

Assessing Progress, Advancing Change

2005-2006 ANNUAL REPORT

P R E S I D E N T ' S C A N C E R P A N E L



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

National Cancer Institute





THE PRESIDENT'S CANCER PANEL

CHAIR:

LaSalle D. Leffall, Jr., M.D., F.A.C.S.

Charles R. Drew Professor of Surgery
Howard University College of Medicine
Washington, DC 20059

MEMBERS:

Lance Armstrong

Founder
Lance Armstrong Foundation
Austin, TX 78746

Margaret L. Kripke, Ph.D.

Executive Vice President and
Chief Academic Officer
The University of Texas M. D. Anderson Cancer Center
Houston, TX 77030

This report is submitted to the President of the United States in fulfillment of the obligations of the President's Cancer Panel to appraise the National Cancer Program as established in accordance with the National Cancer Act of 1971 (P.L. 92-218), the Health Research Extension Act of 1987 (P.L. 99-158), the National Institutes of Health Revitalization Act of 1993 (P.L. 103-43), and Title V, Part A, Public Health Service Act (42 U.S.C. 281 *et seq.*).

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For further information on the President's Cancer Panel or additional copies of this report, please contact:

Abby B. Sandler, Ph.D.
Executive Secretary
President's Cancer Panel
6116 Executive Boulevard
Suite 212, MSC 8349
Bethesda, MD 20814-8349
301-451-9399
pcp-r@mail.nih.gov

PRESIDENT'S CANCER PANEL

Assessing Progress, Advancing Change

2005-2006
Annual Report

Suzanne H. Reuben
for
The President's Cancer Panel

June 2006

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

National Cancer Institute

The President
The White House
Washington, DC 20500

Dear Mr. President:

The President's Cancer Panel is charged to report to you at least annually on barriers to the fullest development and execution of the National Cancer Program (NCP). In its two most recent reports, the Panel recommended particularly urgent actions necessary to better meet the needs of the nation's 10 million cancer survivors and accelerate the translation of basic science discoveries into cancer prevention, diagnosis, and treatment interventions. In 2005, the Panel dedicated its efforts to assessing progress toward implementing the most pressing among these recommendations to reduce the terrible burden of cancer on those afflicted, their loved ones, and the country.

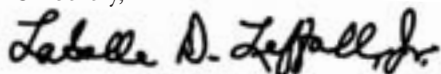
Success in implementing the Panel's recommendations, described in the attached report, has been uneven at best. Initiatives to improve awareness of survivorship issues are becoming more robust, yet patients, health care providers, researchers, and insurers still lack crucial information about cancer and cancer care that is essential to improve treatment choices and ensure access to and coordination of post-treatment care. Most people with cancer still leave treatment with neither a summary of the therapy they received nor a follow-up care plan to guide their journey after cancer. Many millions remain uninsured or underinsured for the initial and continuing costs of cancer care.

Though encouraging steps are being taken to remove the disincentives to participating in collaborative science that permeate the research culture, much more remains to be done. Similarly, major changes still are needed to attract, train, and retain the translational and clinical researchers whose work leads to better cancer care and patient outcomes. In addition, the critical contributions to improved cancer care of both dissemination research – discovering how best to convey and reinforce cancer-related information to diverse audiences – and dissemination activities must be more fully recognized and supported.

The Panel found that these and other continuing deficits all can be traced to the impact of four longstanding issues. **Funding** cuts and drug development costs are limiting research progress, discouraging the creation of new anticancer therapies, and putting the continued availability of proven cancer drugs at risk. Comprehensive **health care reform** and universal access to care remain crucial national needs that cannot be met by fragmented, incremental initiatives. Inadequate **education and communication** pervades nearly every cancer research and care issue, and unintended consequences of HIPAA privacy provisions still impede appropriate data sharing, cancer care provision, and research. Lack of **coordination** across NCP activities slows progress and results in suboptimal use of available resources.

The Panel was particularly struck by the disturbingly diminished expectations for progress these problems have engendered, which were expressed repeatedly by the diverse cancer community stakeholders who attended the Panel meetings. We can no longer allow these problems to deny people with cancer the care they need. Nor must these barriers be permitted to discourage the best minds from choosing careers in cancer research and care, or to sap the creativity of those who do. Despite competing national priorities, the Panel believes that these issues, which have such significant and detrimental effects on the health and productivity of the nation must be resolved, and entreats you to make the necessary financial commitments and use the power of your office to do so.

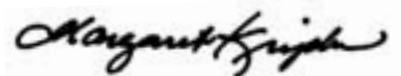
Sincerely,



LaSalle D. Leffall, Jr., M.D., F.A.C.S.
Chair



Lance Armstrong



Margaret Kripke, Ph.D.

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Executive Summary

Between August and October 2005, the President's Cancer Panel (the Panel) convened four meetings to assess progress toward implementing key recommendations from each of its two most recent annual reports to the President of the United States:

- ***Living Beyond Cancer: Finding a New Balance*** (May 2004) described physical, psychosocial, employment, educational, financial, and legal issues that may affect cancer survivors across the lifespan. Among the recommendations contained in that report, the Panel was particularly interested in assessing improvement in the following areas:
 - Providing treatment summaries and follow-up care plans to all survivors upon discharge from treatment for their primary cancer and any secondary or recurring malignancies.
 - Expanding the body of research on adolescents and young adults with cancer.
 - Improving access to care and insurance coverage for health care services needed by survivors.
- ***Translating Research into Cancer Care: Delivering on the Promise*** (June 2005) examined the numerous, interrelated barriers that impede the transformation of basic research findings into better preventive, diagnostic, and therapeutic interventions and their delivery to the American public. At its meetings, the Panel revisited essential core issues related to:
 - Influencing the culture of research to encourage participation in multidisciplinary team research, which is an essential element for moving scientific discoveries forward into clinical practice.
 - Building and retaining the translational and clinical research workforce needed now and in the future to develop and test new technologies and interventions for people with cancer and those at risk.
 - Improving the dissemination of research advances and new interventions to improve patient outcomes.

A total of 75 stakeholders from government, academia, industry, the nonprofit sector, the advocacy community, and community-based health, social service, and other provider organizations participated in dynamic roundtable discussions of these topics.

The Panel asked participants to: (1) identify progress to date in implementing the selected recommendations, (2) suggest the most critical priorities for the next two years, (3) brainstorm ideas for potential partnerships, collaborations, and necessary resources, and (4) indicate explicitly how – either individually or organizationally – they could commit to advancing change.

As the sections below summarize, these productive discussions both facilitated communication among stakeholders about recent activities and generated numerous possibilities for new approaches and partnerships to address identified problems and priorities. The attached report catalogs these activities and ideas, and it is the Panel's hope that it will be used by

diverse cancer constituencies to establish new partnerships for action and to expand ongoing activities. At the same time, the meetings illuminated both uneven progress and in some cases, disturbingly diminished expectations for change related to specific survivorship and research translation concerns. These real and perceived limitations, almost without exception, could be traced directly to the impact of one or more of several longstanding, overarching issues.

Progress on Survivorship Issues

...the [cancer] community has an obligation to the survivor population to really take some actionable steps. And whether [for now] that's a standard treatment summary in lieu of a more rigorous guideline set, I think we should move that forward.

– Patient advocate

The Panel was pleased with the progress made in some areas, most notably partnerships and programmatic initiatives to increase public and health provider awareness of survivorship issues. These increasingly robust activities include outreach and other programs designed to empower survivors with available knowledge about possible late effects of cancer treatment, sources of information and support, and tools to help maintain their personal health records and protect their health. Efforts to date to develop a standard treatment summary template have been productive albeit somewhat fragmented, and will benefit from collaboration among those who thus far have worked on this issue.

Progress was less encouraging in other areas, however. Lack of a solid knowledge base to support follow-up care guideline development for the many types of cancer and individual patients' circumstances is a continuing problem. However, meeting participants agreed that even while this evidence base is being strengthened, follow-up care plans must nonetheless be provided, based on best practices and the best available expert opinion.

Although research on some survivorship issues appears to be increasing, research on adolescents and young adults diagnosed with cancer continues to lag far behind the study of other age groups. This dearth of knowledge is particularly alarming given that cancer survival rates for this population have not improved appreciably for more than two decades. The Panel is optimistic that forthcoming recommendations from the recent review of research to date in this population will help stimulate and focus the national research agenda on cancer in this age group.

In addition, the vast majority of survivors of all ages continue to suffer from limited access to medical, psychosocial, and supportive care they need following cancer treatment, including in some cases, prosthetic and fertility-related services. These access barriers take two major forms. For many survivors, needed services simply are not available where they live and they cannot travel to reach them. For even more survivors, available services remain out of reach due to lack of insurance coverage for needed care and/or inability to pay for care out-of-pocket.

The database for patients diagnosed during adolescence and young adulthood is pitiful and there's no infrastructure....because it's a rare disease, [NCI's surveillance program] is inadequate to capture that population. They are spread out between pediatric oncologists, medical oncologists, and community medical oncologists at academic centers. We have no databases to capture the on-treatment and survivorship data for [these] patients.

– Adolescent and young adult survivorship clinic program director

Progress Related to Research Translation

The Panel was aware that little progress was likely to have been made toward implementing its research translation-related recommendations since only a short period of time had elapsed since the report's publication. There were, however, indications of new initiatives and partnerships that can be expected over time to influence the culture of research to more fully embrace and value team science and other collaborative cancer research. For example, some Federal and other cancer research funders are revising grant award criteria to place a higher priority on team efforts. Several academic institutions and professional societies have established team science recognition awards, and scientific journal editors have begun to explore ways to improve attribution for individual contributions to team projects. Steps such as these should raise the visibility and perceived value of collaborative translational and clinical research at individual institutions and dissipate current hiring, promotion, and tenure barriers that now discourage participation in these types of research.

The promise of basic science discoveries in cancer will never be realized if we lack the cadre of translational and clinical researchers whose work turns these discoveries into better care for people with cancer. It is too soon to expect substantial progress toward implementing the Panel's research workforce recommendations, but it should be underscored that it is equally crucial to recruit young scientists to careers in translational and clinical research, and to retain them in science once they have completed training by ensuring that a viable career path exists. Greater support and protected time are needed for these investigators across their career trajectory, particularly to relieve the increasing pressure on physician-scientists to generate patient care revenue. Special initiatives may be needed to recruit and retain individuals from minority and underrepresented groups, including women.

The Panel was encouraged by new National Institutes of Health commitments to strengthen support for young investigators despite declining budgets. Similarly, other research institutions, professional societies, and foundations are providing a range of career development and new investigator awards; more are needed. Some institutions are developing innovative M.D.-Ph.D. programs, and the number of physician-scientists appears to be stabilizing after a period of significant decline. Meeting participants emphasized, however, that the scientific community must reach back to the undergraduate



We're beginning to explore...another program that would be related to our comprehensive cancer centers but would be based in not-for-profit community hospitals where we would develop a cancer program – an NCI-designated, peer-reviewed, supported program – that would be built more on the requirements...[for] dissemination of information and quality of care, getting us ready in the community where the patients are for the new era of molecularly targeted therapies and new era of getting new therapy regimens right to the patient in the community.

– NCI deputy director

population to nurture early interest in a research career. Further, it was recognized that crucial academic decisions affecting later career choices are made as early as the middle school years.

Dissemination research still is in its infancy, but its utility for reaching public and health provider audiences with new cancer knowledge and interventions appears to be gaining recognition. For example, the National Cancer Institute's Comprehensive Cancer Centers may now apply for support of a dissemination research program as a supplement to the center's core grant; one such program has been funded. Dissemination activities, however, remain almost entirely unfunded at the cancer centers and in large measure continue to be conducted in a fragmented fashion by foundations and underfunded Federal, state, and community-based agencies. To leverage resources and expertise and reduce public confusion about health-related information, meeting participants suggested that information and advocacy organizations focused on chronic diseases with similar risk factors (e.g., cancer, heart disease, diabetes) join forces to meld similar disease prevention, management, and wellness messages into a broader approach that crosses disease boundaries. At a higher level, however, the continuing lack of leadership and support for both dissemination research and dissemination activities must be addressed.



Overarching Issues

Several themes suffused the discussions at the Panel's meetings, regardless of the specific topic at hand. None are new; the Panel has addressed each in numerous previous reports. Yet these pervasive issues are more pressing with each passing year as the American population ages, the total number of cancer cases increases as a function of age-related risk, and health care costs, including for both the most basic and the most advanced life-saving cancer interventions, continue their upward spiral as insurance benefits shrink.

Fiscal Constraints

For the first time in more than 70 years, the U.S. cancer death rate declined slightly, even though the number of new cancer cases continued to increase.¹ Albeit small, this success in reducing cancer mortality reflects the impact of research advances, including earlier cancer detection methods, better diagnostic tools, and better treatments. This momentum must not be lost. Current fiscal constraints affecting cancer research and cancer care derive from three detrimental trends: declining Federal research budgets, the potential for escalating mandatory contributions from the NCI budget to broad NIH initiatives, and increasingly meager insurance reimbursements by public and private health care payors. This situation cannot help but have a negative impact on the twin goals of making cancer a disease people can live with, rather than die from, and rendering cancer a largely preventable disease.

The debilitating impact of scarce funding could be traced throughout the Panel's meetings. For example, oncology professionals noted that reimbursement seldom is available for the considerable time and costs associated with developing and discussing the detailed treatment summaries and follow-up care guidance needed by newly discharged cancer patients. Creative ideas for improving cancer information and care services were immediately met with questions about where the necessary funding would come from.

