

NCI Cancer Bulletin

Eliminating the Suffering and Death Due to Cancer

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Targeted Drug Helps Delay Progression of Advanced Breast Cancer

Women with HER-2 positive breast cancer whose disease progressed following treatment with trastuzumab (Herceptin) benefited from taking the experimental drug lapatinib along with the standard treatment, capecitabine, researchers said last week at the American Society of Clinical Oncology (ASCO) annual meeting in Atlanta.

The combination therapy delayed the growth or the spread of the cancer by about 4 months compared with capecitabine alone (8.5 months vs. 4.5 months).

"We believe that this is an effective regimen for women with HER-2 positive breast cancer and should be the new standard of care (for treating these women after trastuzumab fails)," said Dr. Charles E. Geyer, Jr., of the Allegheny General Hospital in Pittsburgh, who led the trial and presented the results at ASCO.

Lapatinib, or Tykerb, inhibits two proteins involved in cancer, the epidermal growth factor receptor (EGFR) and HER-2, which is also targeted by trastuzumab. HER-2 sits on (continued on page 2)

Honored to Help Bring New Treatments to Patients

Last week Department of Health and Human Services Secretary Mike Leavitt appointed me Acting NCI Director, effective June 11. It's an honor to be asked to head the largest cancer research organization in the world for any period of time, and I am eager to continue the work I've been engaged in at NCI over this past year.

It cannot be stressed enough that the NCI senior leadership team is committed to ensuring that, during this time of transition and uncertainty over budgetary issues, we remain focused on supporting scientific excellence, addressing high priority areas of research, and engaging in an

Niederhuber Named **Acting Director**

On May 31, Dr. John Niederhuber was named Acting Director of NCI. For more information, go to http://www.cancer.gov/aboutnci/ acting-director-appointed.

ongoing dialogue with all members of the cancer community.

Since my earliest days as a surgeon and cancer researcher, my inspiration has been the many patients I have known and treated. I am always mindful that NCI's investment in (continued on page 2)

(Targeted Drug continued from page 1) the surface of cells, and trastuzumab binds the part outside the cell, while lapatinib binds the part inside the cell.

Trastuzumab has helped many women with HER-2 positive tumors, but the drug eventually stops working in some women. Tumors that produce excess amounts of the HER-2 protein—about 20 to 25 percent of breast cancers—are often aggressive and likely to recur.

"This study is good news," said Dr. Jo Anne Zujewski of NCI's Cancer Therapy Evaluation Program. "Lapatinib is an oral drug that is effective in women who have progressed following trastuzumab therapy."

The new regimen was generally well tolerated, Dr. Geyer reported. The addition of lapatinib to capecitabine did not appear to increase side effects significantly, although some women experienced mild diarrhea and rashes.

Dr. Geyer said that the cardiac health of women in the study was monitored very carefully and no major events were reported.

Fewer women in the combination group than in the capecitabine group experienced a recurrence of the cancer in the brain (4 women vs. 11 women). Unlike trastuzumab, lapatinib is a small molecule that may cross the blood-brain barrier and may be active in the brain.

The phase III study randomly assigned 160 women to receive lapatinib plus capecitabine and 161 women to receive capecitabine alone. All of the women had advanced or metastatic breast cancer that had recurred or progressed following prior therapy with an anthracycline drug, a taxane, and trastuzumab.

The inhibition of lapatinib's second target, EGFR, may not benefit women

with breast cancer but could make the drug useful against other cancers, said Dr. Julie Gralow of the University of Washington, who commented on the study at ASCO.

Lapatinib is currently in clinical trials for advanced kidney cancer. The trial's leader, Dr. Alain Ravaud of the University Hospital of Bordeaux, France, said at ASCO that the drug appeared to benefit patients whose tumors produce high levels of the EGFR protein.

GlaxoSmithKline intends to seek FDA approval for lapatinib as a treatment for breast cancer this year. The company said it would soon make the drug available through a compassionate use program. •

By Edward R. Winstead

(Director's Update continued from page 1) research is, in no small part, a tribute to their perseverance, strength, and dignity in the face of such a devastating disease.

There is always a sense of renewed excitement related to the treatment of cancer this time of year, as our nation's top clinical cancer researchers gather for the annual meeting of the American Society of Clinical Oncology (ASCO). At this year's meeting I was struck by the many new treatment options emerging for those affected with cancer. In 2006, our nation's previous investment in basic, epidemiologic, and clinical research continues to pay off as the efficacies of new therapies are demonstrated.

