

May 3, 2005
Volume 2 | Number 18

In this issue:

Localized Prostate Cancer Deaths Remain Low After 20 Years...1

Director's Update...1

Cancer Centers: Providing Leadership and New Opportunities

Spotlight...3

Cancer Epigenetics: Beyond Genetic Mutations

Cancer Research Highlights...4

Potential Prostate Cancer Vaccine Plus Radiation Proves Safe in Clinical Trial

Lung Cancer Clinical Trial for Gefitinib Closes Early

Removing Lymph Nodes Doesn't Increase Survival in Advanced Ovarian Cancer

HPV Found in Half of Patients with Colorectal Cancer

A Conversation With...5

Dr. Richard Pazdur

CCR Grand Rounds...6

Featured Clinical Trial...6

Therapy for Treatment-Resistant or Recurrent Gliomas

Notes...7

Science Writers' Seminar Focuses on Childhood Cancers

NCI Sponsors New International Research Fellowships

Grodzinski Joins OTIR

Brochure on Reducing Radiation Risks Available

Community Update...8

Patient Navigator Program



A Publication of the National Cancer Institute
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
NIH Publication No. 05-5498

<http://www.cancer.gov>

Localized Prostate Cancer Deaths Remain Low After 20 Years

The death rate in patients with localized prostate cancer remained stable and low after more than 20 years of follow-up, a large retrospective study reported in the May 3 *Journal of the American Medical Association (JAMA)*.

The study is based on a risk analysis of 767 men in the Connecticut Tumor Registry (CTR) diagnosed with prostate cancer between 1971 and 1984 and treated by either observation or delayed androgen withdrawal. "Men with low-grade prostate cancers have a minimal risk of dying from prostate cancer during 20 years of follow-up," note the researchers, who were led by Dr. Peter C. Albertsen of the University

of Connecticut Health Center.

The study updates and confirms the authors' initial report published in 1998 on the same patient cohort. "Because these men have been followed continuously by the CTR, we had an opportunity to extend our follow-up to 20 years to determine whether prostate cancer mortality rates declined, remained constant, or increased after 15 years," the researchers explain.

The prostate cancer death rate among the patient cohort was 33 per 1,000 person-years during the first 15 years and 18 per 1,000 person-years after 15 years of follow-up. These *(continued on page 2)*

Director's Update

Cancer Centers: Providing Leadership and New Opportunities

Yesterday marked the second annual retreat of National Cancer Institute-designated Cancer Center directors. The retreat provides a forum for NCI leaders to brief the directors on important NCI initiatives, and for an open and honest dialogue on the national cancer program.

Just like the inaugural retreat last spring, this year's retreat was gratifying and educational. It allowed NCI leaders to better understand the complexity of the challenges facing Cancer Centers, as well as the breadth of the opportunities before us.

As the recent special issue of the *Cancer Bulletin* described, NCI-designated Cancer Centers have evolved into the core of the national cancer program. The majority of individual R01 and P01 awards, for example, go to researchers at NCI-designated Cancer

Centers, as do the majority of funds for training grants and Specialized Programs of Research Excellence.

Given their many strengths, I believe it's vitally important to expand Cancer Centers' sphere of influence. To *(continued on page 2)*

(Prostate Cancer continued from page 1)
rates were not statistically different after adjusting for the more favorable histology profiles among men who survived more than 15 years from diagnosis. “The annual mortality rate from prostate cancer appears to remain stable after 15 years from diagnosis, which does not support aggressive treatment for localized, low-grade prostate cancer,” the researchers conclude.

The authors contrasted their findings with a similar, Swedish long-term follow-up study published in *JAMA* on June 9, 2004. That study of 223 men with localized prostate cancer diagnosed between 1977 and 1984 found an unexpected and substantial three-fold increase in mortality rates from prostate cancer among men who were alive 15 years after diagnosis.

One factor that may contribute to this difference, the researchers suggest, is that the Swedish study classified prostate tumors using the World Health Organization grading system. Patients in the Connecticut study were classified using Gleason scores. The two grading systems “are based on fundamentally different criteria and may result in different classifications, especially among men with moderately differentiated disease,” say the researchers.