In addition, the Panel's 2004–2005 report on research translation highlighted the escalating threat to continued progress against cancer due to fiscal realities related to the drug patent, development, approval, and marketing processes. The cost of bringing a drug to the marketplace currently exceeds \$800 million,² and the number of new cancer drug approvals is low.³ Even if used to treat common cancers, the potential market for any new cancer drug is small compared with medications for hypertension, diabetes, or heart disease management. Moreover, our success in identifying subgroups of common cancers that require different treatments actually is further shrinking the markets for individual anticancer drugs and industry's interest in developing them.

Of equal concern, as older cancer drugs (e.g., cisplatin) that are the mainstay of many current treatments lose patent protection and their profitability, some pharmaceutical companies are electing to cease production of these essential agents, potentially leading to short supplies of life-saving medications. The Panel reiterates its contention that to encourage new cancer drug development and ensure adequate supplies of mainstay treatments, cancer should be designated an orphan disease,⁴ thereby enabling drug developers and manufacturers to obtain support to offset specific elements of cost and extend patent protection for approved agents.

...we face a continued decline in reimbursement....we are constantly fighting that battle so that clinical research programs can stay alive, because the patients are...staying in the community.

– Community oncologist

The myriad ramifications of scarce funding for critical cancer research and cancer care activities are cause for urgent concern. Even if these problems are addressed, all stakeholders involved in cancer research and cancer care must seek out and seize every opportunity to work collaboratively and efficiently to make the most of available resources.

Health Care Coverage

People who have had cancer need lifelong care to monitor for and treat late effects of cancer therapies, recurrences, and second cancers, and to address psychosocial, nutritional, rehabilitation, and other needs that may arise years after treatment ends. More than 10 million people in this country are living with a history of cancer; in 2006, nearly 1.4 million new cases of cancer will be diagnosed.⁵ According to the most recent available estimate, 45.8 million people in the United States lack health insurance of any kind,⁶ and many millions more are underinsured for the costs of initial and ongoing cancer care. Employer-sponsored employee and retiree health benefits are declining in terms of the numbers of people covered, the scope of benefits, and increased premium, deductible, and copayment cost-shifting onto insureds.⁷ Medicaid budget cuts scheduled over the next five years are very likely to put targeted, individualized cancer care – or even standard care – further out of the reach of the nation's poor and widen disparities in cancer care and outcomes already experienced by poor and underserved individuals. In addition, the existing health care system continues to focus on acute care rather than disease prevention and the benefit to national productivity that accrues from maintaining individual wellness.

The Panel has strongly recommended a renewed effort to craft national comprehensive health care reforms, and reiterates this recommendation here. In the Panel's view, incremental remedies, including those currently proposed (e.g., Health Savings Accounts/high-deductible consumer-directed health plans), are not and will not be adequate to address fundamental health system problems and may even have the effect of reducing coverage by increasing out-of-pocket costs, particularly for those least able to afford them.

...once you're diagnosed with a life-threatening illness, it is there for life. I don't care whether you had cancer when you were a child, that's going to follow you for the rest of your life as far as insurance is concerned.

– Patient advocate

Education and Communication

Education and communication needs permeate nearly every cancer research and care issue. Though critical for success across the research and care continuum, education and communication activities often get short shrift and small budgets.



The need to improve public understanding about cancer and the importance of cancer research is virtually undisputed. For example, cancer myths and misconceptions (e.g., that exposing cancer to air can cause it to spread, that research participants are “guinea pigs”) continue to flourish. Nearly half of U.S. adults who participated in a recent national survey believe they have little or no control in reducing their risk of cancer.⁸ To counter discrimination still experienced by some cancer survivors, employers, lenders, and insurers (including health, life, and disability coverage providers) must be informed of the longevity and renewed productivity most survivors can now expect due to research advances. People diagnosed with cancer and their caregivers need immediate access to accurate information about treatment options and available resources. Likewise, survivors need reliable, up-to-date information sources to stay abreast of research and care advances relevant to their individual situations.

For the public to benefit from research advances, new knowledge, technologies, and resources must be disseminated rapidly to the provider community, with follow-up information and communication to encourage new intervention adoption. In addition,

It's wonderful to develop all of these things and provide the evidence that there are interventions that work. It's another thing to get them outside of the cancer centers and into the community.

– Cancer center executive

health and ancillary care providers of all types need ongoing education about cancer as a disease, and about the importance of early detection, the value of clinical trials, and survivorship issues. This information is critical if providers are to make appropriate treatment recommendations and referrals (including to clinical trials); explain treatment options, informed consent, and other issues to patients; and coordinate patient care effectively.

Information and communication needs in the research community also are diverse. For example, researchers involved in drug or medical device development must understand regulatory requirements and communicate effectively with regulators, funders, and insurers. Effective communication with patients and family members about specific clinical trials and informed consent for treatment or use of tissue or other biologic samples is crucial. In addition, researchers from different disciplines and institutions must be able to communicate and share data as needed to best design and carry out research projects.

The unanticipated consequences of privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) remain a significant continuing impediment to data sharing, cancer care provision, research, and other communications. Electronic health records development and use, health provider-patient/caregiver communication, restrictions on researchers' ability to use stored tissue samples or to contact survivors to inform them about new findings or treatments – all are affected adversely by HIPAA. The Panel has called for an evaluation of HIPAA-related barriers to guide whatever legislative or regulatory changes may be needed to alleviate them, and urges that this evaluation be undertaken and completed with all possible speed.

Coordination

The Panel has commented frequently on the need for coordination of National Cancer Program activities. The need for coordination emerged again strongly at the Panel's meetings, however, the form such coordination should take was repeatedly at issue. Many meeting participants maintained that any centralized coordinating function would create an additional layer of bureaucracy comprised principally of individuals whose scope

of knowledge could not possibly encompass all of the relevant research- and care-related issues. Targeted, subject-specific partnerships and collaborations were viewed as the preferable approach.

It continues to be the Panel's observation, however, that this piecemeal approach often produces uneven results, and further, that collaborative efforts often are preceded by redundant and/or incompatible activities that can waste limited resources and create proprietary stances that later may be difficult to relax. In the Panel's view, the diverse stakeholders within the cancer community have the responsibility, if they do not want centralized coordination, to find more effective and efficient ways to communicate about ongoing and planned activities, and to work together earlier and more cohesively to address issues across the cancer research and cancer care enterprises.

In summary, the Panel believes progress has been made toward resolving some of the issues described in its recent reports, but a great deal remains to be accomplished. Importantly, many of these findings apply not only to cancer research and cancer care, but to biomedical research in general and the entire health care system. Therefore, to maintain progress and advance the pace of change in the current challenging health care and economic environments, all of us who strive to improve the lives of people with cancer, their families, and others at risk for cancer must bring to bear the maximum measure of our creativity, skills, resources, and dedication for their benefit.

Suggested Priorities for Advancing Change

Selected Recommendations of the President's Cancer Panel

2003-2005

Recommendations from *Living Beyond Cancer: Finding a New Balance*

Suggested Priorities

Treatment Summaries and Follow-Up Care Plans

1. Upon discharge from cancer treatment, including treatment of recurrences, every patient should be given a record of all care received and important disease characteristics. This should include, at a minimum:
 - Diagnostic tests performed and results.
 - Tumor characteristics (site(s), stage, and grade; hormonal status; marker information).
 - Dates of treatment initiation and completion.
 - Surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, gene, or other therapies provided, including agents used, treatment regimen, total dosage, number and title(s) of clinical trial(s) (if any), indicators of treatment response, and/or toxicities experienced during treatment.
 - Psychosocial, nutritional, and other supportive services provided.
 - Full contact information for treating institutions and key individual providers. (Report Recommendation 1a)
2. Upon discharge from cancer treatment, every patient should receive a follow-up care plan considering evidence-based standards of care. This should include, at a minimum:
 - A description of recommended cancer screening and other periodic testing and examinations, as well as the schedule on which they should be performed.
 - Information on possible late and long-term effects of treatment and symptoms of such effects.
 - Information on possible signs of recurrence and second tumors.
 - Information on the possible future need for psychosocial support.
 - Specific recommendations for healthy behaviors (e.g., diet, exercise, sun and virus protection, smoking cessation).
 - Referrals to specific follow-up care providers, support groups, and/or the patient's primary care provider.
 - A listing of cancer-related resources and information (Internet-based sources and telephone listings for major cancer support organizations). (Report Recommendation 1b)

- Gain consensus on and implement with all possible speed an initial uniform treatment summary template.
- Conduct research to build the evidence base for follow-up care guideline development and to determine whether treatment summaries and follow-up care plans lead to improved patient outcomes.
- Accelerate efforts to develop and disseminate survivorship follow-up clinical care guidelines based on the best available evidence (including best practices and expert opinion) until the evidence base is further developed through targeted outcomes and related research.
- Establish interoperable media and related standards for electronic health records (including standard terminology for data reporting) so that treatment summaries and follow-up care plans will be comparable and accessible regardless of the format in which they are provided (e.g., CD/DVD, paper, Internet).
- Address data access issues, including but not limited to those related to the privacy provisions of the Health Insurance Portability and Accountability Act of 1996.
- Secure provider reimbursement through the Centers for Medicare and Medicaid Services and other public and private insurers for preparing and presenting treatment summaries and follow-up care plans to patients.
- Develop and provide education to patients, the public, health care providers, and medical students.

Adolescents and Young Adults

1. A working group comprised of representatives from the public agencies and private organizations with established surveillance databases should be convened to determine what additional data collection, infrastructure, and related funding would be required to better capture treatment and survival data on adolescent and young adult cancer survivors. (Report Recommendation 11a)
2. The National Cancer Institute and other cancer research sponsoring agencies should increase the priority of and funding for research on the issues of cancer survivors diagnosed as adolescents or young adults. Studies of biologic differences in cancer type and host factors, and of late effects of cancer and cancer treatment in this population should be emphasized to improve the knowledge base and inform the design of treatment, prevention, and quality of life interventions designed to benefit this population. (Report Recommendation 11b)
3. Further research should be conducted to determine what fertility preservation options are possible for children and young adolescent cancer patients. (Report Recommendation 6c)

- **Build a comprehensive database on all adolescent and young adult (AYA) cancer survivors.**
- **Improve the delivery infrastructure for and communication with AYA survivors to encourage continued contact with the health care system and make it possible to collect data on their long-term outcomes.**
- **Conduct research in the following priority areas:**
 - **Host factors and the biology and pathogenesis of tumors in the AYA age group.**
 - **Whether specific types of follow-up care and surveillance for AYAs with cancer improve outcomes, the cost-benefit of follow-up in terms of quality of life and overall survival, and the incidence of second cancers beyond age 40 among adolescents treated with radiation and chemotherapy.**
 - **Measures to identify survivors at high risk for late effects due to genetic predisposition or other factors.**
 - **Psychosocial factors and their influence on access to care and adherence to recommended care.**
- **Establish a separate National Institutes of Health study section, or modify the mix of reviewer expertise in existing study sections, to help ensure fair and informed evaluation of survivorship research proposals.**
- **Conduct research to develop improved fertility preservation options for children, adolescents, and adults of reproductive age.**
- **Develop mechanisms to ensure that children and adolescents with cancer, their caregivers, adults of reproductive age, and oncologists are aware of opportunities for fertility preservation.**

Insurance and Access

1. Adequate reimbursement for prosthetics must be provided and it must be recognized that: (i) many such items must be replaced periodically and (ii) access to prostheses is an integral part of psychosocial care for cancer. (Report Recommendation 7b)
2. Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment. (Report Recommendation 6d)
3. Coverage should be provided routinely for psychosocial services for which there is evidence of benefit both during treatment and post-treatment as needed. (Report Recommendation 7c)
4. Public and private insurers should provide reimbursement for risk assessments, surveillance, and other follow-up care for cancer survivors, including care provided by appropriately trained non-physician personnel. (Report Recommendation 7d)
5. Existing follow-up care clinic models should be evaluated and compared to ascertain their impact on survivor outcomes and their cost effectiveness. (Report Recommendation 7e)

- **Work collaboratively for the legislative, regulatory, and health care financing changes needed to make comprehensive quality care a reality for survivors.**
- **Increase the health insurance coverage rate of the young adult population to improve the likelihood that individuals diagnosed with cancer will have coverage for treatment costs and subsequently will not be subject to preexisting condition exclusions.**
- **Explore creative mechanisms for providing needed services outside of traditional insurance mechanisms.**
- **Standardize data collection to the extent possible so that data can be shared and studies of specific interventions or follow-up care programs more broadly will have greater statistical power.**

Team Science and the Culture of Research

1. The existing culture of cancer research must be influenced to place more value on translational and clinical research. To effect this culture change, a task force representing key stakeholders in academic research should be convened to examine and modify existing reward systems (e.g., compensation, promotion/tenure, space and resource allocation, prestige) to encourage collaborative research and ensure that all contributors (including but not limited to pathologists, radiologists, and research nurses) benefit from participating in these activities. (Report Recommendation 1)
2. Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research. (Report Recommendation 2)

- **Overcome academic barriers to appropriately crediting the work of co-principal and other investigators who participate in translational, clinical, and team science efforts so that they are not penalized in promotion and tenure decisions.**
- **Identify ways to increase involvement, recognition, and resources for academic and community pathologists, radiologists, nurse scientists, biostatisticians, and other professionals participating in multidisciplinary team research.**
- **Explore innovative ways to leverage existing funding to provide greater support for clinical, translational, and team science.**

