make the material more usable in your current practice?

III. Review and Workshop Introduction: Mary Daly

1. How clearly was the material presented?
 - very clear, I understood everything
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 - somewhat clear, I understood some things
 - not clear, I understood very little

2. How could we improve the clarity of the presentation?
 - extremely useful
 - fairly useful
 - somewhat useful
 - not useful at all

4. How could we make the material more usable in your current practice?

IV. Workshop: Case Study Review of Risk Assessment and Counseling

1. How clearly was the material presented?
 - very clear, I understood everything
 - fairly clear, I understood most things
 - somewhat clear, I understood some things
 - not clear, I understood very little

2. How could we improve the clarity of the presentation?

3. How useful do you feel the material will be to you in your practice?
 - extremely useful
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 - not useful at all

4. How could we make the material more usable in your current practice?

5. Please describe on the back of the page what you liked or found most useful in the whole class.

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Appendix C

DOD High Risk Registry Predisclosure Genetic Counseling Protocol

Purpose: The predisclosure session serves to:

1. Review the benefits and limitations related to genetic testing
2. Review the risk associated with genetic test results
3. Help to examine anticipated psychosocial and emotional concerns and impact from either a positive or negative genetic test result for her and her family.
4. Identify support system available to the consultand
5. Identify coping issues that need to be addressed prior to receipt of genetic test results

Format: Predisclosure counseling session (approximately 1 to 1 and 1/2 hours) utilizing presentation of information, counseling, and role play. The role play specifically makes use of cognitive affective processing to help the consultand more realistically understand the impact of genetic test results.

Staff Considerations:

- Genetic Counselor **and/or**
- Nurse trained in Counseling aspects of genetic test results **and/or**
- Social Worker or staff with counseling skills

Predisclosure Process

1. Announcement of availability of test results
 - a. Letter or phone call announcing availability of test results
 - b. Arrange appointment date for predisclosure counseling session
 - c. consultand and other family members can attend
 - d. consultand informed that present at the session will be:
 - a genetic counselor and a nurse trained in genetic counseling or
 - both a genetic counselor and social worker or
 - both a nurse trained in genetic counseling and a social worker
2. Predisclosure counseling session
 - a. Explain purpose of visit
 - b. Provide consultand with information on the following:
 - 1) the implications of carrying an alteration in BRCA1 or BRCA2 gene
 - 2) the implications of not carrying an alteration in BRCA1 or BRCA2 gene
 - 3) spectrum of cancers involved
 - 4) limitations of test results
 - 5) sensitivity and specificity of test results
 - 6) possible impact of positive result of BRCA1 or BRCA2 on confidentiality, insurance, medical decisions, family dynamics.
 - 7) early detection and preventive options for carrier and non-carrier status
 - c. Conduct assessment of coping mechanisms for the following:
 - 1) impact of being a carrier
 - 2) impact of not being a carrier
 - 3) the choice of not receiving results
 - 4) impact on relaying genetic test information to other family members,
 - 5) impact on relaying genetic test information to medical professionals
 - 6) use of social supports

- d. Role play two scenarios for receipt of genetic test results
 - 1) Patient is asked to imagine that they are receiving their results as a carrier of an alteration in the BRCA1 gene with exploration of the following:
 - what is the personal impact
 - what is the impact that this will have for family and significant others
 - 2) Patient is asked to imagine that they are receiving their results as not being a carrier of an alteration in the BRCA1 gene with exploration of the following:
 - what is the personal impact
 - what is the impact that this will have for family and significant others
- e. Discuss psychology referral if necessary
- f. Ascertain if results are still wanted
- g. Obtain informed consent
- h. Obtain sample of blood for re-testing for quality assurance
- i. Determine arrangements for result notification (i.e. alone, with family, timing)
- j. Inform consultant that notification for appointment will be in 4 to 6 weeks
- k. Inform consultant of professional participants who will be present for disclosure (See requirements for disclosure)

Predisclosure Staff Considerations: to have a least two staff persons attend predisclosure

Options (O) /Limitations (L)/ Benefits (B):