Among the Connecticut patients with low Gleason scores (2-4), there were 6 deaths per 1,000 person-years, after a median observation period of 24 years. In contrast, those with high Gleason scores (8-10) had a “high probability of dying from prostate cancer within 10 years of diagnosis,”—121 deaths per 1,000 person years, the researchers report.

Dr. Howard L. Parnes, chief of NCI’s Prostate and Urologic Cancer Research Group, concurred with Dr. Gann that the patient cohort in the

Connecticut study is very different from many patients seen today after the advent of widespread prostate-specific antigen (PSA) testing in the 1990s. Most of the Connecticut patients were found to have prostate cancer based upon transurethral resection of the prostate, Dr. Parnes noted. “On the other hand,” he said, “in the PSA era, high-grade disease is likely to have a better prognosis than previously, because we are now more likely to find high-grade disease when it is smaller volume and confined to the prostate than we did in the pre-PSA era.” ♦

(Director’s Update continued from page 1)
achieve that end, we are following a two-pronged strategy: continuing to provide opportunities for Cancer Centers to excel as individual institutions serving large, diverse communities, while also working to integrate the work of these state-of-the-art institutions so that the whole of the Cancer Centers Program is greater than the sum of its parts.

Evidence of the latter can be seen in the technology initiatives such as the cancer Biomedical Informatics Grid, molecular imaging, and nanotechnology, all of which take advantage of Cancer Centers’ acumen in research and forming partnerships and, consequently, are enhancing the capacity of technologies to speed us toward the molecular oncology era.

Our goal is to integrate Cancer Centers into all of NCI’s strategic initiatives. Cancer Centers provide remarkable infrastructures and are often centers of technological and scientific excellence. As a result, they offer, for example, ideal backdrops for the initiatives between the Food and Drug Administration and NCI aimed at improving the development process for new cancer drugs and diagnostics.

As we anticipate the official release in June of recommendations from the Clinical Trials Working Group—a group that included a number of Cancer Center representatives—center directors voiced optimism about the role their institutions will play in reshaping the clinical trials process to accelerate progress in prevention, diagnosis, and treatment.

An area in which I believe Cancer Centers can have a dramatic impact involves disparities in cancer care and outcomes. As many center directors stressed during the retreat, addressing these disparities is absolutely critical if we are to achieve the 2015 goal, and many Cancer Centers have the expertise and established community networks needed for this line of research.

Cancer Centers’ involvement is not relegated to domestic initiatives. They are providing important training to international researchers and clinicians, often through programs run by the NCI Office of International Affairs. In many instances, this involves hospital-based training on the latest cancer treatment techniques, allowing oncologists from around the world to improve cancer care in their countries.

Cancer Centers are leaders in the effort to eliminate the suffering and death due to cancer. They have the power to influence and transform cancer research and care at every level. In fact, I see the Cancer Centers Program as a model for creating change across the health care system—a model that NCI can nurture and guide, not via a cancer-centric approach, but rather a cancer-led approach that delivers on the promise of the cancer community’s expertise, strength, and commitment to life and good health. ♦

*Dr. Andrew C. von Eschenbach
Director, National Cancer Institute*



Spotlight

Cancer Epigenetics: Beyond Genetic Mutations

Genetic mutations often get much of the credit for causing cancer, but another important factor is genes that turn on or off at the wrong times, despite being free of mutations. This abnormal gene activity often involves “epigenetic” changes to DNA and in some cases may be reversible.

Epigenetic changes alter gene activity without modifying the genetic code, and are essential to normal development. But the changes can cause problems if they occur when they shouldn't or disable genes that suppress tumors and control growth.

Studies have suggested that epigenetic changes may be as common in some tumor cells as genetic mutations, and many researchers now say that epigenetic changes are critical to understanding, detecting, and treating cancer.

“If you focus only on genetic mutations and ignore epigenetic changes in tumor cells, you may be missing half of the information you need to understand the disease,” says Dr. Stephen Baylin of the Johns Hopkins School of Medicine.

A recent study led by Dr. Andrew Feinberg, also of Johns Hopkins, suggests that epigenetic changes in normal tissue can create the perfect environment for cancer to develop if genetic mutations arise later.

Dr. Feinberg's team studied mice with an epigenetic defect found in 30 percent of colon cancer patients and 10 percent of the general population. In people and in mice, the defect causes

elevated levels of a cancer-related protein: insulin-like growth factor 2.