Workforce Infrastructure

To attract and retain young investigators to careers in translational and clinical research:

- Protected research time and mentoring must be provided earlier and potentially for a longer duration than is now the norm. Government training funds may be needed to enable academic institutions to provide this supportive environment.
- New or expanded student loan buy-back programs should be established to enable young investigators to pursue the additional training necessary for a career in translation-oriented research.
- Academic institutions should make special efforts to recruit and retain young scientists from underrepresented population groups. (Report Recommendation 5)

- **Provide greater assistance to junior faculty in identifying potential mentors. Consider other support mechanisms that may help enable initial career advancement.**
- **Seek partnerships between Federal, voluntary health, and philanthropic organizations to help increase the number of physician-scientists.**
- **Medical schools should establish mentoring programs for M.D.-only students to ensure that they are exposed to clinical research and increase the possibility that they will pursue research in their postgraduate training and/or be receptive to participating in research in their medical practices.**
- **Develop creative mechanisms other than loan repayment programs to make careers in science financially feasible for young people.**

		• Intensify and modify recruitment activities to increase the number of physician-scientists. • Develop new or expanded training mechanisms in translational and clinical investigation and supportive fields. • Consider system changes that could help attract new talent to translational and clinical research.
Dissemination and Community Participation 1. A lead agency for cancer-related dissemination activities should be designated and provided with the budget and authority to carry out this crucial function. (Report Recommendation 14) 2. The National Cancer Institute should significantly increase funding for research and implementation activities to improve dissemination and adoption of cancer research advances. As part of this effort, Comprehensive Cancer Centers should be required and funded to take an active role in disseminating new cancer-related interventions into their communities/regions and facilitating their adoption by community cancer care providers, including non-physician personnel. (Report Recommendation 15) 3. Clinical and prevention research funders should require community participation early in protocol design and in research implementation. (Report Recommendation 17) 4. Existing community-based participatory research models should be evaluated to determine the potential for adopting them in other geographic areas and populations. (Report Recommendation 20)		• Strengthen the evidence base for dissemination science. • Explore options for registering and monitoring dissemination research and activities to avoid redundancy, assess their effectiveness, and report on the state of dissemination science. • Identify new ways to bridge the gap between successful dissemination intervention research and the actual implementation of information dissemination strategies, and prevention, cancer control, therapeutic, and supportive interventions in the community. • Improve community participation in research through focused public education about cancer and cancer research. • Identify effective community-based participatory research models and other strategies for involving the community in collaborative research and dissemination efforts.

PART I



The President's Cancer Panel (the Panel) was created by the National Cancer Act of 1971 (P.L. 92-218). Its charge is to monitor and evaluate all aspects of the National Cancer Program (NCP) and report at least annually to the President of the United States on barriers to the most effective development and execution of the Program.

Typically, the Panel identifies and conducts an inquiry into an area of concern or on emerging issues in cancer-related science or cancer care. Findings from these inquiries, together with related recommendations, are reported to the President and Congress and also are distributed to diverse stakeholders in the cancer community. In 2005, the Panel elected to depart somewhat from this process to follow up on key recommendations contained in its two most recent reports:

- ***Living Beyond Cancer: Finding a New Balance***,⁹ published in May 2004, reported on physical, psychosocial, employment, educational, financial, and legal issues that may affect cancer survivors across the lifespan.
- ***Translating Research into Cancer Care: Delivering on the Promise***,¹⁰ published in June 2005, was the culmination of an inquiry into issues and barriers impeding the development of basic research findings into better preventive and therapeutic cancer care interventions and their delivery to all of the American public.

The specific recommendations discussed in the current report were selected because the Panel believes them sufficiently critical to the NCP to require follow-up at this time.

Four meetings – two focused on each of these reports – were held in 2005 in Washington, DC. A participant roster is provided in Appendix A. The objective was to bring together key stakeholders to review recent activities related to the selected recommendations, identify actionable next steps, discuss existing and possible collaborations, and encourage organizational commitments of support aimed at advancing progress and change in the areas of interest. Specifically, meeting participants were asked to address the following questions:

Discussion:

What has happened with regard to this recommendation since the Panel's report was issued?

What needs to be done to implement this recommendation?

What should be the priorities in this area over the next two years?

Are there other organizations or stakeholders that should be involved but are not at the table today?

Next Steps (following the discussion):

What opportunities for collaboration exist or are possible to move identified priorities forward?

What additional resources are needed?

What commitments can be made today on behalf of your organization?

Progress toward implementation of the selected recommendations, as described in this document, reflects information provided both verbally and in writing by meeting participants, as well as additional information gathered subsequent to the meetings. The Panel recognizes, however, that these lists may not be exhaustive. Further, specific initiatives, activities, reports, or papers described previously are not included in this report unless notable progress occurred since publication of the related report recommendation. It also should be noted that while not addressed in this report, the Panel is aware that progress has been made on other recommendations from the two reports not specifically revisited in this series of meetings.

The remainder of this document contains:

- A report of progress, identified priorities, and other meeting outcomes relative to each selected recommendation
- Conclusions
- Appendices, including a roster of meeting participants, an index of acronyms, and a matrix of selected Panel recommendations and priorities identified by meeting participants

PART II



Recommendations from *Living Beyond Cancer: Finding a New Balance*

Living Beyond Cancer: Finding a New Balance provided 17 recommendations for improving health care and quality of life for people living with cancer through the major stages of life – childhood, adolescence and young adulthood, the middle adult years, and older adulthood. Some of the recommendations were specific to each age cohort, while others were applicable across most or all of the lifespan. The Panel reported on barriers related to physical, psychosocial, insurance, educational, financial, employment, legal, and health data privacy issues.

Among the recommendations, the Panel chose to revisit those targeting particularly urgent needs: cancer treatment summaries and follow-up care plans for survivors leaving cancer therapy, the limited body of research on adolescents and young adults with cancer compared with research on other age groups, and issues of access to care and insurance that affect survivors of all ages.

However, the Panel recognizes that important progress has been made on some of its other recommendations from this report. For example, issues related to applying information technologies (IT) to medical information systems have been a major impediment to better data sharing, both with patients and among health care providers. In its report, the Panel emphasized the importance of involving diverse stakeholders in resolving these issues, specifically:

The Department of Health and Human Services (HHS) should establish a consortium of public and private institutional and community health care providers and payors, patient advocates, and technology experts to develop a blueprint for functional, content, format, and technology standards for creating a nationwide electronic health records system.

The Panel was pleased to note that on September 13, 2005, the Secretary, HHS, established the American Health Information Community (the Community),¹¹ a federally chartered commission providing input and recommendations on how to make health records digital and interoperable and ensure the records' privacy and security. The Community's membership includes representation from all of the constituencies indicated by the Panel. The Community is to be succeeded within five years by a wholly private sector health information initiative to continue and monitor the transformation to electronic health records (EHR).

In November 2005, HHS awarded contracts to four consortia to build pilot EHR systems in 12 geographic regions to serve as models for the nation.¹² By November 2006, the consortia must create personal digital health records and provide physicians with affordable online access to patient records and to diagnostic and billing information. Pilot systems may use different technologies as long as patient information can be transmitted to and from other local systems. The consortia participants also are expected to invest corporate or organizational funds in the project.

Also in November 2005, the Department of Defense (DoD) launched AHLTA, its global EHR system.¹³ Developed in partnership with leading American IT companies, it will be fully implemented by December 2006. AHLTA is the largest EHR system to date, and will contain the medical records of more than nine million service members, retirees, and their families. DoD and eventually, Veterans Administration (VA) health care providers worldwide will be able to access patient data. The initial system design does not, however, enable patients to access their medical records. Lessons learned from implementing and operating AHLTA should inform civilian EHR system development.

These are encouraging steps that will benefit not only people with cancer and their families, but the public as a whole.

Chapter 1



Treatment Summaries and Follow-Up Care Plans

The Panel has remained particularly concerned by repeated testimony and continuing indications that the majority of cancer patients/survivors leave treatment with neither documentation of the care they received nor a plan to guide their subsequent medical and psychosocial care, including but not limited to monitoring for cancer recurrence. For this reason, the Panel convened a group of stakeholders to discuss progress toward routine provision of this information to survivors, and the actions still needed to fully reach this goal. The Panel's recommendations concerning treatment summaries and follow-up care plans were as follows:

2003-2004 Survivorship Report Recommendations – Treatment Summaries and Follow-Up Care Plans

1. Upon discharge from cancer treatment, including treatment of recurrences, every patient should be given a record of all care received and important disease characteristics. This should include, at a minimum:
 - Diagnostic tests performed and results.
 - Tumor characteristics (site(s), stage, and grade; hormonal status; marker information).
 - Dates of treatment initiation and completion.
 - Surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, gene, or other therapies provided, including agents used, treatment regimen, total dosage, number and title(s) of clinical trial(s) (if any), indicators of treatment response, and/or toxicities experienced during treatment.
 - Psychosocial, nutritional, and other supportive services provided.
 - Full contact information for treating institutions and key individual providers.
(Report Recommendation 1a)
2. Upon discharge from cancer treatment, every patient should receive a follow-up care plan considering evidence-based standards of care. This should include, at a minimum:
 - A description of recommended cancer screening and other periodic testing and examinations, as well as the schedule on which they should be performed.
 - Information on possible late and long-term effects of treatment and symptoms of such effects.
 - Information on possible signs of recurrence and second tumors.
 - Information on the possible future need for psychosocial support.
 - Specific recommendations for healthy behaviors (e.g., diet, exercise, sun and virus protection, smoking cessation).
 - Referrals to specific follow-up care providers, support groups, and/or the patient's primary care provider.
 - A listing of cancer-related resources and information (Internet-based sources and telephone listings for major cancer support organizations).
(Report Recommendation 1b)

Progress Toward Implementation

Participants outlined recent activities in four categories that support implementation of the Panel's recommendations: (1) treatment summaries for survivors, (2) follow-up care plans for survivors, (3) electronic health records (EHR) development and data collection, and (4) education and communication.

Progress on Treatment Summaries for Survivors

Since the Panel's recommendations were made, several documents, plans, and activities have been developed, initiated, or advanced to delineate the specific information that should be included in a treatment summary, and how this information should be made available to cancer patients leaving treatment:

- The American Society of Clinical Oncology (ASCO), in direct response to the Panel's recommendation, established a Survivorship Task Force¹⁴ that is developing a template for practicing physicians to use to summarize therapy and other care received by patients. The template also will provide information on possible long-term effects of treatments received and guidance on monitoring for disease recurrence.
- The Veterans Administration (VA) is developing the MyHealthVet¹⁵ Web site that takes advantage of the EHR (known as VistA) already established throughout the VA health system. The goal is for the patient's entire medical record to be made available to him/her through the Web site. However, because medical records are complex, the information also may be summarized using a standard template. The VA EHR system is separate from AHLTA (see p. 6), which is for active service personnel, their families, and military retirees.
- The Children's Oncology Group (COG) has developed a clinical care summary that will be implemented in all of its 231 participating institutions, which collectively care for a large majority of children with cancer in this country. The parameters of the summary are similar to those outlined by the Panel and by ASCO.

I'm stunned by the number of patients who don't have a copy of their pathology report.

– Oncology nurse and association executive

- The Lance Armstrong Foundation (LAF) has developed a free LIVESTRONG™ Survivorship Notebook¹⁶ that includes a medical treatment summary and personal records section. The treatment summary includes most of the elements specified by the Panel.

Progress on Follow-Up Care Plans for Survivors

Participants described activities now underway that support follow-up care plan development:

- In November 2005, subsequent to the Panel's follow-up meeting on this recommendation, the Institute of Medicine (IOM) released its report on issues related to the care of adult cancer survivors.¹⁷ The report reiterates the Panel's recommendation that both treatment summaries and follow-up care plans should be provided to all people treated for cancer.

- The Texas Children's Cancer Center is developing Passport for Care,¹⁸ an Internet-based resource for survivors and caregivers that will enable them to access individualized follow-up care guidelines and resource lists. It will be implemented in partnership with COG. Upon inputting clinical care summary information, the program will generate for each patient a tailored list of possible side effects, follow-up guidelines (e.g., tests/examinations to be performed and recommended time intervals), and local, regional, or national resources for information and care. Patients will be able to allow physicians and other health professionals from whom they seek care to access the information online.
- Certain community health centers (CHCs) funded by the Health Resources and Services Administration (HRSA) have moved to paperless systems in which all patient data are entered on an EHR system. Patients receive printouts on all care provided to them. Though not as yet studied formally, the effect appears to be that primary care physicians are using this information to work with community oncologists to develop tailored follow-up plans, and physicians associated with the CHCs are developing cancer patient/survivor management guidelines for various cancers for their own use.
- In direct response to the Panel's recommendation on follow-up care plans, LAF is developing a network of adult survivorship centers of excellence around the country. All of the centers currently are located in National Cancer Institute (NCI)-designated Comprehensive Cancer Centers, with many being connected to community-based cancer centers. A pilot program has been implemented at the Dana Farber Cancer Institute and as of March 2006, a total of five centers were in operation. LAF hopes to create a new paradigm of survivorship care, including developing evidence-based care guidelines and making survivorship services more broadly available, including to underserved populations. It is envisioned that as many as 15 such centers, which could collaborate in studies to compare follow-up care regimens, will be operational in the next two years. LAF also provides support to other survivorship centers that are not part of this network.
- LAF and the Centers for Disease Control and Prevention (CDC) collaborated to produce a National Action Plan for Cancer Survivorship¹⁹ that identifies and provides recommendations for research, programs, policies, infrastructure development, and other activities to improve the understanding of survivor needs across the care continuum and guide public health resource allocation to improve survivor quality of life. To date, more than 20,000 copies of the plan have been disseminated and priorities identified in the plan have been adopted by a number of states as they create their state cancer plans. Currently, CDC is conducting a "gap analysis" to determine the extent to which priorities in the plan are being addressed.
- Researchers are linking the NCI Surveillance, Epidemiology, and End Results (SEER) program and Medicare databases to determine where survivors of non-Hodgkin's lymphoma, breast, colorectal, prostate, and gynecologic cancers currently are receiving their follow-up care and their patterns of care. Results of these studies may inform the development of follow-up care guidelines for older cancer survivors.