As this issue of the *NCI Cancer Bulletin* documents, for instance, two large phase III clinical trials presented in Atlanta demonstrated the superiority of two different agents, sunitinib and temsirolimus, for the treatment of metastatic renal cell

carcinoma (RCC) compared with the current standard of care. Little progress has been made in the treatment of this most common form of kidney cancer over the past several decades, so the availability of new, more effective options is particularly welcome. Importantly, these advances in the treatment of RCC are due in large part to the pioneering work of Drs. Marston Linehan and Berton Zbar and their colleagues in the NCI Center for Cancer Research.

This year's ASCO annual meeting also represents the continued development of the next generation of targeted therapies. We are now learning that some of the first-generation targeted agents have more than one therapeutic target in the cancer cell. But a host of newer agents having notable successes in phase II and III clinical trials—including lapatinib (Tykerb), sunitinib (Sutent), and dasatinib—were designed specifically to target multiple proteins in signaling pathways that play an important role in carcinogenesis and tumorigenesis.

The first-generation targeted therapies such as imatinib (Gleevec) and trastuzumab (Herceptin) have only been in the clinic for a few years, so the progress seen in transporting this next generation of agents to the bedside is impressive indeed.

The mathematician and philosopher Alfred North Whitehead wrote, "Fundamental progress has to do with the reinterpretation of basic ideas." That gets to the heart of much of what we are doing in clinical cancer research today. We know we need to kill the cancer cell, and we are proving to be remarkably adept at reinterpreting how to go about it. •

Dr. John E. Niederhuber NCI Deputy Director and Deputy Director for Clinical and Translational Sciences



Spotlight

Targeted Drugs Make Gains Against Kidney Cancer

For the first time in two decades, patients are benefiting from new treatments for kidney cancer, and many physicians are optimistic about a disease that has been hard to treat and difficult to detect in its early stages.

Two targeted drugs have been approved by the Food and Drug Administration (FDA) for kidney cancer in the last 7 months—the first new therapies since biological agents were developed in the 1980s.

Over the weekend, there was more good news. At the American Society of Clinical Oncology (ASCO) annual meeting, researchers presented findings from two final-stage clinical trials that favored targeted drugs over standard therapy with interferon, the most commonly used biological agent.

"It's an exciting time," said Dr.
Robert J. Motzer of Memorial Sloan-Kettering Cancer Center, who presented results from a trial involving sunitinib (Sutent). The drug was approved in January as a second-line treatment for advanced kidney cancer.

The study he presented at ASCO tested sunitinib as a first-line treatment in patients with advanced kidney cancer. The drug nearly doubled the amount of time it took for the cancer to grow or spread compared with interferon (47 weeks vs. 24 weeks).

"This is a treatment that works," said Dr. Motzer, noting that the drug is a pill patients take at home. "It has changed the whole atmosphere of my clinic."

The study cannot yet say whether sunitinib helps patients live longer. But anecdotally Dr. Motzer pointed out that several of his patients who were expected to do poorly on biological agents are doing "extremely well" more than 2 years after starting on sunitinib.

The second trial presented at ASCO asked whether an experimental intravenous drug called temsirolimus could help high-risk patients with poor prognoses live longer. The drug inhibits a protein called mTOR that regulates other proteins, some of which drive cancer.

In the study, temsirolimus increased survival among these patients (11 months) beyond what was achieved by interferon (7 months) or interferon plus temsirolimus (8.4 months).

The improvement in survival was "remarkable" considering that most high-risk patients with advanced disease live less than 6 months, said lead researcher Dr. Gary R. Hudes of the Fox Chase Cancer Center.

Following the presentations at ASCO, Dr. Michael B. Atkins of the Beth Israel Deaconess Medical Center put the new results in context.

Sunitinib, he said, could now be considered the new standard first-line treatment for advanced kidney cancer in patients with favorable or intermediate prognoses, while temsirolimus could be the new first-line treatment for patients with poor prognoses.

Sorafenib (Nexavar), which the FDA approved last December, would be the standard second-line treatment for patients who have received prior biological therapy, he said.

Asked why the new drugs seem to have appeared all at once, Dr. Motzer said that although no new treatments emerged in the 1990s, researchers identified a number of genes and proteins involved in the disease.

Some of these molecules turned out to be the targets of experimental drugs like sunitinib, and for this reason early in their development the drugs were tested against kidney cancer.