According to findings published in the March 25 *Science*, the flaw did not cause colon cancer in the mice, but it significantly increased the risk among mice that also carried a genetic mutation associated with the disease.

“The idea is that epigenetic and genetic factors may cooperate in causing tumors,” says Dr. Feinberg. “We may therefore want to think about what sorts of epigenetic changes might occur in normal tissue that set the stage for mutations that come along later.”

To identify epigenetic changes that confer cancer risk, researchers first need to know which changes are normal. This presents a challenge because unlike genetic code, epigenetic changes are dynamic and vary by cell type, age, and sex, among other factors.

The most commonly observed epigenetic change is DNA methylation, in which chemicals called methyl groups attach to DNA, often silencing a nearby gene. DNA methylation can be detected in body fluids such as blood and urine, and new technologies can rapidly scan genomes for epigenetic changes.

Perhaps the most exciting prospect for the field is the potential for detecting epigenetic changes linked to cancer and then doing something about them.

“We cannot reverse genetic mutations, but there is the hope and the potential for reversing epigenetic changes,” says Dr. Mukesh Verma of NCI's Division

of Cancer Control and Population Sciences. “That's why interest in epigenetics is so high right now.”

At least a dozen drugs that target epigenetic changes such as methylation are in clinical trials and more are in development. Last May, the Food and Drug Administration (FDA) approved a methylation inhibitor to treat the rare bone marrow disorder myelodysplastic syndrome (MDS), which can lead to leukemia.

The drug, azacitidine (Vidaza), had nearly been abandoned two decades ago but found new life as researchers showed that it helps MDS patients when given at low doses.

Diet and certain nutrients such as folic acid may also have an effect on epigenetic changes. An NCI-sponsored clinical trial is evaluating folic acid as a tool for preventing colon cancer, and the researchers will be documenting certain epigenetic changes in participants.

“Our diets may alter epigenetic information over the course of many years, but right now we know very little about the effects of diet on epigenetic changes in the long term,” comments Dr. Jean-Pierre Issa of M.D. Anderson Cancer Center.

Similarly, Dr. Issa adds, the links between aging and epigenetic changes are important but poorly understood: “We need to develop a better understanding of the epigenome and its interactions with environmental exposures if we hope to understand age-related diseases.”

Two collaborative pilot projects on epigenetics are underway in Europe, and there have been discussions about a U.S.-led effort analogous to the Human Genome Project. A meeting on the subject, sponsored by the American Association for Cancer Research, will take place near Washington, D.C., in June. ♦



Cancer Research Highlights

Potential Prostate Cancer Vaccine Plus Radiation Proves Safe in Clinical Trial

Researchers at NCI's Center for Cancer Research (CCR) testing an experimental vaccine against prostate cancer have found it to be safe when given to patients undergoing local radiation therapy, according to a pilot study published in the May *Clinical Cancer Research*.

The study was the first clinical trial to combine radiation and a cancer vaccine to treat prostate cancer. Larger clinical trials can now go forward to evaluate the therapy as a treatment for localized forms of the disease.

"We have shown that this combination therapy is safe and well tolerated," says lead author Dr. James L. Gulley of CCR's Laboratory of Tumor Immunology and Biology. "This is the first step toward finding alternative treatments for patients with localized prostate cancer." About a third of patients who receive radiation or surgery for localized prostate cancer relapse within a decade.

Cancer vaccines are intended either to treat existing cancers or to prevent the development of new ones. The experimental vaccine in this study was designed to strengthen the body's natural defenses against prostate cancer. "The idea is that you can stimulate the body's immune system to recognize and attack tumor cells through the use of a vaccine," explains Dr. Gulley.

Thirteen of 17 patients who received the experimental therapy (vaccine plus local radiation of tumor) had at

least a threefold increase in the immune cells that attack a protein made by the tumor cells, compared with no detectable increases in those immune cells in 8 patients who received radiation alone. A strong immune response is an indication that the body is fighting the cancer.

Lung Cancer Clinical Trial for Gefitinib Closes Early

Researchers have closed a clinical trial testing gefitinib (Iressa) for patients with non-small-cell lung cancer (NSCLC) as a maintenance therapy following chemotherapy and radiation. Review of interim data indicated that gefitinib would not improve survival in the patient group studied.