1. O: • Send consultant to Fox Chase for predisclosure.
 L: • The relationship that was built with Network staff will be missing.
 • Issues that may have been identified by Network staff may not be as clear.
 B: • Privacy will be better ensured.
 • No additional Network staff or travel required.
2. O: • Genetic Counselor from Fox Chase and Network nurse trained in genetic counseling conduct predisclosure at Fox Chase.
 L: • Require patient and Network staff to travel
 B: • Relationship built by Network staff will be maintained.
 • Consistency in addressing issues already identified by Network Staff
 • Privacy will be better ensured since only Network staff person with the patient will know that person is coming for predisclosure counseling.
3. O: • Genetic Counselor from Fox Chase and Network nurse trained in genetic counseling conduct predisclosure at Network Hospital.
 L: • Possible delays due to scheduling
 • Possible privacy issues where patient is better known in their own community setting.
 B: • Relationship built by Network staff will be maintained.
 • Consistency in addressing issues already identified by Network Staff
4. O: • Network nurse and genetic counselor or social worker receive training from Fox Chase to conduct predisclosure at Network Hospital.
 L: • Possible privacy issues where patient is better known in their own community setting.
 • Requires staff and time commitment by Network Hospital
 B: • Relationship built by Network staff will be maintained.
 • Consistency in addressing issues already identified by Network Staff

DOD High Risk Registry Disclosure Genetic Counseling Protocol

Purpose: The disclosure session serves to:

1. Provide consultand with genetic testing results
2. Provide consultand with the opportunity to obtain the following:
 - a. answers to questions regarding the results
 - b. information regarding support resources, i.e. social work, referrals
 - c. information on preventive options
 - d. information on medical management
 - e. implications of test results for family
3. Help to adjust to psychosocial and emotional concerns and impact from either a positive or negative genetic test result for her and her family.
4. Identify support system available to the consultand
5. Identify coping issues that need to be addressed
6. Help to develop a plan for communicating results to family
7. Help to develop a plan for communicating results to medical professionals

Format: Disclosure counseling session (approximately 1 hour) utilizes a team approach with presentation of information, discussion and counseling.

Staff Considerations:

- Genetic Counselor **and/or**
- Nurse trained in Counseling aspects of genetic test results **and/or**
- Social Worker or staff with counseling skills **and**
- Medical Oncologist

Disclosure Process

1. Appointment made for disclosure
 - a. confirm desire to receive results
 - b. confirm configuration of disclosure session
 - 1) who will accompany consultand
 - 2) which health professional will be present at the session
 - c. arrange appointment date
2. Provide information on the purpose of the visit.
3. Obtain informed consent for receipt of genetic test results.
4. Communicate test results
5. Assess understanding of test result
 - a. if necessary review implications of test result
 - b. answer any questions
6. Provide information and counseling on medical management
 - a. screening
 - b. lifestyle/behavior changes
 - c. medical follow-up
 - d. preventive options/prophylactic surgery

7. Discuss plan for communicating results
 - a. privacy issues - at the present time Fox Chase does not include genetic test results as part of the medical record and will not communicate the results to other health care professionals. Options are given
 - 1) permission to team to share results with a medical professional
 - 2) consultant will share result with medical professional
 - 3) consultant will share result with other family members or friends
 - b. discuss privacy implications if consultant chooses to share results.
 - c. obtain informed consent for communicating results to medical professional or other parties.

8. Discuss follow-up resources
 - a. Staff availability to answer future questions or to provide direction to resources
 - b. Follow-up plan
 - 1) inform patient of scheduled telephone follow-up (See Follow-up)

9. Identify outstanding concerns or psychological issues.
 - a. address issues or provide referrals as necessary

10. Inform consultant regarding follow-up research
 - a. as genetic information advances consultant may be contacted with new information
 - b. follow-up questionnaires. Explain rationale for follow-up. Since genetic testing is new it will be very helpful for the client and future participants to understand the long-term impact of receiving genetic test results. Therefore, the consultant and those receiving test results will be contacted by the Fox Chase Cancer Center either by phone or mail to complete follow-up questionnaires.

Disclosure Staff Considerations: to have a least two staff persons attend disclosure, medical oncologist or physician should be part of the team.