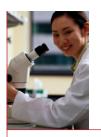
None of the targeted drugs, however, is a cure, and the disease will kill nearly 13,000 Americans this year. Tobacco use is the only known risk factor.

"This is really the beginning," said Dr. Alison Martin of NCI's Cancer Therapy Evaluation Program at ASCO.

The challenge now is to learn how best to use the drugs, she added, and to see whether these or other targeted agents provide more benefit when given in combination.

Another priority is to test single agents earlier in the disease to try to

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Cancer Research Highlights

Imatinib Performs Well in Patients after 5 Years

There was some good news last week for patients with chronic myeloid leukemia (CML), said Dr. Brian Druker of Oregon Health & Science University Cancer Institute at the ASCO annual meeting.

The first piece of good news is that imatinib (Gleevec) is "performing extremely well" in patients who have taken the drug for 5 years or longer, according to Dr. Druker, who led the development of imatinib for CML. The first study to assess the drug's benefit after 5 years found that nearly 90 percent of patients who received imatinib as their initial therapy were still alive. The survival rate was 95 percent when only CML-related deaths were included.

The drug was well tolerated over the long term: Only 5 percent of patients stopped taking it because of side effects. And after about the third year of taking the drug, the risk of relapse appears to begin to decrease. Moreover, the better a patient's response to the drug, the less likely it is that the patient will progress to advanced disease.

The second piece of good news is that "another drug is coming along" for patients who cannot tolerate imatinib, Dr. Druker noted. On Friday, the FDA's Oncologic Drugs Advisory Committee recommended accelerated approval of dasatinib for treating CML that resists prior therapy, including imatinib.

Combination trials will be undertaken, said Dr. Druker, who is planning a head-to-head trial comparing the drugs as first-line treatments. The question of which one to use will come down to response rate and tolerability, he said. Citing imatinib's impressive record over the long term, Dr. Druker has decided to use it as the first-line therapy for now. "But if dasatinib turns out to be better," he added, "I will go with it."

Adjuvant Gemcitabine Extends Survival for Pancreatic Cancer

Even if a patient's pancreatic cancer can be removed surgically, surgery alone rarely provides a cure. New results from a large randomized trial presented at the ASCO annual meeting suggest that the addition of the drug gemcitabine to adjuvant chemoradiation therapy using 5-fluorouracil (5-FU) for patients with pancreatic adenocarcinoma can significantly extend survival compared with adjuvant chemoradiation therapy using 5-FU alone.

In the RTOG 9704 trial, investigators randomly assigned patients to one of two groups: surgery, followed by gemcitabine given both before and after chemoradiation (experimental arm); or surgery, followed by 5-FU given both before and after chemoradiation (control arm).

Patients with tumors in the pancreatic head (the most common location) and patients with tumors in the pancreatic body or tail were included

in the trial. Because of potential differences in the biology of tumors located in the body or tail of the pancreas, investigators increased the number of patients to be enrolled in the trial in order to have enough data to analyze patients with pancreatic head cancer as a subgroup.

More than 400 eligible patients participated in the trial. The addition of gemcitabine-based therapy significantly extended survival for patients with pancreatic head tumors: Those who received gemcitabine had a median survival of 20.6 months and 32-percent 3-year survival, compared with a median survival of 16.9 months and 21-percent 3-year survival in those who received only radiation therapy and 5-FU. But, when patients with pancreatic body or tail tumors were included in the analysis, the increase in survival was no longer significant.

"The addition of gemcitabine to postoperative adjuvant 5-FU chemoradiotherapy improves survival in patients with pancreatic head adenocarcinoma," stated Dr. William Regine, chief of radiation oncology at the University of Maryland Medical Center, Baltimore, who presented the results of the study, adding that future clinical trials can now build on this new treatment regimen to better improve survival for patients with this rare but deadly malignancy.

Breast Cancer Drug Anastrozole Increases Bone Loss

Women who take the drug anastrozole, an aromatase inhibitor, to prevent the recurrence of breast cancer should have their bone mineral density monitored and should take calcium and vitamin D supplements during therapy, researchers said at the (continued on page 5)

(Highlights continued from page 4) ASCO annual meeting.

They made the recommendation based on a 5-year study showing that anastrozole was associated with a steady decline in bone mineral density. The bone loss was, on average, about 6–7 percent, or about twice the amount that would normally occur over that period.

However, no patients whose bone mineral density was normal at the start of the study developed osteoporosis after 5 years of treatment. To develop the condition, a woman would need to lose 15–20 percent of her normal bone mass.

