Volume 3
Issue 1

Spring 2003

NATIONAL CANCER INSTITUTE

THE NEALON REPORT

Bridging advocacy, scientific, and government communities in the progress of cancer research

Contents

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

When Treatment Ends . . .

"Congratulations, you are finished with treatment!" These are words that mark the end of an extended and demanding journey for many cancer survivors. Eagerly anticipated, the end of cancer treatment is a time of paradoxical feelings for most. While relieved to put this part of their life behind them, survivors are often filled with questions and a sense of uncertainty: "Will my cancer return now that I am no longer receiving anticancer drugs or radiation?" "Who will follow and care for me now that my therapy is done?" "What can I do to prevent my cancer from coming back?"

Literally hundreds of publications, tapes, books, and online resources now exist for patients and families facing a new cancer diagnosis and coping with the demands of active care. Once treatment ends, however, this wealth of supportive information seemingly disappears. Many survivors making the transition from active treatment to recovery report a sense of being abandoned and confused; they are unsure how to feel or what to expect next.

To bridge this important communication gap, staff from the Office of Cancer Survivorship (OCS), along with colleagues from NCI's Office of Education and Special Initiatives, have jointly developed a set of publications that address the posttreatment period. The first booklet in a planned set of four, referred to as the "Facing Forward" series, is: *Facing Forward: Life After Cancer Treatment*. Released in English and Spanish in late Spring 2002, the booklet covers what survivors can expect after treatment ends with respect to their medical care, their body, mind, emotions, and social well-being, as well as practical concerns, such as dealing with work and insurance issues. Information from published survivorship research and survivors themselves is used to provide those completing treatment with information about what to expect and tips for managing the challenges and changes that cancer may have brought to their lives. Suggestions for how to put together a personal plan for health after cancer are also included. At the same time, OCS members, in partnership with staff from the Cancer Information Service (CIS), have produced a Fact Sheet for survivors titled: "Questions and Answers About Follow-up Care." This provides answers to typical concerns that many survivors have as treatment ends, such as "How often do I need to be seen and by whom?"

The good news is that growing numbers of those diagnosed with cancer will live years and, increasingly, even full lifetimes after their diagnosis. Cancer for many will be a chronic illness. The challenge now is to extend the focus of cancer research beyond finding a cure. More attention should be given to ensuring the optimal quality of life and health after cancer for all survivors—for as long as their futures allow.

NOTE: These publications can be ordered directly by visiting the Cancer Information Service's Publications Locator Web site at **http://www.cancer.gov/publications**, or by calling 1-800-4-CANCER

Written by Julia Rowland, Ph.D.
NCI Office of Cancer Survivorship

THE NEALON REPORT

The NEALON Report is dedicated to Ms. Eleanor O'Donoghue Nealon, first director of the Office of Liaison Activities. Ms. Nealon passed away in 1999 from breast cancer.

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NCI's CTSU Introduced Significant Innovations in 2002

While operations began in July 2000, the NCI's Cancer Trials Support Unit (CTSU) has only now begun to fully operationalize the systems that were envisioned by its planners. Created as the linchpin of a far-ranging plan to restructure NCI's large, phase III adult clinical trials program, the CTSU has two important functions. The most visible is the development of a national menu of phase III trials in multiple common cancers (for example, lung, prostate, breast, and colorectal) and in some rarer diseases (for example, sarcoma, multiple myeloma, head and neck cancer, and cervical cancer). These trials, previously restricted only to members of the Cooperative Clinical Trials Groups that developed them, are now available to any Cooperative Group member—from any of the eight adult U.S. Cooperative Groups and, in Canada, from National Cancer Institute of Canada members—thereby permitting the establishment of a national network of physician investigators, with access to a broad variety of studies, more likely to appeal to their patients' diverse needs.