...there's a sense of frustration, I think, that we don't have the standards yet for the electronic medical records. And for any of the things that we do for just about any technology in medicine...there has to be a standard way of reporting the data.

– Pathology informatics program director

- Through its NCI-funded gastrointestinal cancer-oriented Specialized Program of Research Excellence (SPORE), the Eppley Cancer Center has established a Web-based worldwide pancreatic cancer registry. Patients, physicians, nurses, and family members can enter data over time into a data bank that can be analyzed by researchers. Patients always have access to their information and can grant access to physicians. It is envisioned that information derived from the data would be made available to patients, NCI, the Food and Drug Administration (FDA), and guidelines developers. In addition, such disease-specific registries may provide a model for addressing the complex information dissemination issues associated with keeping survivors informed about new findings.

Progress on Electronic Health Records Development and Data Collection

In addition to the HHS and DoD EHR initiatives cited above (p. 6), other activities related to EHR development and data collection are progressing that may generate new data on survivor outcomes, including late effects of cancer treatment. These data will be useful in determining guidelines/best practices for survivor follow-up care.

- The Agency for Healthcare Research and Quality (AHRQ) has launched an initiative to study national requirements for a health information technology (IT) system, including personal health care records. Such a system would provide patients with access to their own medical records, including laboratory test results, thus empowering them with improved understanding of and control over their care. The role of the Federal Government would be to develop standards for interconnectivity of health care information and address access issues. In February 2006, the AHRQ National Resource Center on Health Information Technology launched a suite of “learning resources”²⁰ designed to help health care providers adopt health information technologies quickly and effectively.
- The Centers for Medicare and Medicaid Services (CMS) is offering physicians the opportunity to participate in a test of VistA-Office, the EHR system used by the VA, which is estimated to be far less expensive and labor intensive to install and maintain than systems offered by private vendors. The test will help CMS assess VistA-Office’s interoperability with other computer systems and help the HHS public-private American Health Information Community create a process for certifying electronic health records software.²¹
- The Panel’s report noted that some insurers and hospitals have begun donating or awarding grants to health centers and provider groups to purchase medical recordkeeping hardware and software to hasten movement toward electronic medical records. In a step to remove physician hesitation to accept such donations or grants due to fear of prosecution under the Federal anti-kick back statute, HHS has proposed “safe harbor” exceptions to the statute. A final rule is expected to be issued in 2006.²²

- In June 2005, NCI co-sponsored a conference, “Critical Issues in eHealth Research”²³ at which issues such as how to capture information on risk and behavior and medical record portability were addressed. A supplement on the conference outcomes, to appear in the *American Journal of Preventive Medicine*, is forthcoming.
- CMS is developing a data warehousing project that would improve the ability of researchers and others to access Medicare data. Input on system requirements is being sought from the National Institutes of Health (NIH). The possibility exists to have stage at diagnosis included as a data point. Such a step would vastly improve the utility of the data for disease surveillance and patterns of care studies and would respond directly to Recommendation 8²⁴ in the Panel’s report, *Translating Research into Cancer Care: Delivering on the Promise*. The data also would advance research to identify late effects of cancer therapy.

Progress in Education and Communication Related to the Recommendations

- ASCO has updated its core curriculum outline for oncology professionals,²⁵ adding requirements for instruction on survivorship, psychosocial aspects of cancer, and supportive care. The outline is designed for use by oncology training program directors in developing the educational framework of oncology fellowships. In addition, ASCO has revised its prevention curriculum to address prevention of second cancers among cancer survivors.
- In December 2004, guidelines issued by COG for long-term follow-up care for childhood, adolescent, and young adult cancer survivors were published in the *Journal of Clinical Oncology* (JCO).²⁶ In July 2005, JCO published a paper and accompanying editorial addressing the opportunity for oncologists to play a greater role in the long-term care of cancer survivors.²⁷

Suggested Priorities for the Next Two Years

Participants noted the difficulty of establishing priorities for standardizing and implementing treatment summaries and follow-up care plans because developmental activities related to the content, format, and communication of these documents and the evidence that supports them must be approached from a coordinated systems perspective that is not well formed at this point.

The discussants agreed that the principal goal is for practitioners to make treatment summaries and follow-up care plans integral components of quality cancer care and to provide them consistently to survivors. Priority activities for the next two years pursuant to this goal were identified, and fell into three categories: (1) those related to research and data, (2) priorities specific to insurance reimbursement and other policy decisions, and (3) priorities for communication and education needed to advance progress. Discussants were asked to identify potential partnerships and collaborations that would accelerate progress toward implementing the recommendations. There was strong consensus that implementing the recommendations must be a collaborative, partnership effort to avoid duplication and to make the most effective use of expertise and fiscal resources.

Priorities Related to Research and Data

- **Gain consensus on and implement with all possible speed an initial uniform treatment summary template.** This template should be refined as guidelines or other relevant information becomes available. Because survivors' needs for information about their treatment is immediate, paper- or disk-based (e.g., CD, DVD) summaries should be used until electronic medical records become standardized and widely available.

Potential Partnerships, Collaborations, and Support

- CMS, NCI, or another Federal agency could provide funding to accelerate the process of developing a treatment summary template. It was suggested that the CEO Roundtable on Cancer²⁸ or LAF also might be sources of support for this initiative. Current efforts (e.g., Passport for Care, ASCO Survivorship Task Force activities) are being conducted with private donations and organizational funds that are insufficient to fully support necessary developmental activities.
- Continuing efforts should include the NCI-funded clinical trials groups, with a goal of ensuring that every clinical trial participant receives a clinical care summary. Doing so could help set a precedent to facilitate adoption of this standard in community oncology settings, where most patients receive treatment.
- **Conduct research to build the evidence base for follow-up care guideline development and to determine whether treatment summaries and follow-up care plans lead to improved patient outcomes.** The models/best practices that have been developed in pediatric oncology should inform similar research in adult survivorship. In addition, ongoing research is needed to support guideline refinement as new therapies and drugs become available and new diseases or disease subsets are identified. NCI should take the lead in this effort.

Potential Partnerships, Collaborations, and Support

- NCI could redirect funds to provide supplements to its designated Cancer Centers or other centers to stimulate research to develop the evidence base for survivorship care, perhaps establishing centers of excellence for survivorship research.
- Insurers should be encouraged to partner with NCI/NIH to fund major survivorship research initiatives, such as a large-scale prospective study using data on captured populations (e.g., VA, Medicare, Medicaid) to compare models of follow-up care provided to cancer survivors. The NCI Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial comparing screening approaches for these specific diseases may provide a model for such a study. Private insurers stand to benefit greatly from the generation of evidence on follow-up care; this may be particularly true regarding long-term survivorship care needs. Currently, insurers are paying for diverse follow-up care regimens without knowing whether some are more efficacious than others for specific cancer types or population groups (e.g., defined by age, gender). The NCI-funded Cancer Research Network, a consortium of 14 managed care entities, many of which already have EHR systems, also could be called upon to take part in this type of research. In the public sector, CMS, through its “evidence under coverage” demonstration projects, is reimbursing providers for specific services in order to collect evidence to improve standards of practice.

- CMS could establish a patient registry to examine follow-up care practice patterns over time in order to compare the efficacy of various follow-up approaches for different cancers. The VA population base also could be used in a similar manner to study follow-up care for cancers common among veterans. In December 2005, subsequent to the Panel's meeting, AHRQ launched, as part of its new Effective Health Care Program,²⁹ a project to develop a "how-to" reference guide to help health care organizations create patient registries to track the outcomes of medical treatments, including drugs. The guide is to be completed by the end of 2006 and will reside on both the AHRQ and CMS Web sites.³⁰
- **Accelerate efforts to develop and disseminate survivorship follow-up clinical care guidelines based on the best available evidence (including best practices and expert opinion) until the evidence base is further developed through targeted outcomes and related research.** The guidelines should cover screening, evaluation, psychosocial, and other services. The medicolegal implications of guidelines must be addressed as part of this effort. All guidelines will need to be refined as the body of evidence grows and as late effects associated with newer therapies become apparent. Guideline development efforts should focus initially on the most commonly occurring cancers (e.g., lung, prostate, breast, colorectal, Hodgkin's disease, non-Hodgkin's lymphoma). According to a participant, many of the existing adult survivorship centers have taken this approach, which has had the effect of increasing demand among survivors of other cancers for similar attention to their survivorship care needs. Participants underscored the particularly urgent need for care guidelines for long-term survivors.

I convened a group of cancer experts to try to do a survivorship guideline and they were just overwhelmed with the immensity of that task. Is cancer survivorship generic? Is every cancer survivor the same or is a breast cancer survivor much different than a Hodgkin's disease survivor? So these are the kinds of issues that to say to people, "Write a discharge summary" – it's not all that easy. It isn't as though this just flows easily through the pen.

– Cancer care quality project director

Though NIH and/or the IOM could sponsor conferences to implement this activity, the guidelines effort must be led by a coalition of private sector professional, advocacy, and insurer groups, with appropriate public sector (e.g., NCI, AHRQ, CMS, CDC) participation. Such a joint effort is needed to alleviate current barriers due to multiple sets of proprietary guidelines and disagreements concerning levels of evidence. In addition, guidelines developed through a collaborative public-private effort are more likely to be accepted by practicing physicians. Studies to evaluate the utilization and usefulness of guidelines should be built into their initial development and distribution; to facilitate these studies, the Web site(s) on which the guidelines reside should be capable of tracking and communicating with visitors to the site.

Potential Partnerships, Collaborations, and Support

- The IOM’s National Quality Forum and the National Comprehensive Cancer Network should be involved in the follow-up care guidelines development process.
- Guideline adoption could be accelerated with the participation of the National Committee for Quality Assurance, to provide a means of measuring effectiveness; the Joint Commission on Accreditation of Healthcare Organizations, which could include clinical care summaries and guideline adherence as part of its hospital surveys; and the American College of Surgeons Commission on Cancer, which could accredit cancer programs that adhere to guidelines.
- Social workers, rehabilitation specialists, psychologists, nutritionists, and other professionals who work with cancer survivors should be involved in discussions regarding psychosocial and supportive care components of follow-up care plans.
- The internal medicine, family practice, other primary care, preventive medicine, community oncology, health services research, and hospital administration communities should participate in activities related to implementing the Panel’s recommendations.
- Pharmaceutical companies that produce cancer treatment drugs and the leaders of clinical trials groups should be included in guideline development, as both have expertise and data needed to delineate possible long-term effects of specific treatments and follow-up care needs.
- The U.S. National Preventive Services Task Force should be involved in standardizing cancer survivor surveillance data collection parameters.
- **Establish interoperable media and related standards for electronic health records (including standard terminology for data reporting) so that treatment summaries and follow-up care plans will be comparable and accessible regardless of the format in which they are provided (e.g., CD/DVD, paper, Internet).**

Potential Partnerships, Collaborations, and Support

- Organizations already involved in developing interoperability and other EHR-related standards (i.e., AHRQ, Office of the National Coordinator for Health Information Technology (ONCHIT), American Health Information Community, DoD, private insurers, VA) should coordinate their activities to avoid redundant efforts. The National Health Council, which has formed a national commission on patient-centered care, also is exploring EHR issues and should be included in future conversations on this topic.
- Technology representatives (e.g., Microsoft, Intel, Apple), the HHS Secretary’s 500 Day Plan,³¹ and the eHealth Initiative³² should be part of the effort to move the treatment summaries and follow-up plans into electronic formats.
- A broader spectrum of consumer advocates should be brought into discussions of how to computerize patient information to help ensure that issues of usability and privacy are considered fully.



- **Address data access issues, including but not limited to those related to the privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191).** The Panel recommended an IOM evaluation of the impact of HIPAA provisions on data access for survivors, caregivers, and researchers in *Living Beyond Cancer: Finding a New Balance* (Recommendations 3a and 3b). This recommendation was reiterated in Recommendation 13³³ of the Panel's 2004–2005 report, *Translating Research into Cancer Care: Delivering on the Promise*. ONCHIT is studying variations in state privacy and security laws and business practices that may affect electronic exchange of health information, and also is identifying privacy-related health information technology issues. None of these analyses, however, examine the impact of HIPAA privacy provisions.

Priorities for Reimbursement and Other Policy Changes

- **Secure provider reimbursement through CMS and other public and private insurers for preparing and presenting treatment summaries and follow-up care plans to patients.**

Potential Partnerships, Collaborations, and Support

- CMS and private payors should be included in discussions of how best to operationalize provision of clinical care summaries and follow-up care plans, including physician reimbursement for the time required to produce them. To determine the level of funding needed, CMS could conduct a demonstration/pilot project providing payment for the time required to develop and explain treatment summaries and follow-up plans, as it has done recently to pay oncologists for asking about fatigue, pain, and nausea/vomiting.³⁴ Based on these findings, CMS should develop specific billing codes and reimbursement rates for post-treatment evaluation of survivors, completion of treatment summaries and follow-up care plans, and their presentation to the patient/survivor.