The results are from the Arimidex, Tamoxifen, Alone or in Combination (ATAC) trial, which previously showed that anastrozole was superior to tamoxifen in preventing recurrences in women following surgery and radiation for early-stage breast cancer. Anastrozole is generally better tolerated than tamoxifen with fewer gynecological or thrombo-embolic complications, but is associated with more fractures and osteoporosis than tamoxifen, which preserves bone, according to the researchers.

"The overall risk-benefit ratio still favors taking anastrozole over tamoxifen," said Dr. Robert E. Coleman of the University of Sheffield, in the United Kingdom, who presented the findings at ASCO. But he said that women should have their bone mineral density measured at the start of treatment and then monitored every 1–2 years on therapy.

Treatments at End of Life Grew More Aggressive in 1990s

By the late 1990s, cancer patients were more likely to receive aggressive treatments near the end of their lives than patients who were treated at the start of the decade, researchers reported at the ASCO annual meeting. The findings, from an effort to identify quality measures for end-of-life care, confirm previous reports of a trend, for some physicians, toward intervening aggressively to treat patients very near death.

The trend includes an increase in the use of chemotherapy on patients within 2 weeks of death; an increase in multiple emergency room visits and admissions to intensive care units during the last month of life; and a greater proportion of patients admitted to hospice within 3 days of death.

Dr. Craig Earle of the Dana-Farber Cancer Institute and his colleagues analyzed statistics from NCI's Surveillance, Epidemiology, and End Results (SEER) database and Medicare billing records on 215,000 patients who died of cancer between 1991 and 2000.

Dr. Earle's team first described this trend several years ago. Although the aggressive treatments were not necessarily inappropriate, Dr. Earle says, they were often given to patients who had little or no chance of benefiting from them.

By developing quality measures for end-of-life care, the researchers intend to help physicians determine the most appropriate treatments for these patients. They also hope to raise awareness about issues related to end-of-life care.

Chemotherapy for NSCLC Benefits Elderly Patients

New data presented at the ASCO annual meeting on June 2 provided evidence that chemotherapy following surgery for elderly patients with non-small-cell lung cancer (NSCLC) improves survival, without an

increase in treatment-related toxicity or hospitalization compared with younger patients.

Dr. Carmela Pepe of Princess
Margaret Hospital in Toronto presented a retrospective analysis of the results from a clinical trial led by the National Cancer Institute of Canada in which patients with NSCLC had been randomly assigned following surgery either to chemotherapy with vinorelbine and cisplatin or to observation alone.

In the retrospective analysis, the investigators looked at whether the trial's previously reported overall survival advantage for the surgery plus chemotherapy group held even if the patients were elderly. They also examined whether there were differences between the elderly and younger patients in terms of the number of chemotherapy doses they received, the intensity of the doses, or the side effects.

Sixty-six percent of elderly patients who received chemotherapy were alive 5 years after treatment, compared with 46 percent in the surgeryalone group. This survival advantage was seen even though elderly patients received fewer—and less intense—doses than younger patients. Elderly patients who received chemotherapy were no more likely to experience toxic side effects or be hospitalized during treatment than were younger patients.

These results indicate that "Platinum-based chemotherapy can be given safely to elderly patients without significant risk of increased toxicity," said Dr. Pepe. "Therefore, adjuvant chemotherapy should not be withheld from elderly patients on the basis of age alone." •

Funding Opportunities

Circulating Cells in Cancer Detection

Announcement Number: PA-06-423 New Application Receipt Date: Oct. 1, 2006.

This is a renewal of PA-04-035 and will use the R21 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3479. Inquiries: Dr. Padma Maruvada—maruvadp@mail.nih.gov; Dr. Sudhir Srivastava—ss1a@nih.gov

Phased Innovation Research in Cancer Prognosis and Prediction

Announcement Number: PA-06-434 New Application Receipt Dates: Oct. 1, 2006; Feb. 1, June 1, and Oct. 1, 2007; Feb. 1, June 1, and Oct. 1, 2008; Feb. 1, 2009.

This is a renewal of PA-04-102 and will use the R21 and R33 award mechanisms. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3480. Inquiries: Dr. Tracy G. Lively—livelyt@mail.nih.gov; Dr. Magdalena Thurin—thurinm@mail.nih.gov; Dr. James V. Tricoli—tricolij@mail.nih.gov; Dr. John M. Jessup—jessupj@mail.nih.gov

Phased Innovation Research in Cancer Prognosis and Prediction

Announcement Number: PA-06-435 New Application Receipt Dates: Oct. 1, 2006; Feb. 1, June 1, and Oct. 1, 2007; Feb. 1, June 1, and Oct. 1, 2008; Feb. 1, 2009.