Options (O) /Limitations (L)/ Benefits (B):

1. O: • Send consultant to Fox Chase for disclosure.
 L: • The relationship that was built with Network staff will be missing.
 • Potential lack of consistency in medical management and follow-up issues.
 B: • Privacy will be better ensured.
 • No additional Network staff or travel required.

2. O: • Genetic Counselor from Fox Chase and Network nurse trained in genetic counseling conduct disclosure at Fox Chase.
 L: • Require patient and Network staff to travel.
 B: • Relationship built by Network staff will be maintained.
 • Consistency in addressing follow-up and medical management issues.
 • Privacy will be better ensured since only Network staff person with the patient will know that person is coming for disclosure counseling.

3. O: • Genetic Counselor from Fox Chase and Network nurse trained in genetic counseling conduct disclosure at Network Hospital.
 L: • Possible delays due to scheduling
 • Possible privacy issues where patient is better known in their own community setting.
 B: • Relationship built by Network staff will be maintained.
 • Consistency in addressing follow-up and medical management issues.

- 4. O: • Network nurse and genetic counselor or social worker receive training from Fox Chase to conduct disclosure at Network Hospital.
- L: • Possible privacy issues where patient is better known in their own community setting.
 - Requires staff and time commitment by Network Hospital
- B: • Relationship built by Network staff will be maintained.
 - Consistency in addressing follow-up and medical management issues.

DOD High Risk Registry Post-disclosure Follow-up

Purpose: The post-disclosure follow-up serves to :

1. Evaluate the impact of genetic test results.
2. Assess sequela of test results related to psychological, social, and family issues.
3. Assess adherence to screening and medical management plan.
4. Provide information on resources/referrals if needed.

Format: Telephone call at 1 month and 12 months post-disclosure.

Staff Considerations:

- Genetic Counselor **and/or**
- Nurse trained in Counseling aspects of genetic test results **and/or**
- Social Worker or staff with counseling skills
- Availability of resources or referral to social work or counseling services

Follow-up Process

1. One month follow-up telephone call for feedback and assessment of impact of results.
 - a. structured survey tool to help identify impact of test results, changes in medical or family history, current medical and screening practices.
 - b. address clients questions or concerns.
 - c. provide Network resources or referrals as needed.
 - d. inform client of next scheduled follow-up (at 12 months) and encourage earlier contact if issues arise.
2. Twelve month follow-up telephone call for feedback and assessment of impact of results.
 - a. structured survey tool to help identify impact of test results, changes in medical or family history, current medical and screening practices.
 - b. address clients questions or concerns.
 - c. provide Network resources or referrals as needed.
 - d. inform client of possible future contacts for research or genetic updates.

Post-disclosure Staff Considerations: to have a staff persons available to make phone call and address issues of client

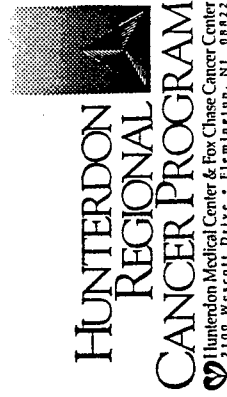
Options (O) /Limitations (L)/ Benefits (B):

1. O: • Have Fox Chase Staff provide follow-up. This option is possible only for those who received test results at Fox Chase.
L: • Potential lack of consistency in medical management and follow-up issues.
B: • No additional Network staff required.
2. O: • Network nurse trained in genetic counseling conducts follow-up
L: • Requires additional staff time.
B: • Relationship built by Network staff will be maintained.
• Consistency in addressing follow-up and medical management issues.
• Better linkage to community resources.

Appendix D

Family
Risk
Assessment
Program

An educational program
designed for individuals
with a personal or family
history of breast cancer.