...if there's something they can...get reimbursed for, then it's going to happen....Physicians who had no clue about survivors are going to look and say, "Wow, here are these three or four things. And if I do this, if I fill out a clinical care summary, I'm going to get paid for it"....you would see a real sea change in behavior...

– Pediatric oncologist

- The Cancer Quality Alliance,³⁵ a forum for diverse stakeholders in the cancer community dedicated to improving the quality of care for people with cancer, was formed in October 2005. It is co-chaired by leaders from ASCO and the National Coalition for Cancer Survivorship. Like the Ambulatory Care Quality Alliance³⁶ that informs and advises CMS on ambulatory care issues, the Cancer Quality Alliance should provide a mechanism for sharing information about ongoing cancer follow-up care activities and discussing with CMS opportunities for moving effective care models into practice.
- The CEO Roundtable on Cancer should be considered a forum through which to vet the issue of authorizing reimbursement through employer-sponsored health insurance for physicians to provide treatment summaries and follow-up care plans to cancer patients.

Priorities in Communication and Education

- **Develop and provide education to patients, the public, health care providers, and medical students:**

- (1) **Patients and the public.** (a) Empower patients to demand a treatment summary and follow-up care plan, (b) Help survivors understand appropriate follow-up for their specific disease, including why some tests are not done, and (c) Help them understand the importance of collecting and maintaining their own medical records. In advance of follow-up care guideline development, educational materials should be developed for patients/survivors that will help them direct their own follow-up care.
- (2) **Health care providers.** (a) Educate oncologists regarding the importance to patients of this information as they leave the treatment environment and as to the relative ease of dictating and sharing a treatment summary, an activity that in many cases may be reimbursable as a complex patient visit according to existing insurer procedure codes, and (b) Educate primary care physicians regarding the value of using the treatment summary and follow-up care plan to educate themselves about survivorship issues and the problems with which patients may present long after treatment has ended.
- (3) **Medical students.** Increase students' awareness and knowledge of survivorship issues. Medical school curricula currently do not include in any depth, if at all, the follow-up care or information needs of people who have had cancer.

Potential Partnerships, Collaborations, and Support

- The U.S. National Preventive Services Task Force has longstanding relationships with primary care constituencies that may be helpful in developing and disseminating follow-up care guidance to the primary care community.
- Oncology nurses and social workers are well positioned to collaborate in developing and providing patient education, particularly in collaboration with survivor groups.

Getting across the importance of having a clinical care summary on every patient that's treated within the clinical trial group mechanism or environment certainly would go at least some way along the road to having all patients have them.

– *Oncologist*

- AARP (formerly the American Association of Retired Persons) should be brought into the promotion of treatment summaries and follow-up care plans to its constituency, which encompasses the age group most affected by cancer. AARP has a significant educational and advocacy role and also sponsors health insurance products available to its membership.
- The Association of American Medical Colleges should develop or review medical school curricula related to cancer survivor issues, including survivors' follow-up care and information needs.

Commitments Made – Treatment Summaries and Follow-Up Care Plans

In addition to identifying priorities and potential partnerships, meeting participants indicated support and other commitments they could make immediately to advance implementation of the Panel's recommendations. Specifically:

- Under the aegis of the Institute of Medicine (IOM), the National Coalition for Cancer Survivorship, in partnership with the Lance Armstrong Foundation (LAF) and the National Cancer Institute (NCI), is sponsoring a May 2006 workshop to resolve issues and delineate the specifics of how to implement survivor treatment summaries and follow-up care plans. An expected output of the workshop is the design for a national demonstration program to test the value of survivorship care planning. Conclusions and commitments made at this forum will be reported through the IOM.
- The National Quality Forum will begin initial work on a draft plan for coordinating priority activities required to implement the Panel's recommendations. The discussants agreed that any such plan should include timelines to enable progress assessment.
- The American Society of Clinical Oncology (ASCO) will continue to provide intellectual and human capital, including staff support, to its Survivorship Task Force and other survivorship activities specific to implementing the Panel's recommendations.
- LAF indicated its willingness to partner with ASCO and the Oncology Nursing Society to adapt the pediatric treatment summary and Passport for Care program for use by adult oncology patients/survivors.
- In September 2006, the American Cancer Society will sponsor Celebration on the Hill, an initiative conducted through its 501(c)4 organization to bring several thousand trained "relay ambassadors" to visit members of Congress concerning key survivorship issues. It was suggested that the need for treatment summaries and follow-up care plans could be one of the key messages imparted during this event.
- NCI committed to help develop and support clearly focused projects pursuant to implementing the Panel's recommendations.
- The Veterans Administration (VA) will explore the possibility of involving its Cooperative Studies Program in collaborative studies to develop the evidence base regarding the value of treatment summaries and follow-up care plans for adult cancer survivors. Such studies could take advantage of the VistA patient records system already established at the VA.

Chapter 2



Adolescent and Young Adult Cancer Research Issues

In the Panel's examination of cancer survivorship issues across the lifespan, adolescents and young adults (AYA) stood out starkly as a population of patients/survivors that has been studied far less than younger and older age groups, and whose health care and other survivorship-related needs are poorly understood and poorly served.

Nearly 68,000 people aged 15 to 39 years are diagnosed with cancer annually – seven times more than diagnoses among children under age 15.³⁷ Yet adolescent and young adult cancer patient survival rates have not improved despite dramatic improvements both in childhood cancer survival rates and survival for many adult cancers. For those 25–35 years of age at diagnosis, survival rates have not increased substantially in more than 25 years.³⁸

The Panel convened a meeting of individuals representing organizations whose missions focus specifically on young cancer survivors and other organizations serving survivors of all ages who could help to identify priorities, partnerships, and next steps to address the relative dearth of research on this population.

2003-2004 Survivorship Report Recommendations – Adolescents and Young Adults

1. A working group comprised of representatives from the public agencies and private organizations with established surveillance databases should be convened to determine what additional data collection, infrastructure, and related funding would be required to better capture treatment and survival data on adolescent and young adult cancer survivors. (Report Recommendation 11a)
2. The National Cancer Institute and other cancer research sponsoring agencies should increase the priority of and funding for research on the issues of cancer survivors diagnosed as adolescents or young adults. Studies of biologic differences in cancer type and host factors, and of late effects of cancer and cancer treatment in this population should be emphasized to improve the knowledge base and inform the design of treatment, prevention, and quality of life interventions designed to benefit this population. (Report Recommendation 11b)
3. Further research should be conducted to determine what fertility preservation options are possible for children and young adolescent cancer patients. (Report Recommendation 6c)

Progress Toward Implementation

Since 2003, numerous programs or activities have been initiated or advanced related to research on adolescents and young adults with cancer. Some of these are germane to all of the Panel's recommendations, while others specifically address the need to enhance data collection and research on this age cohort, or special research issues related to fertility preservation in young people with cancer.

Activities Addressing All AYA Recommendations

Recent activities related to a coordinated effort to advance AYA surveillance data, health infrastructure, and research funding include:

- The National Cancer Institute (NCI) and Lance Armstrong Foundation (LAF) have partnered to conduct a Progress Review Group (PRG) on adolescent and young adult oncology. The PRG will emphasize issues related to young people diagnosed between the ages of 15 and 39 years, and will include issues (e.g., late effects, second cancers) of childhood cancer survivors who have reached adolescence and young adulthood. Though survivorship issues will be addressed, the principal focus is on identifying biologic, prevention, risk factor, psychosocial, and other research priorities for this age group. It is expected that this PRG, which will complete its report in early Summer 2006, will take up many of the data collection/surveillance, health infrastructure, research, and funding questions discussed at the Panel's meeting. In general, PRGs³⁹ are charged to recommend research priorities that are used to inform a national research agenda in the area of interest. The PRG process typically is followed by an implementation phase, during which activities that NCI can implement are ascertained and partnerships and collaborations needed to accomplish other recommendations are identified. In addition, PRG recommendations are revisited in approximately three years to determine where additional or refined efforts and related resources are needed.
- The Children's Oncology Group (COG) Adolescent and Young Adult Committee has formed a Survivor Transition Task Force dedicated to finding adult health care for survivors of childhood cancer who no longer can depend on the pediatric health services. With more than 100 volunteer members of COG participating, the Task Force has been working on ways to overcome the reluctance of AYA survivors to maintain contact with the health care system and improve the ability to track and assess the outcomes of this population.
- LAF spearheaded development of the LIVESTRONG™ Young Adult Alliance,⁴⁰ a new coalition of organizations dedicated to improving the survival rate and quality of life for young adults living with cancer. The Alliance will promote relevant research and improved patient care, generate awareness of the AYA cancer issue, advance helpful community-based programs and services, and serve as a voice for AYAs with cancer.

...we do need this infrastructure and we need to know whether what we're planning for follow-up is going to work, whether we can induce young adults and adolescents to really have their data captured someplace, and so these are sociologic questions and economic questions.

– Survivorship program director

Progress in Enhancing Data Collection and Research on Adolescents and Young Adults with Cancer

- The quality of AYA cancer survival data available through the NCI Surveillance, Epidemiology, and End Results (SEER) program has improved because the Census Bureau now provides SEER with year-by-year data, rather than data on five-year age intervals. In conjunction with community partners, SEER has recently completed a monograph on AYA survivorship data.⁴¹
- Although many of the registries and databases are relatively new, the capacity has now been built into SEER that will better enable the future identification of second primary cancers due to treatment of the initial primary tumor.
- Databases in other countries (e.g., Australia, Canada) have become available for use by U.S. researchers, enabling comparative studies of AYA treatment and survival patterns.
- NCI is exploring ways to use databases (e.g., Nurses Health Study) on older cohorts that have accumulated data on generations of patients to identify second tumors and differences in long-term functional outcomes between younger and older groups within these cohorts.
- Interest in, and the volume of survivorship research (including AYA) has increased in the past two years. Principal funders have been NCI, LAF, and the American Cancer Society (ACS). In 2004, for example, a Request for Applications (RFA) issued by the NCI Office of Cancer Survivorship (OCS) attracted 125 applications; of these, 17 were funded. OCS now manages more than 120 grants and receives approximately 150 new applications per year through the regular grant cycle.
- Some of the NCI Cooperative Groups (Cancer and Leukemia Group B, the Southwest Oncology Group, and COG) are seeking funding for a collaborative trial of acute lymphoblastic leukemia in young adults under age 30 to try to determine why this group tends to have much poorer outcomes than teenagers and younger children.
- The M. D. Anderson Cancer Center held a conference to raise awareness of AYA survivor issues and is working to establish institutional research collaborations on questions of interest to this population.
- The NIH National Institute of Nursing Research (NINR) held a workshop in August 2003 that focused on developing a research agenda for children and adolescents with cancer. The proceedings of the workshop⁴² suggest joint NINR/NCI funding possibilities for studies of this population.

Progress in Research on Fertility Preservation

- The American Society for Reproductive Medicine (ASRM) formed a special interest group on fertility preservation in men and women after chemotherapy. The group's mission is to educate colleagues and the public about the importance of this issue and to foster collaboration.
- ASCO convened a guidelines committee to develop fertility preservation guidelines for oncologists.⁴³

I'm really surprised by the many questions that I get from practicing physicians [who] have no [idea about] a given treatment regimen and the likelihood that a given male or a female at a given age would be rendered infertile or a woman would have premature menopause – or at least [can make] a good educated guess.

– *Oncology society president*

- A number of recent publications, based primarily on privately funded, investigator-funded, or patient-funded studies of fertility preservation have helped to raise awareness of fertility issues among cancer patients and survivors of reproductive age. The papers appear to be garnering increasing levels of attention from the media and the public, but significant regional variations in awareness are known to exist.
- The Eastern Clinical Oncology Group has included baseline fertility analyses in its current study of Hodgkin's disease. The study, which will include 800 patients, will follow up on fertility-related treatment effects in addition to other outcome measures.
- A fertility preservation program has been established within the Center for Reproductive Medicine and Fertility at Weill-Cornell Medical Center. Women with cancer are treated as emergency cases; upon contacting the program, they immediately speak with a counselor, are brought in for an appointment, and appropriate treatment is initiated. The program is partnering with the Memorial Sloan-Kettering Cancer Center to further streamline fertility preservation care for cancer patients in the region. The partnership also will educate both cancer and fertility specialists about the costs of fertility preservation treatment. In addition, all oncology trainees who will be working with young adults will serve a rotation in the program so that they become educated about cancer-related fertility issues and treatment options.
- The NCI Clinical Trials Working Group (CTWG)⁴⁴ recommended that NCI set aside funds for correlative studies associated with clinical trials; these funds could be directed to issues relevant to adolescents and young adults with cancer.

Suggested Priorities for the Next Two Years

Priority activities for the near term were identified in three major areas: (1) improving data on and infrastructure for AYA cancer survivors, (2) advancing research on this population, and (3) research activities specifically addressing fertility preservation for children with cancer and others diagnosed during their reproductive years.