Less apparent, but no less important, the CTSU has helped the Cooperative Groups streamline their administrative functions and has recently implemented a pilot program for online-automated data collection software. The prime advantage of this concerted effort is that investigators at local sites will not have to deal with redundant demands for credentialing or institutional review board certification, and they can expect standardized data collection tools regardless of the Group leading a particular study. These unified systems should help to reduce staffing requirements and training costs, a frequently cited barrier to physician participation in clinical trials participation.

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CTSU Innovations
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Several new CTSU-led programs were launched in 2002. In March, all physicians received a single, annual registration packet (1572 form and supplemental form) that covers them for all NCI-supported treatment and prevention trials (phase I–III) including all Cooperative Group trials.

In May, physicians who are not members of the Cooperative Groups were offered the opportunity to enroll in the CTSU and obtain access to the CTSU menu of trials. Enrolled physicians will receive reimbursement for their research costs directly from the CTSU, and will be provided with online training and educational materials for both staff and patients.

Finally, in October, the CTSU began accepting all IRB approval documents for phase I–III treatment and prevention trials. This will facilitate the processing and storage of IRB approvals and continuing reviews by providing a single repository for appropriate documents, and initiate a reminder system for local sites.

With the implementation of these changes in 2002, the CTSU took a major step toward accomplishing its dual objectives of increasing the speed of accrual to important phase III trials and deburdening the Cooperative Groups of administrative responsibilities so they can focus more of their resources on designing, implementing, and analyzing innovative clinical trials.

By Jeanne Adler R.N., and Jeffrey Abrams, M.D., NCI's Cancer Trials Support Unit

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Information Resources

Office of Liaison Activities (OLA) Web site
http://la.cancer.gov
This Web site provides NCI information and links for advocacy and professional societies.

NCI's Web Site
http://cancer.gov
Go to the NCI's Cancer.gov Web site to get all the latest information from the National Cancer Institute including updated PDQ® summaries, our clinical trials database, details about NCI research programs, and grants and funding opportunities in easy-to-use Web format. LiveHelp instant messaging is available 9:00 a.m. to 10:00 p.m., Eastern Time, Monday–Friday. Through LiveHelp, Cancer Information Service information specialists provide answers to questions about cancer and help in navigating the NCI's Web site.

NCI's Cancer Information Service
1-800-4-CANCER (1-800-422-6237)
TTY: 1-800-332-8615
The Cancer Information Service (CIS) is a nationwide information and education network for cancer patients and their families and friends, the public, and health professionals. Through the CIS toll-free telephone service, callers speak with knowledgeable, caring staff who are experienced at explaining medical information in easy-to-understand terms. CIS information specialists answer calls in English and Spanish Monday through Friday from 9:00 a.m. to 4:30 p.m. local time. Recorded information about cancer is also available 24 hours a day, 7 days a week.

NCI's Smoking Quitline
1-877-44U-QUIT (1-877-448-7848)
Established by the Cancer Information Service, this toll-free quitline provides a one-on-one telephone session to support callers who want more information about smoking and advice on quitting. Service is available in English or Spanish.

New NCI Studies Focus On Cancer-Prone Families: Advocates Can Help Spread the Word

People, and often entire families, can carry susceptibility genes which, when altered or mutated, may serve as genetic markers that identify individuals who are at increased risk of developing a certain type of cancer. Which specific genes cause familial or hereditary cancer, how do these genes work, why are some families at higher risk, and what types of monitoring and intervention strategies are best for members of cancer-prone families?

These are the questions researchers want to answer as they meet with North American families fitting specific high-risk profiles. The studies, led by Dr. Mark H. Greene, chief of NCI's Clinical Genetics Branch in the Division of Cancer Epidemiology and Genetics, will offer selected families a comprehensive medical and genetic research evaluation at the NIH Clinical Center in Bethesda, MD. Some eligible families may also participate by sharing their medical information without traveling to the NIH.

According to Dr. Greene, "High-risk families provide us with a unique opportunity to gather the epidemiological, clinical, genetic, behavioral, statistical, and laboratory information necessary to define the role of susceptibility genes and other risk factors in cancer development. The goal of our studies is to improve the health care, quality of life, and overall survival for persons at increased genetic risk of cancer."