19012/2093

*Ms. Agnes Murray, RN, MPH
Family Risk Assessment Program
Fox Chase Cancer Center
510 Kourmalip Drive Road
Chestertown, PA 19012*

The Family Risk Assessment
Program will be coordinated by:

Margaret Doyle, RN, BSN, OCN

Medical Advisors to this program

Brian M. Quinn, MD
medical oncologist

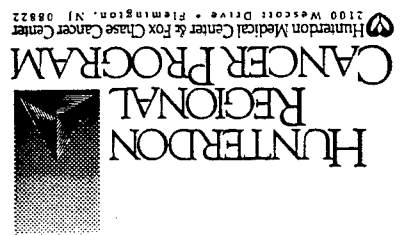
♦ ♦ ♦ ♦ ♦

Carla Jardim, MD
family physician

For more information.....

If you would like more information
about this, or other health-related
educational programs through the
Hunterdon Regional Cancer Program

call 908-788-6514.



Some Cancers Can "Run In Families"

Studies have shown that certain cancers may be inherited, or "run in families." Breast, ovarian, colon, uterine, skin and prostate are some of the cancers that can run in families.

Technological advances in genetics are revolutionizing the way medicine is practiced. Scientists are trying to understand these hereditary factors, or genes, that can influence the risk for cancer.

D5
08

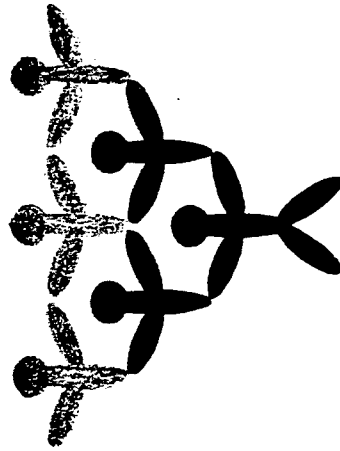
Family Risk Assessment Program

The *Family Risk Assessment Program* at Hunterdon Medical Center is an educational program designed to help individuals with a family history of breast cancer understand hereditary factors that can influence their risk of breast cancer.

The *Family Risk Assessment Program* is modeled after the Margaret Dyson Family Risk Assessment Program established in 1991 by Fox Chase Cancer Center in Philadelphia. This multi-disciplinary cancer risk assessment and counseling program is open to individuals with a family or personal history of breast cancer. Participants should be at least 20 years old.

Family Risk Assessment Program includes:

- ◆ a group educational session about risk factors and familial patterns associated with breast cancer
- ◆ a detailed evaluation of the family history (if desired)
- ◆ a description of recommended screening tests and personalized screening recommendations
- ◆ instruction in breast self exam techniques if desired
- ◆ the option of participating in genetic research through Fox Chase Cancer Center for eligible individuals.



Hunterdon Regional Cancer Program

The Hunterdon Regional Cancer Program is a member of the Fox Chase Network, a select group of hospitals in New Jersey and Pennsylvania working with Fox Chase Cancer Center in Philadelphia to offer the latest in cancer prevention, detection, and treatment to people in their own communities. Fox Chase Cancer Center, one of 27 NCI-designated comprehensive cancer care centers, has demonstrated a long tradition of excellence in genetics research. The creation of the *Margaret Dyson Family Risk Assessment Program* was in response to a growing public demand for more information about genetics and the risks of developing breast cancer.

Hunterdon Regional Cancer Program and YOU...together we are partners in prevention.

FAMILY RISK ASSESSMENT PROGRAM

To Identify Breast Cancer Risk

**Programs will
be held in
The Priscilla
Payne Hurd
Education
Center**

**Please call
610-954-3580
for information
on dates and
times of
programs.**

Are you a female over the age of 20 with a mother, sister or daughter who has, or has had, breast cancer?

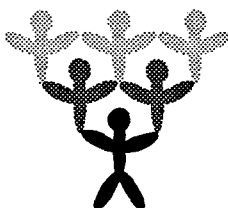
The Family Risk Assessment Program at St. Luke's Hospital's Regional Cancer Center is designed to educate and monitor women who have an increased risk of developing breast cancer based on family history.