The NCI-sponsored study was designed to evaluate whether gefitinib could control NSCLC and extend survival when given to patients whose disease has not spread beyond nearby tissues or lymph nodes and is responding or stable after primary therapy. After reviewing the available study data, the independent committee overseeing the trial recommended closure.

"Based on the analysis, the use of gefitinib following chemotherapy and radiation should not be prescribed for this group of patients," said Dr. Scott Saxman of the Cancer Therapy Evaluation Program, who oversees lung cancer clinical trials for NCI.

The trial was conducted by the Southwest Oncology Group (SWOG). A total of 672 patients were to be randomized to 1 of 2 treatment groups following chemotherapy and radiation: one group would receive

gefitinib daily and the other would receive a placebo daily. By early March 2005, 611 patients had been entered and 276 had been randomized.

"The interim analysis indicates that even with accrual of more patients or with longer follow-up, the gefitinib arm would not improve survival," explained Dr. Laurence Baker, SWOG chairman and professor of internal medicine and pharmacology at the University of Michigan.

On April 22, the National Cancer Institute of Canada (NCIC) closed its clinical trial of gefitinib for NSCLC after a review of the SWOG results by its Data and Safety Monitoring Committee, according to Dr. Joe Pater, who directs the NCIC Clinical Trials Group.

Removing Lymph Nodes Doesn't Increase Survival in Advanced Ovarian Cancer

Removing the aortic and pelvic lymph nodes during surgery for advanced ovarian cancer improves progression-free survival but not overall survival, according to a study in the April 20 *Journal of the National Cancer Institute*.

To determine whether systematic aortic and pelvic lymphadenectomy improves progression-free and overall survival, researchers at the Università La Sapienza in Rome conducted a clinical trial in which 427 patients with advanced ovarian cancer were randomly assigned to undergo either primary cytoreductive surgery followed by lymphadenectomy or cytoreductive surgery alone, which only removes the tumor and lymph nodes in the abdominal cavity. The patients were followed for an average of 68.4 months.

Researchers found that, on average, women receiving lymphadenectomy surgery went 7 months longer without recurrence of their

cancer. However, the study results also confirmed the higher incidence of complications associated with lymphadenectomy surgery, which requires longer operating times and the increased likelihood for blood transfusions. They noted that overall survival was not improved for lymphadenectomy patients.

In an accompanying editorial, Dr. Setsuko Chambers of the Arizona Cancer Center commented, “This pivotal trial should be considered definitive, and the findings used to dictate clinical management...As disappointing as the result may be to some gynecologic oncologists, the body of evidence does not favor including systematic lymphadenectomy as part of front-line maximal surgical debulking in the management of advanced ovarian cancer.”

HPV Found in Half of Patients with Colorectal Cancer

Human papillomavirus (HPV) infection was found in more than half of patients with colorectal cancer, an NCI study reported in the April 15 *Clinical Cancer Research*.

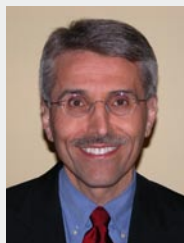
Researchers in the HIV and AIDS Malignancy Branch of NCI’s CCR found that 28 of 55 (51 percent) of the colorectal cancer patients studied were positive for HPV based on examination of samples from tumors and adjacent tissues. Colorectal tissue from 10 control individuals, who didn’t have colorectal cancer, were all negative, they noted.

The findings confirm previous controversial studies linking HPV with colorectal cancer, but the NCI researchers were careful to avoid the cross-contamination of tissue samples in the detection that may have affected earlier research.

Dr. Zhi-Ming Zheng, principal investigator in the study, explained
(continued on page 6)

A Conversation with Dr. Richard Pazdur

FDA recently appointed Dr. Richard Pazdur to lead its newly established Office of Oncology Drug Products. He spoke with the NCI Cancer Bulletin about his plans for the new office.



What are some of the challenges for this newly established office?

The challenge is to coordinate activities within the FDA’s centers as well as with the external community, including our stakeholders—patients, physicians, NCI, pharmaceutical companies, and biotechnology companies. Another challenge is to have consistency in the review of drugs and biological products. Uniform regulatory principles must be applied throughout the drug development process irrespective of the product.