Priorities for Improving Data and Infrastructure for Adolescent and Young Adult Cancer Survivors

- **Build a comprehensive database on all adolescent and young adult cancer survivors.** Little data exist on adolescents and young adults diagnosed with cancer. The Childhood Cancer Survivor Study (CCSS)⁴⁵ includes 14,000 of 20,000 eligible patients diagnosed during childhood; the database, while one of the most robust available on young survivors, lacks sufficient data on minority survivors and the many survivors who are lost to follow-up. The collaborative model used by SEER, the Centers for Disease Control and Prevention (CDC), the American College of Surgeons (ACoS), and state tumor registries may be adaptable, with additional private philanthropic funding, to enable data collection on young people with cancer. Though tumor samples from this age group are limited (relative to the incidence of cancer in older and younger age groups), even those that are available have been understudied, and tumor samples are difficult to acquire unless a patient is treated on a clinical trial.

Potential Partnerships, Collaborations, and Support

- The primary care community (e.g., family and other primary care physicians, internists, obstetricians/gynecologists) should be brought into surveillance and research efforts to identify the ongoing health care needs of AYA cancer survivors.
- An estimated 22,000 patients under age 39 are enrolled on Cooperative Group Trials. Data on these patients could be gathered from each of the Cooperative Groups and entered into a comprehensive database.
- The NCI Division of Cancer Prevention could work with the community outreach component of the Community Clinical Oncology Programs (CCOPs) to locate the 85 to 90 percent of adolescent and young adult survivors who do not have contact with an NCI-designated Comprehensive Cancer Center.
- Though currently inadequate in terms of follow-up, the CCSS database could, with additional funding, be enhanced to better capture data on childhood cancer survivors who are now adolescents and young adults, and could be linked to the Passport for Care database and survivorship clinics.

Most of these young adults don't make it to a designated NCI cancer treatment center and we need to go find the patients and take note of the treatment [they received] and not just the follow-up.

– Adolescent and young adult oncology clinic director

- **Improve the delivery infrastructure for and communication with AYA survivors to encourage continued contact with the health care system and make it possible to collect data on their long-term outcomes.** Available data on AYA cancer survivors in the U.S. are not representative of this population because relatively few survivors have regular contact with physicians that would enable surveillance data collection.

Potential Partnerships, Collaborations, and Support

- Most young adults do not want to go back to the hospitals at which they were treated, but hospital-associated or freestanding facilities for this population are few. Focus groups and community-based participatory research (CBPR) approaches should be used to design facilities and programs in which AYA survivors will be willing to participate.
- Participants suggested that the AYA population may be more responsive to certain marketing strategies than other age groups. Computer hardware manufacturers and software designers (e.g., Intel, Apple, Microsoft), entertainment outlets popular with youth (e.g., cable channels MTV and Comedy Central), and high school educational systems could be brought together to devise multi-level marketing strategies to reach young survivors and more generally, to make cancer visible and “hip” to the target populations (young survivors and other young people) so that they will seek out information on cancer prevention, early diagnosis, and survivorship issues. For example, some oncology nursing researchers have begun using cell phones to conduct surveys and other research. It also was suggested that adolescents could be reached with cancer information by making cancer-related curricula a requirement under the No Child Left Behind Act (P.L. 107-110) administered by the Department of Education.

Priorities for Research on Adolescent and Young Adult Cancer Survivors

- **Conduct research in the following priority areas:**
 - Host factors and the biology and pathogenesis of tumors in the AYA age group. Categorizing by tumor biology would be a more precise measure of relevant disease than patients’ chronological age.
 - Whether specific types of follow-up care and surveillance for AYAs with cancer improve outcomes, the cost-benefit of follow-up in terms of quality of life and overall survival (see also p. 37), and the incidence of second cancers beyond age 40 among adolescents treated with radiation and chemotherapy.
 - Measures to identify survivors at high risk for late effects due to genetic predisposition or other factors.
 - Psychosocial factors and their influence on access to care and adherence to recommended care.

Potential Partnerships, Collaborations, and Support

- ASCO and other organizations, including insurers, that fund young investigator, career development, or mid-career awards to cancer researchers could collaborate to target these awards to investigators interested in AYA cancer survivor research. Funding mechanisms that require interdisciplinary (e.g., pediatric oncology and adult medical oncology) collaboration would strengthen AYA as a research topic and help to create a career pathway for AYA research.
- Jointly funded mechanisms for survivorship research, particularly on young adults, should be pursued. For example, NCI and ACS could jointly fund an RFA to support innovative community-based research on AYA cancer survivors. It was suggested that the Program Announcement mechanism would provide for more sustainable funding than an RFA.
- The American Association for Cancer Research, though not a funding agency, could help raise the visibility of AYA cancer research needs and encourage funding organizations to increase resources targeting this age cohort.
- ASCO also can promote the importance of AYA research through its educational meetings, which should increase interest among researchers if there is funding to support survivorship studies. In addition, increasing interest and awareness may lead to studies re-analyzing existing data and related tissue from NCI Cooperative Group, cancer center, and other trials to study findings specific to the AYA age group (e.g., age as a function of biological outcomes, biological mechanisms, survival issues).
- Editors of the principal oncology specialty journals publishing basic, translational, clinical, and applied cancer studies should be encouraged to increase their focus on issues pertaining to the AYA population.
- NCI or a group of funders should consider establishing a survivorship-specific Specialized Program of Research Excellence (SPORE), consortium, or similar mechanism to improve collaborative research on interdisciplinary issues of importance to this population and to encourage researchers working in other areas to pursue survivorship research. Currently, no mechanism exists to fund multi-institutional consortia for survivorship research.
- As a condition of continuing core grant support, NCI could require comprehensive cancer centers to identify their research activities specific to young adults with cancer.
- NCI and other funders of research on AYA populations should collaborate with researchers from Australia, where five-year survival rates for AYAs (aged 20 to 35 years) with cancer exceed those of the U.S. by 10 percent,⁴⁶ and the United Kingdom, where enrollment of young adults (aged 20–40 years) in clinical trials has increased over the past five years from three percent or less to 12 to 13 percent,⁴⁷ to learn how these successes might be replicated in this country. Recent NCI data indicate that only 1.5 percent of young adult cancer patients in the U.S. enroll in trials, and this percentage is dropping.⁴⁸

- Cancer researchers should consider care models in use for young people with cystic fibrosis, diabetes, or other chronic diseases to determine if these models have lessons applicable to the ongoing care of young cancer survivors. Care models should address psychosocial needs from a human development perspective, not just in terms of an individual's cancer. In addition, all clinical trials should include collection and analysis of data on psychological risk factors, and care providers should use these data to ensure that services are provided when risk factors are identified.
- **Establish a separate NIH study section, or modify the mix of reviewer expertise in existing study sections, to help ensure fair and informed evaluation of survivorship research proposals.** The current structure and membership of standing NIH study sections are not well matched to many of the research issues most relevant for survivorship research (e.g., basic biology, host factors, molecular factors affecting undesirable drug side effects).

Research on Fertility Preservation

- **Conduct research to develop improved fertility preservation options for children, adolescents, and adults of reproductive age.** Much remains to be learned about the gonadal and fertility impact of cancer treatments relative to patient age, gender, and cumulative chemotherapy and radiation exposures. Greater understanding of the effect of the last generation of treatments and those currently used will inform the development of less toxic treatments and provide better treatment choices for patients wishing to preserve their fertility. Most studies to date have measured female fertility by whether a woman continues menstruating; however, this is a crude measure that underestimates infertility. Similarly, sperm count has been the crude measure of fertility in men. Measures should be based on hormonal or other biologic factors. It was suggested that the actual incidence and severity of infertility problems experienced by men and women following cancer treatment is unknown and is an important area for continued research.

Cryopreservation of sperm is less complex than egg or embryo preservation. Fertility preservation for prepubertal children presents a special challenge since extensive tissue cryopreservation is required and maturation of testicular or ovarian tissue *in vitro* may be necessary. Alternative methods of ovarian stimulation are needed to enable women with hormone-sensitive cancers to develop mature eggs that can be harvested and if desired, fertilized and frozen. Ways must be found to reduce the cost of, and ensure access to, fertility preservation methods since children and young women and men may not use preserved ovarian tissue, oocytes, embryos, or sperm for decades (see also pp. 34–35).

Other research issues related to reproduction include the safety of pregnancy for women with hormone-sensitive cancers and the physiologic and psychosocial issues of menopausal young adolescents and women who receive chemotherapy.

Potential Partnerships, Collaborations, and Support

- Cooperative Group and other clinical trials should routinely include correlative assessments of fertility impact and be designed with fertility preservation as a priority. Measures of fertility in women should be based on biologic or physiologic markers such as follicle-stimulating hormone and estrogen levels. Discussion of pre-treatment fertility and reproductive history could be made a part of trial eligibility criteria and fertility impact could be one of the trial outcome analyses.



- An RFA funded by NCI or a coalition of funding agencies specifically targeting fertility preservation research for cancer patients would greatly encourage researchers interested in this issue. Collaborations between fertility clinics and cancer centers should be encouraged.
- Public and private sector cancer drug developers have a significant role to play in preventing chemical fertility damage. The potential fertility impact of candidate drugs should be assessed by developing *in vitro*, xenograft, or animal models to predict egg loss that could lead to early ovarian failure even though immediate premature menopause is avoided. Related research should explore the mechanisms by which damage occurs and how damage can be prevented during treatment.

Fertility preservation research needs more funding, more creative type funding mechanisms, faster funding mechanisms, and [studies] long enough for us to look at some of the long-term effects of cancer. And on the clinical side, cancer centers and fertility centers should collaborate and their corresponding [professional] societies should collaborate further [on] educating ourselves and the consumers.

– Fertility researcher

- A monograph that assembles and evaluates available data (albeit based on crude measures) on fertility problems and preservation in cancer treatment could be a useful resource for practitioners and also could identify knowledge gaps, thereby sharpening research focus. ASCO and ACS could partner to assemble an expert panel that could produce this analysis and identify research questions based on the results.

- New or expanded grant mechanisms that encourage innovative research are needed to advance the fast moving field of fertility-related research. For example, NCI supports the Rapid Access to Intervention Development program, and a similar program is being launched at the National Institutes of Health (NIH) that will be accessible to a broader spectrum of investigators. The NCI SPORE program also has proven effective in accelerating translation of basic research findings into interventions. Another suitable model may be found in the Howard Hughes Medical Institute (HHMI) Investigators Program,⁴⁹ which identifies one or more researchers and provides funding for five years to pursue innovative research in an area of interest. This mechanism also enables researchers to adjust research aims as new cancer treatment drugs or other important research influences evolve and may provide longer-term funding than traditional three- to five-year R01 grants.
- **Develop mechanisms to ensure that children and adolescents with cancer, their caregivers, adults of reproductive age, and oncologists are aware of opportunities for fertility preservation.** Research should build on limited studies to date to better understand the psychosocial impact of individual choices regarding fertility preservation. Cultural considerations must be taken into account in developing counseling and education protocols related to fertility preservation.

Potential Partnerships, Collaborations, and Support

- The oncology and endocrinology communities could jointly sponsor fellowships to educate physicians who treat children, adolescents, and young adults with cancer about the importance of and options for fertility preservation.
- Implementation of standard cancer treatment summaries and follow-up care plans should have the effect of raising awareness of fertility concerns and reinforcing physician consideration of these issues at the time of treatment selection.
- Oncology and other relevant cancer care professional societies can survey their memberships to assess awareness of fertility preservation issues as a baseline for developing education and counseling interventions and measuring their success.

Commitments Made – Adolescent and Young Adult Cancer Research Issues

Meeting participants made the following immediate commitments to advance implementation of the Panel’s recommendations concerning adolescents and young adults with cancer:

Data and Infrastructure

- The National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results program will explore with its agency and program partners how best to pursue surveillance improvement ideas generated at the meeting and how the surveillance working group recommended by the Panel could be constituted.

AYA Research

- Using the Panel's report as leverage, NCI will continue internal discussions with the Division of Cancer Biology and the Division of Cancer Treatment and Diagnosis to try to increase awareness of and interest in funding extramural basic research on AYA cancer biology and associated survivorship issues.
- The American Cancer Society (ACS) indicated that it can easily augment or change the membership of its grant review sections to ensure that proposals for survivorship-oriented research are reviewed by individuals who understand this population and the relevant science.
- ACS will increase the focus of its fund raising efforts on donations to support research on AYA cancer survivors.
- The Lance Armstrong Foundation (LAF) will continue to fund AYA-specific research and will partner with other organizations to develop new funding mechanisms as needs are identified.
- The American Society of Clinical Oncology's (ASCO) major emphasis on survivorship will continue into 2006, and the Society committed to supporting the activities of the Adolescent and Young Adult Oncology Progress Review Group being co-sponsored by NCI and LAF.
- The National Institute of Nursing Research will explore community-based participatory research related to AYA cancer survivors and joint funding possibilities with NCI.

Fertility Preservation

- NCI will bring the meeting participants' recommendation for correlative studies on fertility preservation to the group now working to develop strategies to implement recommendations of the Clinical Trials Working Group (CTWG). One of the CTWG's recommendations was to set aside dollars specifically for correlative science projects of various types.
- ASCO also will launch an oncology awareness campaign to introduce and market the new fertility preservation guidelines to its membership and will conduct pre- and post-campaign research on oncologists' behavior to assess the campaign's success in increasing awareness and use of fertility preservation measures known to be effective.
- LAF is committed to working with national and community-based organizations to raise cancer survivors' awareness of fertility preservation options and resources.
- Dr. Kutluk Oktay personally committed to developing a postgraduate course or educational program to be presented at the ASCO annual meeting to increase awareness among oncologists of fertility issues and fertility preservation options.
- The American Society for Reproductive Medicine (ASRM) will be approached to determine how ASRM and ASCO might jointly fund creative research on fertility preservation and/or fellowships focused on this topic.