Family Risk Assessment Program Features

- a free two-hour group information session on breast cancer
- an explanation of the known risk factors for breast cancer
- a detailed evaluation of each woman's personal and family history
- a description of breast cancer screening tests and a personalized screening recommendation
- a review of early detection options, including instruction in breast self-examination techniques, and prevention measures
- the option to participate in genetic testing research (for eligible individuals) through Fox Chase Cancer Center

St. Luke's Hospital Regional Cancer Center

St. Luke's Hospital's Regional Cancer Center, an affiliate of the Fox Chase Cancer Center through the Fox Chase Network, offers complete patient cancer care in its state-of-the-art Bethlehem facility. The Regional Cancer Center works with Fox Chase Cancer Center to provide cancer research, prevention, diagnosis and treatment close to home. The center also features a Comprehensive Breast Care Program, a Pain Management Program and a Second Opinion Service.



THE MARGARET DYSON
Family Risk Assessment Program®



*A joint program for
cancer research,
treatment &
education
St. Luke's Hospital
& Fox Chase
Cancer Center*

801 Ostrum St. • Bethlehem, PA 18015 • 610-954-3580

A member of the Eastern Pennsylvania Health Network

FAMILY RISK ASSESSMENT PROGRAM



To Identify Breast Cancer Risk

The Family Risk Assessment Program at St. Luke's Hospital's Regional Cancer Center provides women with the most up-to-date information on hereditary risk factors associated with breast cancer. The program offers education and counseling tailored to the individual needs of each woman, based on her medical and family history.

St Luke's
HOSPITAL

Big-city medicine. Hometown care.

801 Ostrum Street • Bethlehem, PA 18015
610-954-4000

A member of the Eastern Pennsylvania Health Network



St Luke's
REGIONAL
CANCER CENTER

Heredity and Research



Recent studies show that certain types of cancer may be hereditary, or passed from generation to generation. According to current research, genetic factors play a part in 5 to 10 percent of breast cancers.

Scientists continue to study how heredity factors, or genes, influence the risk for cancer. Finding changes or alterations in genes passed from one generation to the next will help researchers understand what makes a person more susceptible to hereditary cancers like breast, ovarian, colon, uterine, skin and prostate cancers.

Program Features

The Family Risk Assessment Program provides participants with the most current research on identifying breast cancer genes. As genes are identified, eligible individuals and their families will have the option to have a blood test to determine if they have inherited a cancer gene. Other parts of the program include:

- a free two-hour group information session on breast cancer
- an explanation of the known risk factors for breast cancer
- a detailed evaluation of each woman's personal and family history
- a description of breast cancer screening tests and a personalized screening recommendation
- a review of early detection options, including instruction in breast self-examination techniques, and prevention measures
- the option to participate in genetic research and testing (for eligible individuals) through Fox Chase Cancer Center

Eligibility

Women with a family history of breast cancer are eligible for the Family Risk Assessment Program. Participants must be at least 20 years old and have at least one first-degree relative — mother, sister or daughter — who has or has had breast cancer.

St. Luke's Hospital Regional Cancer Center

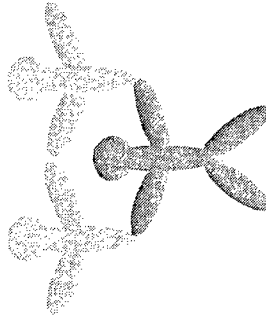
St. Luke's Hospital's Regional Cancer Center, an affiliate of the Fox Chase Cancer Center in Philadelphia, offers complete patient cancer care in its state-of-the-art Bethlehem facility. The Regional Cancer Center works with Fox Chase Cancer Center to provide cancer research, prevention, diagnosis and treatment close to home. The center also features a Comprehensive Breast Care Program, a Pain Management Program and a Second Opinion Service.

For More Information

To learn more about this program, or to register for an information session, call the Regional Cancer Center at 610-954-3580.

Family Risk Assessment Program

New Program to Identify Breast Cancer Risk



THE MARGARET DYSON
Family Risk Assessment Program™

THE CANCER CENTER
OF PAOLI MEMORIAL HOSPITAL & FOX CHASE CANCER CENTER
PAOLI MEMORIAL HOSPITAL

For More Information

For more information about this program, call the Risk Assessment Counselor at Paoli Memorial Hospital, 610-648-1608.