Advocates may wish to share this important information about these NCI studies within their networks. Studies that are open for enrollment currently include:

Breast Imaging in Women at Increased Genetic Risk of Breast Cancer
This study is for women ages 25 to 56 who have had genetic testing and counseling and who know that they carry a mutated breast cancer gene, either BRCA1 or BRCA2. The study offers thorough breast cancer screening using newer techniques such as MRI, breast duct lavage, or PET scans. Participants must be able to travel to NIH yearly, and more frequently if needed. A Web site for this study will soon be available at **www.breastimaging.cancer.gov**.

Familial Testicular Cancer
This study is aimed at families with multiple cases of testicular cancer. Families may refer themselves or be referred by their physician. Participants provide a blood sample and medical history along with personal perspective on feelings and attitudes related to being in a family where several relatives have had this type of cancer. Data from all studied families will contribute to mapping and cloning the familial testicular cancer susceptibility gene on the X-chromosome, and to searching for other genes (not yet identified) which may contribute to the risk of developing testicular cancer. Interested families will travel to the NIH for a comprehensive medical examination intended to more fully understand the clinical features of the familial testicular cancer syndrome. More details about the study can be found at **www.familial-testicular-cancer.cancer.gov**.

Inherited Bone Marrow Failure Syndromes
This study focuses on people with rare inherited bone marrow failure syndromes (IBMFS) and their immediate family members. The study is enrolling families in which at least one member has or had an IBMFS such as:

- Fanconi's Anemia (FA)
- Diamond-Blackfan Anemia
- Shwachman-Diamond Syndrome
- Dyskeratosis congenita
- Severe congenital neutropenia
- Thrombocytopenia absent radii
- Amegakaryocytic thrombocytopenia
- Pearson's Syndrome
- Bone marrow failure other than acquired

There are two subgroups—those who are seen and evaluated at the NIH Clinical Center (called the "Clinical Center Cohort"), and those who provide medical information but are not seen at the Clinical Center (called the "Field Cohort").

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From the Consumer Perspective

Advocates as Peers in Peer Review

In recent years, an increasing number of advocates have participated in review meetings, which used to be reserved for scientists alone. With the launch of the Consumer Advocates in Research and Related Activities (CARRA) program, advocates are now systematically placed in the full range of meetings whose purpose is to evaluate scientific projects' value to advancing research and treatment.

"Peer review" has always meant that a researcher or research institution applying for funding was assured an evaluation that was fair and based on state-of-the-art knowledge. Reviewers were professional peers and shared the same values and standards. A time-honored process, the judgment of professional peers maximizes the chances that the most outstanding research initiatives receive funding. With the participation of patient advocates, however, scientific review teams now count lay people as peers.

But how can advocates actually be peers of scientists? Advocates typically do not have research and medical training and may not fully understand technical issues. They may also show reluctance to engage equally with physicians who care for cancer patients and scientists who work on cancer.

Advocates, however, are indeed the peers of scientists in important ways. All are collaborators, committed to ensuring that cancer research is ethical and efficient. And advocates and scientists have equally strong motivations for seeing that research and treatment are conducted according to the highest standards of quality.

When reviewing clinical projects, advocates' views add separate value about trials' and protocols' practicality and acceptability to patients, views which are independent from researchers who have an investment in a project's science. These views can lead not just to more patient-friendly procedures, they may also result in better patient enrollment. Advocates also lend vital perspectives on the ethics of human research participation.

For all reviews, even projects on developmental therapeutics and basic research, advocates are peers in analyzing the systems and processes that carry out the science. Like other professionals, advocates can apply the principles of high quality work—including clarity and worthiness of goals, the right order of priorities, efficient steps to solutions, and follow-up procedures that progress towards objectives.

A special sensitivity comes from the patient and family cancer experience. When combined with the skills of committed individuals with real-world experience, valuable and useful insights emerge. As the experience of advocates accumulates into wisdom to be shared with newer participants, the quality of peer review and scientific decision-making can only be enriched.