Chapter 3



Insurance and Access Issues for Cancer Survivors

The Panel's 2003–2004 report on survivorship issues identified insurance and other access barriers that prevent survivors across the lifespan from receiving needed care. Some of these barriers affected certain age groups more than others, or restricted survivors' ability to obtain specific types of care. In addition to health care coverage, survivors may experience barriers to obtaining life and disability insurance.

In addition to its *overarching recommendation that the Federal Government revive efforts to implement comprehensive health care reform*, the Panel issued the following recommendations:

2003–2004 Survivorship Report Recommendations – Insurance and Access

1. Adequate reimbursement for prosthetics must be provided and it must be recognized that: (i) many such items must be replaced periodically and (ii) access to prostheses is an integral part of psychosocial care for cancer. (Report Recommendation 7b)
2. Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment. (Report Recommendation 6d)
3. Coverage should be provided routinely for psychosocial services for which there is evidence of benefit both during treatment and post-treatment as needed. (Report Recommendation 7c)
4. Public and private insurers should provide reimbursement for risk assessments, surveillance, and other follow-up care for cancer survivors, including care provided by appropriately trained non-physician personnel. (Report Recommendation 7d)
5. Existing follow-up care clinic models should be evaluated and compared to ascertain their impact on survivor outcomes and their cost effectiveness. (Report Recommendation 7e)

The stakeholders convened by the Panel in August 2005 identified progress made since the 2003–2004 report toward implementing these five recommendations and suggested priority activities for the next two years, as well as potential partnerships, collaborations, and other support needed to speed implementation.

Progress Toward Implementation

Progress in Expanding Insurance Coverage and Access

- In response to concerns among many cancer constituencies, Congress mandated and has set aside nearly one million dollars for a National Institutes of Health (NIH) study of Psychosocial Services to Cancer Patients/Families in a Community Setting.⁵⁰ The study, to be conducted by the National Academy of Sciences/Institute of Medicine, will identify effective models, assess workforce demands, and address reimbursement issues.
- Fertile Hope is a nonprofit organization dedicated to raising awareness of fertility issues related to cancer treatment and assisting people with cancer who have suffered or are at risk of fertility damage. In collaboration with the Lance Armstrong Foundation (LAF), the group has launched an advocacy campaign to educate policymakers about these issues, and a related resolution has received some bipartisan congressional support. A large, self-insured investment bank in New York recently added coverage for infertility services to its employee insurance plan. It is perhaps the first large employer to do so, and is working with Fertile Hope to determine how the new coverage might be announced so as to encourage other employers to follow suit.
- In response to the Panel's recommendation, Fertile Hope established a financial assistance program to increase patient access to infertility and fertility preservation services. The program is a public-private partnership in which pharmaceutical companies are donating all needed medications and physicians are donating their services. To date, the program has helped hundreds of patients, and should be sustainable until widespread insurance coverage for these services is secured. It is not sufficiently large, however, to help all survivors who need assistance with fertility services costs.
- The Children's Cause for Cancer Advocacy partners with community groups that have access to adolescents and young adults in transition to survivorship and other care in adult care settings to educate this population about the health insurance benefits and restrictions in their state of residence and how to access coverage.

The clinical studies involving fertility are very expensive and some of them require very long-term follow-up. For example, I have patients who are five, six [years old] who had frozen their ovarian tissue for future transplantation and they will not use this tissue for [perhaps] another 30 years. [Who] is going to fund a 30 year-long study? These patients all end up using their own funds to sponsor this and as a result access is limited. If you don't have the money, you can't do fertility preservation unless there is a specific grant.

– Fertility researcher

- The CEO Roundtable on Cancer has developed and pilot tested its CEO Cancer Gold Standard™ cancer care benefit guidelines that emphasize coverage for cancer screening, cancer prevention, healthy lifestyle interventions, and clinical trials access. An implementation workbook⁵¹ developed for use by companies seeking the gold standard designation indicates that participating companies must “ensure that health benefit plans provide access to quality cancer care at [American College of Surgeons] Commission on Cancer⁵²-approved facilities and/or [National Cancer Institute] NCI-approved cancer centers.” It does not, however, stipulate what cancer care services must be covered at these facilities. For example, coverage for psychosocial, prosthetic, or fertility services is not required. Over the next two years, the CEO Roundtable expects to expand the number of companies accredited as meeting the Gold Standard.
- The Ulman Cancer Fund for Young Adults (UCF) is taking a two-pronged approach to improving insurance coverage for young adults. First, the organization has begun going to college campuses to educate students about how health insurance works and why it is important to maintain coverage after they no longer are insured under their parents’ policies. According to the Census Bureau, almost 26 percent of 15 to 24 year-olds and 30 percent of 19 to 24 year-olds are uninsured.⁵³ Many others are underinsured for the costs of a major illness such as cancer. UCF also has initiated conversations with insurers locally and regionally to encourage them to reach out to the lucrative but largely untapped young adult market with affordable insurance products. By increasing insurance coverage of this age group, which overall tends to utilize fewer health services than older populations, the relatively few young adults who develop cancer are more likely to have coverage at the time of diagnosis. While these conversations have not as yet yielded concrete results, these ideas and the possibility of mutually beneficial public-private partnerships have been received favorably.
- A small number of individual insurance plans aimed at the young adult market have been available for some time (e.g., Golden Rule, Blue Cross/Blue Shield offerings in some states), and their number appears to be growing. A few such plans also target individuals aged 50 to 65 years, who may not have employer-sponsored health benefits but who are not yet eligible for Medicare. Recently, health insurer WellPoint designed a low-premium, high-deductible health plan for individuals aged 19 years to their early 30s. The program, called Tonik, was launched in California in 2003. It now is available in Colorado and will expand to additional states in 2006. Tonik was developed for young adults who are unemployed or working in positions that do not provide health benefits, and for students no longer covered under their parents’ health plans. Monthly premiums range from \$64 to \$123 based on age, location, and medical history; deductibles range from \$1,500 to \$5,000. About 70 percent of Tonik enrollees to date previously were uninsured.⁵⁴

I don’t see how you can separate out psychosocial supports from the overall quality oncology management system. It has to be integrated...an integral part of everybody’s thinking, from a payor to a patient to a family member, physician, nurse, etc.

– Cancer cooperative group association chair

- Through both individual initiatives and collaborative efforts, patient advocacy organizations, oncology service providers, cancer health policy organizations, and other stakeholders successfully communicated to legislators the importance of providing assistance to patients in navigating the complex health system. This effort culminated in passage of the Patient Navigator, Outreach, and Disease Prevention Act of 2005 (P.L. 109-18), which allocates \$25 million over five years to support community-based programs that train and employ patient navigators.
- In April 2006, the State of Massachusetts legislature passed a bill that would require all residents to buy medical insurance and that would aim to make insurance affordable for all. The goal is to extend coverage to 90 percent of the state's 550,000 uninsured residents by July 2007. It is based on the model of mandatory auto insurance. If successful, Massachusetts would be the first state to achieve near-universal coverage for residents.
- UCF is conducting a pilot patient navigation program at the Johns Hopkins Medical Center in which newly diagnosed young adult cancer patients are matched to a cancer survivor who facilitates the patient's communication with his or her medical team and assists in finding and accessing needed resources.
- The Centers for Disease Prevention and Control (CDC) and LAF have established a cooperative agreement to incorporate legal expertise into the pursuit of public health improvements in cancer. Specifically, the New York Legal Assistance Group assesses legal needs as they relate to cancer care for underserved populations and provides interventions to help individuals access resources they need.

Progress Toward Follow-Up Care Clinic Evaluations

- LAF has begun funding the LIVESTRONG™ Survivorship Center of Excellence Network, a network of adult survivorship clinics to be located in NCI-designated Comprehensive Cancer Centers, that will adapt the pediatric follow-up care clinic model for adult cancer survivors. Applicants for funding must show that they are working with a minimum of three community-based centers, which may include private practice oncology groups. This requirement reflects the reality that most adults receive their care in the community rather than at cancer centers. Center directors will be required to meet twice per year to identify research questions of interest and network-wide study populations. An important goal of the clinics will be to collect data that will support care model evaluation. LAF intends to share data on best practices (i.e., those that improve outcomes) identified through these evaluations. LAF also provides support for four adult survivorship clinics that are not part of the new network.



Suggested Priorities for the Next Two Years

Priorities for the near term fell into two primary categories: (1) activities to improve insurance coverage and access for all survivors, and (2) activities to enable evaluation of survivor follow-up care models.

Priorities to Improve Insurance Coverage and Access

- **Work collaboratively for the legislative, regulatory, and health care financing changes needed to make comprehensive quality care a reality for survivors.**

To persuade policymakers and insurers that psychosocial, prosthetic, fertility, and other follow-up care services are essential components of quality cancer care that should be covered for all survivors, it is necessary to demonstrate that the incremental cost of providing these services to survivors is not excessive and that the cost is offset by reduced service utilization for later physiologic and psychosocial morbidity arising from unaddressed needs.

Potential Partnerships, Collaborations, and Support

- Best practice models for coverage of prosthetics (including hearing aids⁵⁵), fertility services, and psychosocial and other follow-up care should be identified. Data should be collected on the utilization and cost experiences of insurers who cover some or all of these services, e.g., Massachusetts data⁵⁶ showing that providing infertility services costs \$1.71 per person per health plan contract month, an amount that was deemed not excessive; hospice cost of care study conducted by the National Hospice and Palliative Care Organization.⁵⁷
- Demonstration projects and cost-benefit analyses are needed on psychosocial or other follow-up care models. Cost effectiveness studies should routinely collect data on psychosocial risk factors, including socioeconomic distress, specific interventions provided, and outcomes. Some tools exist (e.g., Distress Thermometer⁵⁸) to help measure the severity of psychosocial stressors and should be incorporated into these studies. This research is particularly amenable to collaborative efforts. For example, the Children's Oncology Group (COG) and adult Cooperative Group databases could be used to identify and track patients; oncology social workers, patient support organizations, and mental health and rehabilitation professionals could collaborate on study designs; NCI could fund data collection and analysis; and LAF could support the community organization(s) providing the intervention.
- For psychosocial and other interventions shown to be of benefit, candid discussions among all stakeholders, including public and private payors, must be conducted to determine how these services will be financed (e.g., Federal or state tax dollars, insurance premiums) and for which provider services (e.g., nurse practitioners, social workers, nutritionists) payment will be made. Currently, mental health services typically are an insurance “carve-out” (i.e., reimbursed differently from other health services) that still lack parity with other aspects of health care.
- CMS should be encouraged to conduct a demonstration project on psychosocial care similar to its demonstration project in which reimbursement was provided for physicians to assess patients' pain, nausea, and fatigue. Private insurers tend to conform to CMS reimbursement policies; therefore, changing CMS reimbursement policy is a critical key to expanding access to survivors who are neither Medicare nor Medicaid beneficiaries.

- A standard exception to the conventional definition of infertility (trying to conceive for one year without success) is needed for cancer patients facing treatment-related infertility so that they can access fertility preservation and infertility services. This action could be facilitated by the CEO Roundtable on Cancer. Progress in this area might be made most rapidly by working to revise legislation in the 13 states that now mandate provision of infertility services to those who are infertile as defined above. Another approach might be to first seek coverage under the Federal Employee Health Benefits Program or Medicaid.
- Advocates and health care providers focused on other diseases (e.g., cardiovascular disease, diabetes, HIV) should be contacted to learn how they have addressed or are attempting to address the need for insurance coverage for psychosocial and other ancillary services (e.g., nutrition, rehabilitation). In addition, useful lessons may be learned from studying how coverage for other previously uncovered services (e.g., breast reconstruction after cancer surgery, contraceptives) was obtained.
- **Increase the health insurance coverage rate of the young adult population to improve the likelihood that individuals diagnosed with cancer will have coverage for treatment costs and subsequently will not be subject to preexisting condition exclusions.**

Potential Partnerships, Collaborations, and Support

- Groups such as the Alliance for Childhood Cancer and the LIVESTRONG™ Young Adult Alliance could gather and disseminate state-level information about untapped coverage through Medicaid and SCHIP (the state Medicaid child health insurance programs) that may be available to young cancer survivors.
- Dialogue with major insurers should be continued and expanded to increase their interest in marketing to young adults. A coalition of advocates representing the range of disease conditions affecting young adults could be more effective than any one group in changing health insurance policy for this population.
- Those designing outreach and education interventions to increase young adult knowledge about health insurance should consult with the developers of recent communication models (e.g., the 2004 “Vote or Die” campaign on MTV and other media outlets) that successfully attracted the attention of and motivated action by this age group on political issues.

...[there is] a huge population of children or young adults that are not insured....I think that ought to be our first priority for young adults – to help with that.

– Patient advocate

- **Explore creative mechanisms for providing needed services outside of traditional insurance mechanisms.**

Potential Partnerships, Collaborations, and Support

- Consider partnerships between the LIVESTRONG™ Young Adult Alliance participants and private sector organizations to sponsor events or create promotional/goodwill campaigns that will raise funds for or supply services currently not reimbursed by insurers.
- Use community-based participatory research methods to identify local survivor needs and to assess and build local networks, including patient navigators, to provide psychosocial and other non-reimbursed services. Local solutions will need to be tailored to diverse audiences with varying levels of health literacy and different community resource levels. For example, many seniors who come through the cancer care system are not being connected to services of public health and aging-specific agencies.
- Evaluation of local or regional interventions is crucial to contribute to the evidence base on the efficacy and cost effectiveness of these services.