THE CANCER CENTER
OF PAOLI MEMORIAL HOSPITAL & FOX CHASE CANCER CENTER
PAOLI MEMORIAL HOSPITAL

3/96

Studies show that certain cancers may be hereditary, or "run in families." Breast, ovarian, colon, uterine, skin and prostate cancers are some of the cancers that can be hereditary. Five to ten percent of breast cancers are due to presently known genetic factors that are passed on from one generation to the next.

Heredity and Research

Scientists are trying to understand these hereditary factors, or genes, that can influence the risk for cancer. By finding changes or alterations in genes passed from one generation to the next, we learn what can make a person more susceptible to hereditary cancers.

Family Risk Assessment Program

The program's goal is to help women learn more about risk factors associated with breast cancer. This free program provides participants with up-to-date information on the familial patterns of these cancers and information on how pregnancy history, hormone use and diet may be related to breast cancer. Participants learn about screening guidelines and prevention options.

Eligibility

Women with a family history of breast cancer are eligible for the Family Risk Assessment Program. Participants should be at least 20 years old and have at least one first-degree relative—mother, sister or daughter—with breast cancer.

Program Features

The program offers education and counseling tailored to the individual needs of each woman, based on her medical and family history. The program includes:

- a two-hour, group information session on breast cancer;
- an explanation of the known risk factors for breast cancer and how they work;
- a detailed evaluation of the family history;
- a description of recommended screening tests and personalized screening recommendations;
- instruction in breast self-examination techniques, if desired; and
- the option to participate in genetic research and testing through Fox Chase Cancer Center for eligible individuals.

The current research to identify genes for breast cancer will be explained to program participants. As genes are identified, eligible individuals and their families may have the option to have a blood test to determine if they have inherited a cancer gene. Options for early detection and prevention of cancer also are discussed.

The Cancer Center

The Cancer Center at Paoli Memorial Hospital is affiliated with the Fox Chase Cancer Center through the Fox Chase Network. The Fox Chase Network is a select group of community hospitals that work cooperatively with Fox Chase Cancer Center to provide the latest in cancer prevention, diagnosis and treatment to people in their own communities.

Healthy Neighbors

HEALTH EDUCATION & WELL-BEING

Health and Education Programs
May & June 1996

Family Risk Assessment Program

Be Stroke Smart
A Celebration of Good Health!

Skin Cancer Screening

Kids and Nutrition:
Launch a Lunar Lunch

Registration
610-648-1660

PAOLI MEMORIAL HOSPITAL
Jefferson Health System

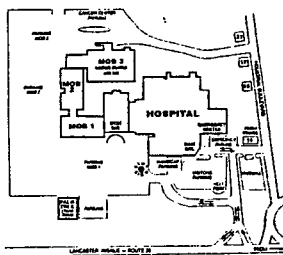
BECAUSE GOOD HEALTH IS PRIMARY



PAOLI MEMORIAL HOSPITAL
Jefferson Health System
255 W. Lancaster Pike, Paoli, PA 19301-1792

NON-PROFIT
ORGANIZATION
US Postage Paid
Paoli, PA
Permit #86

Dated material enclosed



Family Risk Assessment Program

Do you have a mother, sister or daughter
who has, or has had, breast cancer?

Then, the Family Risk Assessment Program may interest you! Having a family history of breast cancer can increase a woman's risk for developing breast cancer. Attend the following meetings to learn about this special program, sponsored by Paoli Memorial Hospital, a Fox Chase Cancer Center Network Affiliate.

Thursday, May 16 and Monday, June 3
7:00-8:30 PM
Malvern Room
Paoli Memorial Hospital

Topics at this information meeting include:

- an explanation of the known risk factors for breast cancer and how they work
- the impact of family history as a risk factor
- a discussion of presently known genetic factors that predispose to hereditary breast cancer
- an introduction to the formal process of Risk Assessment for eligible individuals at Paoli Memorial Hospital and Fox Chase Cancer Center.

To register, call the Community Education Office
at 610-648-1660

Watch "Health Matters" with Pat Ciarrocchi on KYW-TV 3.
Check your local listings for dates and times.