This is a renewal of PA-04-102 and will use the R33 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3481. Inquiries: Dr. Tracy G. Lively—livelyt@mail.nih.gov; Dr. Magdalena Thurin—thurinm@mail.nih.gov; Dr. James V. Tricoli—tri-

In Memoriam: Dr. Anita Roberts

Following a more-than-2-year battle with gastric cancer, Dr. Anita Roberts died on May 26. Dr. Roberts, former chief of the Laboratory of Cell



Regulation and Carcinogenesis in the NCI Center for Cancer Research (CCR), was 64 years old.

Dr. Roberts is remembered by colleagues as a warm person, dedicated to her work and her co-workers. Her published work is among the top 50 most-cited research papers and she is the second most-cited female scientist in the world. Throughout her career, Dr. Roberts received numerous awards, the most recent of which include the Federation of American Societies for

Experimental Biology's (FASEB) Award for Excellence in Science and the Susan G. Komen Foundation's Brinker Award for Scientific Distinction, both of which she received in 2005.

In collaboration with Dr. Michael Sporn, now at Dartmouth University Medical School, Dr. Roberts conducted seminal research into the essential biological role of the protein TGF- β in areas such as immune function and wound healing, and in diseases like cancer.

"Anita was a remarkable researcher and colleague who has left an indelible scientific legacy," said NCI Deputy Director and Deputy Director for Translational and Clinical Sciences Dr. John Niederhuber.

As those who worked closely with her attest, Dr. Roberts was more than just an eminent scientist.

"She was an extraordinary mentor who created a uniquely nurturing environment in her laboratory," said CCR Director Dr. Robert Wiltrout. In 2004, Dr. Roberts received the NIH Mentor Award.

Dr. Roberts—who catalogued her life over the last 2 years on a blog, www.anitaroberts.net/blog/—continued to participate in scientific conferences throughout what was a long and difficult treatment. She delivered her award lecture at the FASEB annual meeting in San Diego in April 2005 and also participated in a conference on TGF- β and cancer in Dallas in February 2006.

She is survived by her husband, Robert, two children, Greg and Karl, and five grandchildren. *

colij@mail.nih.gov; Dr. John M. Jessup—jessupj@mail.nih.gov

Basic and Preclinical Research on Complementary and Alternative Medicine

Announcement Number: PA-06-440 New Application Receipt Dates: Oct. 1, 2006. This is a renewal of PA-05-141 and will use the R01 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3482. Inquiries: Dr. Wendy B. Smith—smithwe@mail.nih.gov; Dr. Cindy Davis—davisci@mail.nih.gov *

Notes

NCAB Meeting Slated for June 14

The National Cancer Advisory Board (NCAB) will meet on June 14 in Room 6C10 of Building 31 on the NIH campus in Bethesda. Overflow rooms, available for closed circuit viewing, include 6C7 and 11A10 in Building 31. The meeting will be videocast at http://videocast.nih.gov.

Gail Receives Marvin Zelen Leadership Award

On June 2, Dr. Mitchell H. Gail, chief of the Biostatistics Branch in the Division of Cancer Epidemiology and Genetics (DCEG), received the 2006 Marvin Zelen Leadership Award in Statistical Science from



the Department of Biostatistics at the Harvard School of Public Health. His award lecture, "Absolute Risk: Clinical

Applications and Controversies," illustrated the clinical applications of a model for absolute breast cancer risk, often referred to as the Gail Model. The Zelen Award recognizes an individual in government, industry, or academia who has significantly affected the theory and practice of statistical science.

President's Cancer Panel Releases Annual Report

On June 3, the President's Cancer Panel released its latest report, Assessing Progress, Advancing Change. The report revisits selected recommendations from the 2003 report on cancer survivorship and the 2004–2005 report on translating research into improved care for people with cancer. The Panel reports on the progress that has occurred for the selected recommendations,

the near-term priorities for continuing progress, and commitments that organizations have made to further recommendations.

The Panel recognized at least four overarching issues that continue to undermine the progress of the National Cancer Program. They include fiscal constraints that have led to decreased funds for cancer research; lack of comprehensive health care reform needed to ensure universal access to cancer care for all Americans; the need for improvements in education and communication to inform the general public about cancer and cancer research and to more effectively disseminate research findings to health care providers; and lack of coordination across the National Cancer Program, which slows progress and prevents optimal use of resources.