Written by Susan L. Weiner, Ph.D.
The Children's Cause, Inc.

Dr. Andrew C. von Eschenbach, Director of the NCI, with CARRA members, on the NIH campus in Bethesda, Maryland.

From left to right: Jim Williams, Ellen Stovall, Bill Stierman, Dr. von Eschenbach, Marian Freeman Chapman, Liz Stierman, and Susan Scherr

From the NCI Director's Consumer Liaison Group (DCLG)

The NEALON Report honors Eleanor Nealon who, in 1997, was appointed to coordinate the newly established NCI Director's Consumer Liaison Group (DCLG). As NCI's first all-consumer advisory body, the DCLG was conceived to offer advice and recommendations to the NCI director. It consists of 15 advocates chosen from a variety of consumer advocacy groups.

The DCLG works with NCI to increase involvement of the cancer advocacy community at NCI. In order to extend the reach of this philosophy, the Consumer Advocates in Research and Related Activities (CARRA) program was established in September 2001. More than 500 applications were received, from which 218 total advocates were selected as CARRA members. They specialize in activities of a scientific nature or in communications. CARRA is designed to enhance NCI's and the DCLG's feel for community needs and to assist in helping cancer survivor groups and the general public in understanding the NCI.

CARRA is an important entity because it multiplies the ability of the patient community to have a voice in NCI activities. Thus far, more than 120 requests have been made for CARRA members to serve in peer review, scientific program development, and communications. This number will continue to swell because NCI staff has embraced this new manner of involving more patient advocates in NCI processes.

The DCLG helped NCI create CARRA and will continue to provide guidance and recommendations about the program. The DCLG also serves as a communications and information-gathering point to consider input from all CARRA members and help in distilling and refining recommendations to the NCI director. The DCLG has appointed one of its members to serve as a liaison to the CARRA program, who establishes two-way communication with CARRA to share information, hear ideas, and answer queries.

Recognizing that each of these functions will be infinitely more successful with input from patients and care givers directly involved with the disease, the DCLG and CARRA assist in developing NCI programs and research priorities. They also help facilitate communication to and from the advocacy community and the NCI. It is this improving climate of cooperation between scientists, physicians, patients, and advocates that will ultimately improve the quality of cancer research. Better research will help improve quality of care, quality of life, and reduction in mortality for those called upon to fight personal cancer battles.

Written by Hank Porterfield, DCLG Liaison to CARRA

Who Is the Office of Centers, Training and Resources?

The Office of Centers, Training and Resources supports four transdivisional programs: (1) the Cancer Centers Program, which supports the infrastructure for basic, clinical, and population science at institutions that are NCI-designated Cancer Centers; (2) the Organ Systems Program, which supports Specialized Programs of Research Excellence (SPOREs) dedicated to cancer site-focused translational research (e.g., breast cancer, prostate cancer) and involves teams of basic, clinical, and population scientists working in highly multidisciplinary research settings; (3) the Comprehensive Minority Biomedical Program, which supports the career development of minority individuals and research partnerships between NCI Cancer Centers and Minority Serving Institutions; and (4) the Cancer Training Program, which provides pre- and postdoctoral training for basic scientists, clinical scientists, and scientists engaged in prevention, control, and behavioral and population research. All four programs relate to every disciplinary group engaged in cancer research. Complete information about these programs can be located at the following Web sites: **http://cancer.gov/cancercenters**; **http://spores.nci.nih.gov**; and **http://cancer.gov/cancertraining/**.

Brian W. Kimes, Ph.D., Director, Office of Centers, Training and Resources, NCI

Tips to Evaluate Web Sites for Health Information

Advocates often find themselves searching the Web for information, or referring fellow survivors to Web sites or chat rooms. In fact, approximately 70 million people in the United States use the Internet for health-related reasons.[1] However, it is important to note that Internet sites, listservs, and chat rooms may not always provide the best medical advice. Many sites can give you good information, while others may give information that is unreliable or misleading. Here are eight questions you should ask yourself as you look for health information on the Internet.