FDA and NCI are already collaborating on several fronts, including the Interagency Oncology Task Force. How will this new office expand the partnership with NCI and other agencies?

One important assignment of the new office is to develop programs that will answer scientific and regulatory questions that impact drug development. Interactions with NCI, the academic community, patients, and sponsors are essential in developing these programs. These include ongoing discussions of regulatory endpoints for drug approval, a pediatric oncology advisory committee, and an evolving chemoprevention program that examines endpoints and safety of drugs that will enter chemoprevention trials. Other initiatives will examine alternative statistical approaches to clinical trial designs and review nonclinical requirements for entry of drugs and biological products into clinical trials.

In what areas are we most likely to see the next wave of significant advances in cancer therapeutics—diagnosis, treatment, or prevention?

All three. Advances in all three require a more basic and fundamental understanding of oncological diseases. True advances in treatment, prevention, and diagnosis will require a more complete understanding of the molecular pathways of disease—moving away from the conventional, historical approaches of histopathological diagnoses.

What is your vision of the future of the oncology drug development process?

Here again, the future of the drug development process will be linked with a more thorough understanding of the molecular basis of the disease. Molecular targets will need to be developed to provide a greater understanding of drugs. This will answer the question of why certain drugs work in particular diseases and also may provide more information about drug safety. The basic understanding will be essential not only for development of drugs in the advanced disease setting, but also in the prevention of oncology diseases. ♦

(Highlights continued from page 5)

the precautions taken: “All samples of normal tissues taken from healthy subjects along with counterpart tumor and tumor-adjacent tissues from colon cancer patients had to be examined in a blinded manner, using three separate nested polymerase chain reactions, each targeting a different region (L1, E6, and E2) of the virus genome.” A positive sample had to be confirmed in multiple repeats to be considered a real positive for HPV, he added.

Dr. Zheng addressed the implications of the study: “Establishing a firm relationship between HPV infection and the development of colorectal cancer will require further research. However, it is quite likely that diseases caused by HPV infection will soon become preventable by vaccination. If this study is confirmed and a substantial proportion of colorectal cancers are ultimately found to be etiologically associated with HPV infections, this would help us to further understand the oncogenesis of colorectal cancer and might change our views on its prevention and treatment.” ♦

CCR Grand Rounds

May 10: Dr. James P. Allison, Chairman, Immunology Program, Memorial Sloan-Kettering Cancer Center: “Checkpoint Inhibition: A New Strategy for Tumor Immunotherapy”

May 17: No lecture. ASCO Annual Meeting, May 13-17, Orlando, Fla.

May 24: Dr. Sam T. Hwang, Senior Investigator, Dermatology Branch, CCR, NCI: “Chemokine Receptors in Organ-Selective Cancer Metastasis”

CCR Grand Rounds are held 8:30 to 9:30 a.m. at the NIH campus in Bethesda, Md., in the Clinical Center’s Lipsett Amphitheater. ♦



Featured Clinical Trial

Therapy for Treatment-Resistant or Recurrent Gliomas

Name of the Trial

Phase I Study of CC8490 in Patients with Recurrent or Refractory High-Grade Gliomas (NCI-04-C-0035). See the protocol summary at <http://cancer.gov/clinicaltrials/NCI-04-C-0035>.

Principal Investigator

Dr. Howard A. Fine, Neuro-Oncology Branch, NCI CCR

Why Is This Trial Important?

Malignant gliomas are the most common type of primary malignant brain tumor found in adults. Currently, there are no effective treatments for malignant gliomas that progress or recur following initial treatment.

In this phase I trial, researchers are testing a new drug called CC8490 in patients with progressive or recurrent malignant gliomas. In preclinical studies, CC8490 inhibited the growth of glioma cells and induced glioma cell death. This trial will determine the maximum dose of CC8490 that can be given to patients and will assess the safety and tolerability of this drug. Additionally, researchers hope to determine the mechanism by which CC8490 affects glioma cells.

“Years ago, doctors observed that the antiestrogen drug tamoxifen occasionally causes regression of glioma tumors, even though those tumors do not possess estrogen receptors,” said Dr. Fine. “Consequently, NCI

screened many compounds called selective estrogen receptor modulators (SERMs) that had tamoxifen-like activity. CC8490 is one SERM that showed very strong antiglioma activity.