MAY/JUNE 1996

PAOLI MEMORIAL HOSPITAL Jefferson Health System

EDUCATION PROGRAMS

Living Well With Arthritis
Join us at Bryn Mawr Rehab for a free event on managing your arthritis. Lectures will be given by a rehabilitation physician and a rheumatologist. Also included will be demonstrations on aquatic therapy and the use of assistive devices. Light meal will be served.
Wednesday, May 8, 5:00 pm
Bryn Mawr Rehab, 414 Paoli Pike, Malvern
No fee; pre-registration required.

Be Stroke Smart

A Celebration of Good Health!
A free program focusing on stroke prevention, treatment and risk factors. Included will be a panel discussion, including a nutritionist, physical therapist and neurologist, free cholesterol and blood pressure testing, educational exhibits and interactive booths. Healthy refreshments will be served.
Speaker: Lester Dewis, MD, Bryn Mawr Rehab, Paoli Pike, Malvern
Tuesday, May 14, 5:30 pm
Bryn Mawr Rehab, Paoli Pike, Malvern
No fee; pre-registration required.

CPR Module 1

Adult CPR and choke-saving class taught by an AHA instructor.
Wednesday, May 1 and Thursday, June 6, 6:00-10:00 pm
Paoli Pointe Building
\$20/person; pre-registration required.

Breast Health Education Program

This interactive program is available for all women's groups in churches, clubs, the workplace, and private homes. The free program, with educational materials supplied through the American Cancer Society, provides women with information and skills needed for good breast health. For more information or to schedule a presentation, please call the BREAST HEALTH EDUCATION line at 610-645-8557. This program could be a gift of a lifetime...

CPR Module 2

Infant/child CPR and choke-saving class taught by an AHA instructor.
May 13 and 14 or June 10 and 11, 6:00-9:00 pm
Paoli Pointe Building
\$27/person; pre-registration required.

CPR Module 3

Two-day class for healthcare professionals
Adult and infant/child CPR, one and two rescuer, and choke-saving class taught by an AHA instructor.
May 21 and 22, 6:00-10:00 pm
Paoli Pointe Building
\$52/person; pre-registration required.

Laparoscopic Procedures Update

Current update on laparoscopic techniques that have revolutionized modern surgery. *Speaker: Robert Fried, MD, PMH Surgeon*
Tuesday, May 14, 7:00-8:30 pm
Malvern Room, West Entrance
No fee; pre-registration required.

Long Term Care Options

An unbiased look at long term care choices including nursing homes, long term care insurance, retirement communities and more. *Presented by PMH's Health Insurance Information Program volunteers*
Monday, May 6, 7:30-9:00 pm
Malvern Room, West Entrance
No fee; pre-registration required.

Migraine Headaches

Attend this program to learn about the causes, symptoms and cures for migraine headaches. *Speaker: Thomas Graham, MD, PMH Neurologist*
Thursday, June 13, 7:00-8:30 pm
Malvern Room, West Entrance
No fee; pre-registration required.
Hosted by Cerenex Pharmaceuticals

WELL-COME Neighbors

Area community members are invited to join us for a light dinner while becoming acquainted with Paoli Memorial Hospital's campus and services.
Tuesday, May 7, 6:00-7:30 pm
Malvern Room, West Entrance
No fee; pre-registration required.

Understanding Facts About Vegetarian Diets

Attend this lecture to learn about plant proteins and how they can meet the nutrient needs of all ages.
Thursday, June 6, 7:00-8:30 pm
No fee; pre-registration required.

Your Feet, Are They Friend Or Foe?

This program offers tips for the care of maturing and diabetic feet. *Speaker: David Bernstein, DPM, PMH Podiatrist*
Wednesday, May 8, 10:30 am
John's Pizza, Frazer
No fee; pre-registration required.
Program will end with a voucher for a free lunch.

SUPPORT GROUPS

Diabetes Support Group
Mondays, May 20 and June 24, 7:00 pm
Conference Room, West Entrance.

Fibromyalgia Support Group
Wednesday, May 22, 7:00-9:00 pm
Conference Room, West Entrance

Pulmonary Support Group
Tuesdays, May 14 and June 11, 1:30-3:30 pm
Conference Room, West Entrance

CANCER PROGRAMS

Breast Cancer Network
"Lowering Your Risk with Low Fat Cooking"
Wednesday, May 15, 6:30-8:00 pm
Conference Room, West Entrance
No fee; pre-registration required.