1. Who runs this site?
Any good health-related Web site should tell you who is in charge of the site and the information on it.

2. What is the purpose of the site?
The purpose of the site should be clearly stated and should help you figure out if the information is reliable. Check the "About This Site" (or similarly titled) link that appears on many sites.

3. Who pays for the site?
It costs money to run a Web site. You should know how the site pays for itself: Does it sell advertising? Does a drug company fund it? The source of funding can have a role in what information is on the site, how it is presented, and what the "owners" want you to know.

4. Where does the information on the site come from?
Many health/medical sites post information collected from other Web sites or sources. If the site "owners" did not write the information, the site should tell you where it came from. If the site talks about medical facts, it should have references. (These tell you where the information came from—such as an article in a medical journal.) Also, opinions or advice should be clearly set apart from information based on research results.

5. How is the information selected?
Is there an editorial board? Do people with good medical qualifications review the material before it is posted?

6. How current is the information?
Web sites should be reviewed and updated on a regular basis. It is important that medical information be current and that its most recent update or review date appears on the site. Even if the information has not changed, you need to know that the site "owners" have reviewed it recently to make sure the information is still correct.

7. How can users contact the Web site "owners"?
There should always be a way for you to contact the site owners with problems, feedback, and questions.

8. How does the chat room or discussion area work?
If the site has a chat room or other online discussion areas, it should tell you how the service works. Does someone lead it? Who leads it and why? It is always a good idea to spend time reading the discussion before joining in, so that you feel comfortable with the environment before you get involved.

For more information on evaluating health information on the Internet, see the Health On the Net Foundation's Code of Conduct, which helps standardize the reliability of medical and health information available on the Web. The HONcode defines a set of rules to:

- hold Web site developers to basic ethical standards in the presentation of information.
- help make sure readers always know the source and the purpose of the data they are reading.

http://www.hon.ch/HONcode/Conduct.html

Written by Margo Michaels
NCI Office of Education and Special Initiatives (OESI)

[1] *ReutersHealth. Americans seek health information online.* ***http://www.reutershealth.com*** *August 6, 1999.*

Cancer-Prone Families
Continued from page 4

Affected individuals, and their immediate family members who come to the Clinical Center, will receive comprehensive physical and laboratory examinations by a team of specialists, along with information and advice regarding the management of any newly identified clinical problems that are detected during the course of their visit. Due to the high risk of cancers in these diseases, participants will be offered age-appropriate, thorough cancer surveillance as part of the study. For more information, visit **www.marrowfailure.cancer.gov**.

Prospective Study of Women at Increased Genetic Risk of Ovarian Cancer
This study will collect detailed information regarding what becomes of genetically high-risk women who choose either preventive removal of the ovaries and tubes, or a new form of ovarian cancer screening (without removal of the ovaries), as strategies to reduce their risk of ovarian cancer. This project will develop better estimates of the cancer risks associated with these two approaches, study the impact of these choices on quality of life, develop a new ovarian cancer screening strategy, and do various laboratory studies of how the BRCA cancer genes actually cause cancer.

This study is a collaboration between the Clinical Genetics Branch, the Gynecologic Oncology Group (GOG) and the Cancer Genetics Network. The official name of this study is **GOG 0199**; it will soon open at GOG member institutions around the country. A limited number of subjects will be enrolled at the NIH Clinical Center. For more information, visit: **http://clinicalstudies.info.nih.gov/cgi/detail.cgi?A_2002-C-0268.html**. For a list of Gynecologic Oncology Group institutions, please visit: **https://webreg.gogstats.org/Members/**

Individuals who wish to be considered for participation in one of these studies may contact the cancer genetics referral nurse, Stephanie Steinbart, at 1-800-518-8474.

By Rhonda Wilt DeJoice, OESI

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