“With this trial, we are trying to determine the highest dose we can give to patients so that we can maximize the antitumor effect of the treatment,” Dr. Fine said. “So far, we have initiated five dose escalations and the drug appears to be very well tolerated.

“We think CC8490 may represent a potentially promising new approach to treatment of recurrent malignant glioma.”

Who Can Join This Trial?

Researchers seek to enroll up to 34 patients aged 18 or older with malignant gliomas that have either not responded to previous treatment or recurred following previous treatment. See the full list of eligibility criteria at <http://cancer.gov/clinicaltrials/NCI-04-C-0035>.

Where Is This Trial Taking Place?

The study is taking place at the National Institutes of Health (NIH) Clinical Center in Bethesda, Md.

Contact Information

For more information about this trial, call a Neuro-Oncology Branch Patient Care Coordinator at 301-402-6298 or the NCI Clinical Studies Support Center toll-free at 1-888-NCI-1937. This call is completely confidential. ♦

An archive of “Featured Clinical Trial” columns is available at <http://cancer.gov/clinicaltrials/ft-all-featured-trials>.



Dr. Howard A. Fine
Principal Investigator

Notes

Science Writers' Seminar Focuses on Childhood Cancers

Advances in diagnosis and treatment of childhood cancers were highlighted at NCI's Science Writers' Seminar at the Children's Inn at NIH on April 26. About 40 people attended the seminar, including more than 24 reporters. Dr. Donald Small, professor of oncology, pediatrics, and cellular and molecular medicine at Johns Hopkins University School of Medicine, announced that his laboratory had just received approval from the biopharmaceutical company Cephalon to test one of its drugs (CEP-701) as a targeted therapy for relapsed acute myeloid leukemia.

Dr. Alan Wayne, clinical director of NCI's Pediatric Oncology Branch, reported on genetic techniques that allow doctors to predict which children are at risk for relapse and might benefit from aggressive treatments. Dr. Wayne also eulogized Killian Owen, who several years ago was the first child to take the targeted drug BL22 for acute lymphocytic leukemia. Although Killian died in August 2003 at age 9, researchers are using medical information from his case in their studies of BL22 and newer versions of that drug. "Killian was an inspiration to know, and he lives on through the studies now underway," Dr. Wayne said.

NCI Sponsors New International Research Fellowships

The NCI Office of International Affairs (OIA) has established three new Joint Research Project Fellowships (JRPFs) with research programs in Japan, the United Kingdom (U.K.), and the Republic of Ireland. The programs are intended to foster relationships between U.S. and foreign investigators through support of a shared postdoctoral fellow. Each

fellowship includes funding for the fellow's salary and a travel allowance for the fellow and the two investigators that share his/her mentoring. The U.S. principal investigator may be from the NCI intramural research program or an NCI grantee.

The partner for the U.K. JRPF is the National Translational Cancer Research Network. This program is intended to support research projects in translational science. The next deadline for this program is May 16, 2005; up to two JRPFs per year will be supported. Details are available at <http://www.ntrac.org.uk>.

The partner for the Ireland JRPF, supported by the Ireland-Northern Ireland-NCI Cancer Consortium, is the Health Research Board of the Ireland Department of Health and Children. Up to five JRPFs are available. The application deadline is July 22, 2005. Details are available at <http://www.hrb.ie/r&d>.

The Japan JRPF is part of the U.S.-Japan Cooperative Cancer Research Program. Fellowships can be proposed in basic, clinical, or behavioral/population science. The application deadline is fall 2005; up to three JRPFs can be supported each year. Details will be posted on the OIA Web site at <http://www.cancer.gov/oia>.

Grodzinski Joins OTIR



On April 4, Dr. Piotr Grodzinski joined the staff of NCI as program director for cancer nanotechnology in the Office of Technology and Industrial Relations. He will manage the activities of the newly formed Alliance for Nanotechnology in

Cancer, as well as related cancer nanotechnology research. Dr. Grodzinski received his Ph.D. in materials science from the University of Southern California in 1992. Subsequently, he held positions in research and research management at Motorola, and most recently with the Los Alamos National Laboratory where he was group leader and interim chief scientist of the Center for Integrated Nanotechnologies.