Skin Cancer Screening
Saturday, June 1, 9 am-12:30 pm
PMH Cancer Center Building
No fee; pre-registration required.

Cancer Prevention Trials
Colo-Rectal Aspirin Study
A study based on the theory that regular aspirin might diminish the development of colon adenomas (polyps). *Study done in cooperation with MD Anderson Cancer Center in Houston, Texas.*
For information on this study, or any of the studies listed below, please call 610-648-1619.
• Lung Study • Head & Neck Study
• Prostate Cancer Prevention Trial
• Breast Cancer Prevention Study

National Cancer Survivor's Day

Sunday, June 2, 1:00-4:00 pm
No fee; registration suggested.

PROGRAMS FOR CHILDREN AND ADOLESCENTS

ABC's of Babysitting
A four-hour program designed to teach the essentials of good babysitting.
Saturday, June 22, 9:00 am-1:00 pm
Malvern Room, West Entrance
\$15/person; pre-registration required.

Bike Rideo
Children ages 5 to 12 and their families are invited to bring their bikes to Paoli Memorial Hospital for a free, fun and informative event on bicycle safety.
Saturday, May 4, 1:00-4:00 pm

Kids and Nutrition
Launch a Lunar Lunch
Kids ages 6-12 are invited to come and make their own "out of this world" nutritious lunch.
Saturday, June 15, 10:30 am-noon
Malvern Room, West Entrance
No fee; pre-registration required.

King of Prussia Mall Walking Program
Walking is an excellent way to stay in shape. So, to get you started on the right track, Jefferson Health System, along with Reebok, Independence Blue Cross and Keystone Health Plan East, and King of Prussia Mall have joined together to form a "Walking Club". Call 610-648-1660 to receive specific information.

CARE-A-VAN SCHEDULE

May: Blood Pressure/Skin Cancer Awareness Information
June: Blood Pressure/Blood Sugar Screening
Clemens's Supermarket, Lionville
Thursdays, May 2 and June 6
11:00 am-1:30 pm

Upper Main Line YMCA, Berwyn
Mondays, May 6 and June 3
11:30 am-1:00 pm

John's Pizza, Route 30, Frazer
Wednesday, May 8
10:30 am-1:30 pm

Charlestown Elementary School, Charlestown Road, Malvern
Thursdays, May 9 and June 13
10:00-11:30 am

KD Markley Elementary School, Church Road, Malvern
Thursdays, May 9 and June 13
Noon-1:30 pm

Great Valley High School, Route 29, Malvern
Thursdays, May 9 and June 13
2:00-3:30 pm

Sugartown Elementary School, Sugartown Road, Malvern
Tuesdays, May 14 and June 11
Noon-1:30 pm

General Wayne Middle School, Grubb Road, Malvern
Tuesdays, May 14 and June 11
2:00-3:30 pm

"Got It at Gary's", Frazer
Wednesdays, May 15 and June 19
11:00 am-1:30 pm

Albert C. Miller Memorial Park, Whiteland Town Center, Exton
Wednesdays, May 29 and June 26
11:00 am-1:30 pm

Genuardi's, Kimberton
Thursdays, May 30 and June 27
11:00 am-1:30 pm

CALL 610-648-1660

... PHYSICIAN REFERRAL 610-648-1217 ...



Appendix E

DOD ADVISORY PANEL

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Fort Washington, PA 19034

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Research Assistant Professor
University of Pennsylvania Medical Center
University Science Center
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Philadelphia, PA 19104

Paul Engstrom, MD
Fox Chase Cancer Center
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Philadelphia, PA 19111

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Paoli, PA 19301

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Montgomery Commons
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Fox Chase Cancer Center
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Philadelphia, PA 19104

Marisa Weiss, MD
Paoli Memorial Hospital
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Narberth, PA 19072

Kathy Gray-Sircusa, RN, MSN, MBA
Senior Director of Oncology
St. Francis Medical Center
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Trenton, NJ 08629