For additional information on the Panel, or to download a copy of the report, go to http://pcp.cancer.gov.

NIH Examines State of the Science in Tobacco Control

The NIH State-of-the-Science Conference on Tobacco Use will take place at the Natcher Conference Center on the NIH campus on June 12–14.

The first day and a half of the meeting will consist of presentations by expert researchers and practitioners, and open public discussions. On June 14, an independent panel will present a statement of its collective assessment of the evidence. The panel will also hold a press conference to address questions from the media. The conference is free, but registration is required. For more details, visit http://consensus.nih.gov/2006/2006TobaccoSOS029html.htm. *

(Spotlight continued from page 3)

improve cure rates among high-risk patients. Toward this end, NCI and its cooperative groups, in a partnership with Pfizer and Bayer, launched a large, national clinical trial last month.

The trial, led by the Eastern Cooperative Oncology Group, will seek to answer a question raised by the success of targeted drugs: Do patients with localized disease who have had their cancers surgically removed benefit from additional treatments with sunitinib or sorafenib? *

By Edward R. Winstead

CCR Grand Rounds

June 13: No lecture. General Motors Cancer Research Foundation Conference— Genomics and Cancer, June 12-13.

June 20: Dr. Ron McKay, Senior Investigator, Laboratory of Molecular Biology, National Institute of Neurological Disorders and Stroke. "Notch Signaling Regulates Stem Cell Numbers in Vitro and in Vivo."

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 Meetings and **Events**

A calendar of scientific meetings and events sponsored by the National Institutes of Health is available at http://calendar.nih.gov *



Community Update

Passport for Care: An Internet-Based Survivorship Care Plan

The large increase in the numbers of children surviving cancer is one of the great success stories of cancer research and treatment. Many children who otherwise would have died shortly after a cancer diagnosis are now living well into adulthood. But, it is becoming increasingly clear that extending lifespan and preserving quality of life for survivors depends on screening for and managing the potential long-term effects of therapy.

Because childhood cancer survivors often lack information about the treatments they received and their long-term health implications, researchers at Texas Children's Cancer Center and Baylor College of Medicine's Center for Collaborative and Interactive Technologies in Houston, Texas, in conjunction with the Children's Oncology Group (COG), are developing an interactive Internet resource, the Passport for Care (PFC).

"The Passport for Care is designed to address the fact that survivors of childhood cancer change physicians frequently, may not be aware of the specific therapies they received, and often seek care from physicians who are unfamiliar with their disease and its treatment," said Dr. David Poplack, director of Texas Children's Cancer Center and a co-developer of the PFC. "Developing portable and acces-

sible summaries of treatment and potential health risks enables survivors to actively participate in their follow-up care."

Survivors of childhood cancer are particularly at risk for second malignancies and other long-term complications of therapy, including learning and cognitive deficits; cardiac and cardiovascular problems; growth, endocrine, and fertility problems; and liver, lung, and kidney dysfunction. Recent studies suggest that between two-thirds and three-quarters of survivors will experience at least one of these late effects, some of which can take years to develop.

Consistent medical follow-up for cancer survivors is complicated by several factors: Americans change primary health care providers every 2 years on average; survivors often are not familiar with the details of their treatment history and cannot accurately share pertinent medical information with their health care providers; and primary care providers often are unfamiliar with cancer

treatments or with the potential longterm complications of cancer and cancer therapy.

To address many of these problems, the PFC Web will include:

- An end-of-treatment care summary with individualized recommendations that can be shared securely with providers at the request of survivors
- Customized recommendations for survivors' follow-up care based on their treatment history, which will inform survivors about their level of risk for late effects
- A system providing survivors with updated changes in their individualized surveillance guidelines as new information becomes available
- Education materials customized to patients' needs based on their disease and its treatment

"The Passport for Care essentially addresses what the 2003 Institute of Medicine report, Childhood Cancer Survivorship: Improving Care and Quality of Life, indicated was necessary to empower survivors—enabling them to get appropriate long-term follow-up," says Dr. Poplack. "Our process of developing an online database for the Care Summary and COG guidelines is on track. Testing will soon begin in the Long-Term Survivor Clinic at Texas Children's Cancer Center, followed by a pilot at three additional survivorship clinics around the country." *

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. Contact the *NCI Cancer Bulletin* staff at ncicancerbulletin@mail.nih.gov.