Brochure on Reducing Radiation Risks Available

A new publication, *Interventional Fluoroscopy: Reducing Radiation Risks for Patients and Staff*, has been produced by NCI's Division of Cancer Epidemiology and Genetics and the Society of Interventional Radiology. Intended primarily for health care professionals, the brochure discusses the increasing use, complexity, and value of interventional fluoroscopy; the associated radiation risks; and the importance of optimizing patient radiation dose. It also outlines the potential clinical effects of radiation exposures to the skin and eye lens, suggests strategies to minimize radiation dose for patients and staff, provides guidelines for dosimetry records and follow-up, and encourages education and training in radiation sciences for health care professionals. The brochure is being distributed at national professional meetings and through mailings to radiologists and other professionals who perform these procedures. It is available on NCI's Web site at <http://cancer.gov/cancertopics/interventionalfluoroscopy>. For a limited number of copies, please contact Ursula Leitzmann at Leitzmau@mail.nih.gov. ♦



Community Update

Patient Navigator Program Guides Underserved Cancer Patients

Much of the research about the causes of cancer health disparities identifies lack of access as a primary factor. People from difficult socioeconomic circumstances often do not know where to go or who to turn to—and in many cases, do not have the resources—to respond appropriately when they receive a cancer diagnosis. In other cases, people live in isolated communities 100 miles or more from the nearest clinic or hospital. One approach to closing this access gap is NCI's Patient Navigator Research Program, which relies on personal guides to shepherd disadvantaged cancer patients into standard care.

The Patient Navigator Program assigns guides to help cancer patients and their families navigate the treatment process, steering them around obstacles that may limit their access to quality care. They help the patient choose a doctor, arrange transportation, assess treatment options, and see that the patient follows the prescribed care regimen.

Patient navigators can be social workers, nurses, or volunteers who are

familiar with the health care system and the cancer care process. Their goal is to ensure that cancer patients from disadvantaged backgrounds get high-quality treatment; patient navigators can make the difference between these patients becoming cancer survivors or dying from the disease.

The Patient Navigator Program is part of a group of initiatives that NCI developed to address cancer health disparities. Variations on the program are in place in several communities, and NCI is expanding the program through a new series of grants. About \$24 million in grants will be awarded over the next 5 years as part of the program.

NCI supports a number of Patient Navigator Program pilot projects in minority communities: two in Native American communities at Indian Health Service sites in the Portland, Ore., area and one each in Rapid City, S.D., and Laredo, Tex., the latter of which serves 50 “colonias,” communities that are home to an extremely poor segment of the Hispanic population, as well as sites in Mississippi,

North Carolina, California, and Pennsylvania.

Recently, NCI held a workshop designed to enhance navigators' knowledge about clinical trials. In the 3-day workshop on April 10-13 in Bethesda, Md., patient navigators from NCI-funded projects across the country participated in sessions dealing with the clinical trials process and how to assess trials for their respective communities.

The patient navigator concept was developed by Dr. Harold Freeman, director of NCI's Center to Reduce Cancer Health Disparities. Dr. Freeman developed the concept when he served as director of surgery at Harlem Hospital in New York City. Dr. Freeman found that the program was successful in saving lives and educating the larger population about cancer prevention and treatment.

“Receiving a cancer diagnosis is traumatic, even though there is more hope today for cancer patients than at any other time,” says Dr. Freeman. “But to be faced with that news and to also lack the resources, knowledge, and confidence to follow through appropriately to get quality care is a tragedy. For these patients, patient navigators are a true lifeline.”

For more information about the Patient Navigator Program, go to <http://crchd.nci.nih.gov/initiatives/#Navigator>. ♦

Featured Meetings and Events

A comprehensive calendar of cancer-related scientific meetings and events sponsored by NCI and other scientific organizations is available at <http://calendar.cancer.gov>. ♦

The *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads the national effort to eliminate the suffering and death due to cancer. Through basic, clinical, and population-based biomedical research and training, NCI conducts and supports research that will lead to a future in which we can identify the environmental and genetic causes of cancer, prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

For more information on cancer, call 1-800-4-CANCER or visit <http://www.cancer.gov>.

NCI Cancer Bulletin staff can be reached at ncicancerbulletin@mail.nih.gov.