Priorities to Advance Evaluation of Follow-Up Care Models

- **Standardize data collection to the extent possible so that data can be shared and studies of specific interventions or follow-up care programs more broadly will have greater statistical power.**

Potential Partnerships, Collaborations, and Support

- See suggestions above, p. 37, regarding collaboration on the design of intervention and cost-benefit studies.

Commitments Made – Insurance and Access Issues for Cancer Survivors

Meeting participants committed to undertake the following activities related to insurance and access:

Research

- The National Cancer Institute (NCI) Office of Cancer Survivorship will continue to pursue and champion research that will provide the evidence base needed to demonstrate the efficacy of care models for survivors. Data from the study of where survivors are receiving follow-up care are expected to lead to refined or special outreach efforts to specific populations such as the elderly, who comprise the largest population of survivors.
- Fertile Hope committed to assisting in any way possible to advance research aimed at demonstrating the efficacy and cost-benefit of providing fertility, psychosocial, and other services to survivors.

- The Children's Oncology Group is seeking collaborators to conduct research on how young survivors can best make the transition to adult survivorship care.
- The Coalition of Cancer Cooperative Groups will take the lead on gathering financial support to conduct and analyze surveys of young survivors using Web-based knowledge network strategies. This could include re-analysis of data gathered in the Coalition's recent survey of 1,700 cancer patients relative to clinical trials.
- The Centers for Disease Control and Prevention (CDC) Division of Cancer Prevention and Control will increase its focus on survivorship clinic and psychosocial care models that CDC could help deliver into communities. CDC also will continue to work with partner organizations to explore the feasibility of novel public health approaches to reducing the burden of cancer.

Education and Outreach

- Consistent with its strategic plan and the recommendations of both the CDC/Lance Armstrong Foundation (LAF) National Action Plan for Cancer Survivorship⁵⁹ and the President's Cancer Panel, LAF will continue its efforts in collaboration with organizations that work directly with survivors to develop informational content appropriate to the health literacy levels of cancer survivors and referral resources in the areas of physical, emotional, and practical challenges following a cancer diagnosis. Practical information will emphasize access to financial resources, insurance coverage, and legal assistance.
- LAF will continue to enhance the patient navigation system, the LIVESTRONG™ SurvivorCare Program, that it has established in collaboration with CancerCare, the Patient Advocate Foundation (PAF), and EmergingMed.
- The Children's Cause for Cancer Advocacy plans to hold three to four educational workshops for young cancer survivors in the next fiscal year in collaboration with local programs, clinics, and grassroots organizations.
- In addition to its current collaborations with LAF, the Association of Oncology Social Work, the National Coalition for Cancer Survivorship, and its continuing direct service to survivors who contact the organization, PAF will make its database and data analyses available to NCI or any other group that may be able to use the data to support implementation of the recommendations.
- The Ulman Cancer Fund for Young Adults (UCF) will conduct focus groups of young adults who are caregivers for parents with cancer with the goal of developing a guidebook for caregivers.
- UCF also will continue its participation in the LAF Young Adult Alliance and its initiatives in patient navigation and young adult survivor education and empowerment.

Access

- LAF is committed to improving access to care by bringing together state, national, and community-level organizations that provide care and resources to survivors to identify resource gaps and potentially establish an ongoing network of provider organizations, institutions, and professionals that will be able to learn from and build on each other's capacities and processes.
- Fertile Hope will continue its financial assistance program until insurance reimbursement for fertility preservation and infertility services is routinely available to cancer survivors.
- The Dana Farber Cancer Institute will continue providing services to survivors of any age, and has established plans to conduct ongoing cost effectiveness, quality of life, and patient satisfaction evaluations.

Policy

- The Children's Cause for Cancer Advocacy also will advocate through its own work and its participation in the Young Adult Alliance and the Cancer Leadership Council (a coalition of advocacy groups that focus on various adult cancers) for survivorship legislation that includes children and young adults.
- PAF will advocate for immediate Medicaid eligibility for young people diagnosed with cancer.

PART III

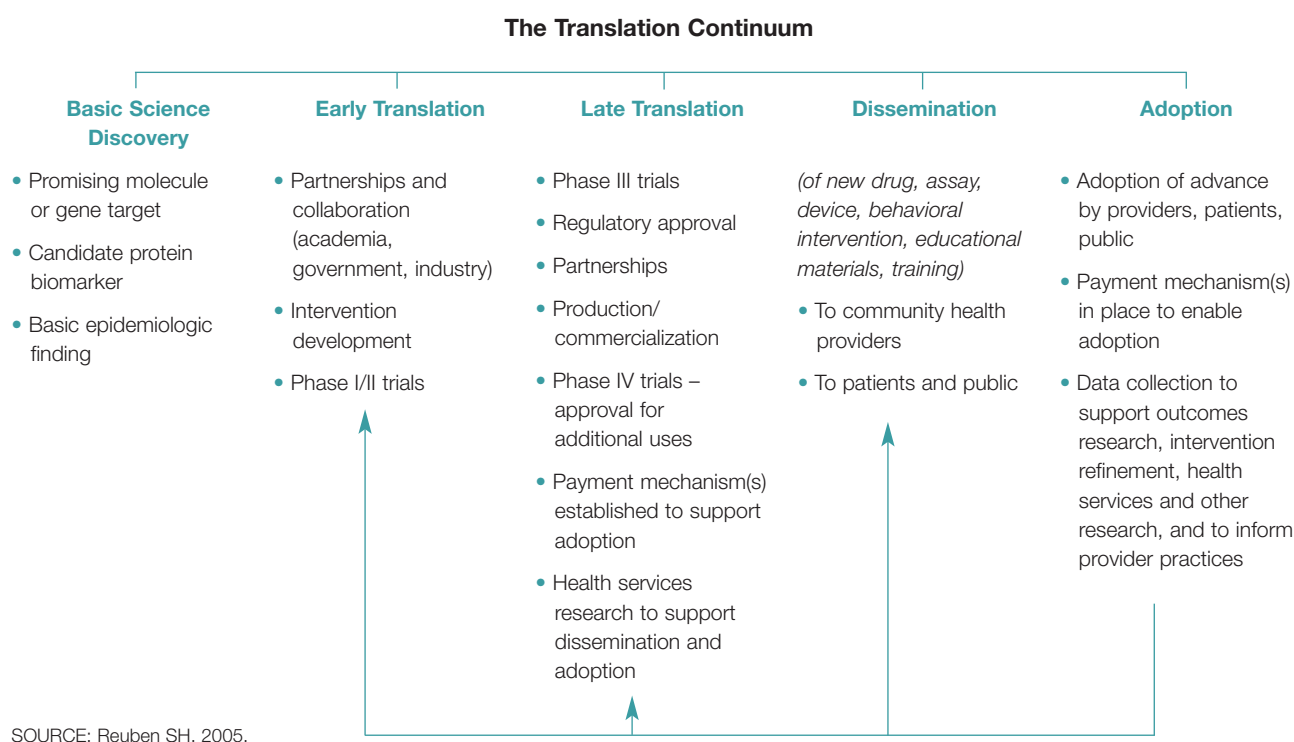


Recommendations from *Translating Research into Cancer Care: Delivering on the Promise*

This report examined barriers that prevent basic science discoveries from being translated more rapidly into improved preventive and therapeutic care for people with cancer and those at risk. The President's Cancer Panel views the translation process as more than translational research alone, but rather as a continuum (Figure 1) that encompasses all of the processes involved in developing promising basic science discoveries into cancer-related drugs and biologics, medical devices, behavioral interventions, methodologies, and instruments, and ensuring their widespread adoption in the health care system.

The Panel convened stakeholders to discuss how best to make progress in three particularly key areas: (1) advancing team science and changing the current culture of research, (2) addressing workforce infrastructure issues, and (3) improving the dissemination of successful interventions and increasing community participation throughout the research translation process. However, the Panel recognized that at the time of its October 2005 meetings on these recommendations, only five months had elapsed since publication of the report. Therefore, the meetings focused on relevant activities newly initiated or planned that had not been described in the report, as well as priorities for action toward implementation; potential partnerships, collaborations, and sources of support; and immediate commitments to advance change.

Figure 1: Translating Research to Reduce the Burden of Cancer



Chapter 4



The Panel determined that the existing culture and structure of the cancer research enterprise, both public and private, are the root of many of the impediments to translating basic science discoveries into improved cancer prevention and treatment interventions. These factors significantly affect cancer research and funding priorities, the perceived desirability among institutions and individual investigators of conducting collaborative research, and institutional resource allocations. Representatives from academic medicine and research, industry, medical and science education, cancer care, advocacy, government, scientific journalism, and academic administration were convened to discuss the following recommendations:

2004-2005 Translation Report Recommendations — Team Science and the Culture of Research

1. The existing culture of cancer research must be influenced to place more value on translational and clinical research. To effect this culture change, a task force representing key stakeholders in academic research should be convened to examine and modify existing reward systems (e.g., compensation, promotion/tenure, space and resource allocation, prestige) to encourage collaborative research and ensure that all contributors (including but not limited to pathologists, radiologists, and research nurses) benefit from participating in these activities. (Report Recommendation 1)
2. Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research. (Report Recommendation 2)

To alter the research culture, discussants underscored the need to move away from an entrenched ideal, the so-called “triple threat” (an individual who excels as a clinician, teacher, and laboratory scientist), and toward a tripartite system⁶⁰ that accommodates the reality that research and teaching have become more specialized than in the past. In such a system, excellence in one area would be valued equally to excellence in either of the other two realms. This system also would help to clarify the role and importance of the clinical investigator, whose greatest contributions come from developing and testing hypotheses through competitive, peer-reviewed (often Phase II) studies. However, these pursuits may not always align well with scientific and/or fiscal priorities of the institution or its clinical chair, which may value revenue generation by these scientists over their research activities. With revenue pressures on these researchers escalating in the current fiscal environment, mechanisms are more than ever needed to better support clinical investigators at all stages of their careers (see also Chapter 5, Workforce Infrastructure Issues). The meeting participants also emphasized the importance of differentiating between translational research, clinical research, and team science, which may overlap in specific circumstances but are distinct, albeit not well defined.

Participants discussed current fiscal realities affecting the likelihood of markedly increased funding for translational and clinical research, and questioned whether collaboration creates economies of scale or actually is more expensive. Data warehousing and data sharing are areas in which initial investments should reap far greater rewards, as long as all researchers who may benefit from the data can access it. Team science projects involving multiple disciplines may not be more economical than single investigator projects, but increasingly are required to address certain scientific questions. Their true cost should be measured in terms of the value their products bring to the patient.

Since substantial new funding is unlikely and reallocating funds from other activities may not be possible, existing funds must be used more efficiently. One way to save money is to redesign processes. Examples include standardizing institutional review board (IRB) protocol review (including use of centralized IRBs), linking data repositories so that experiments with negative results are not repeated, and addressing technology incompatibilities that increase costs. Concern was expressed at the degree to which clinical and biotechnology research already has been outsourced, and the possibility that translational research likewise could be moved to other countries with lower labor costs and less stringent regulatory environments.

...[team science] may not be more economical, but it might be required.

– NIH grant review program director

Progress Toward Implementation

Numerous activities are newly underway or planned that either directly or indirectly support implementation of these Panel recommendations.

Activities Addressing Team Science and the Cancer Research Culture

No task force as described in the recommendation has emerged or appears to be planned; however, recent activities to advance team science and create a culture more conducive to collaborative research include the following:

- The National Cancer Institute's (NCI) Clinical Trials Working Group (CTWG) issued final recommendations in June 2005⁶¹ that were accepted in full by NCI's National Cancer Advisory Board. The CTWG determined that the productivity of the national cancer clinical trials enterprise will depend increasingly on collaborative team science, but indicated that the incentives implicit in NCI's current modes of evaluating program accomplishment, making grant or contract renewal decisions, and allocating funds are not fully congruent with the needs of collaborative science. To help ensure that institutional and professional rewards accrue to those who participate collaboratively in the enterprise as a whole, CTWG is launching an initiative to realign NCI funding, academic recognition, and other incentives to promote collaborative team science and clinical trial cooperation. In this way, NCI hopes to send a clear message as to the importance of collaborative science in bringing effective new treatments to patients. Program award guidelines and scoring systems will be revised to allocate credit for the behaviors needed to advance collaborative science. In addition, the CTWG recognized the crucial role of translational and clinical scientists in the conduct of team science and has suggested designating resources to support larger portions of their time.
- Changes in Federal funding criteria and other outside influences are beginning to affect institutional behavior. Meeting participants noted, however, that unless universities and medical schools are explicit about the value of clinical research in promotion and tenure decisions, external rewards will be of insufficient value to encourage participation in team science. Emory University has made clear in its appointment and promotion rules that collaborative research and publications emanating from it are valued on par with single investigator studies and publications.
- The National Institutes of Health (NIH) has initiated discussions with the Accreditation Council for Graduate Medical Education on how to define, recognize, and accredit good clinical investigators and their institutions.
- The American Society of Clinical Oncology (ASCO) is conducting focus groups with academicians at five major university medical centers to identify their concerns about translational and clinical research issues and discuss how this type of research could be more highly valued by an institution.

- Some scientific journal editors are trying to develop innovative ways to increase the number of articles published on translational research and to enhance the recognition of individuals involved in team research. The number of papers published has been relatively small because translational studies tend to be large and lengthy. The number of papers produced also is related to the level of funding available for this type of research and the number of well-trained investigators who can compete successfully for these grants. In addition, some journal editors seek out articles and commentaries on methodologic issues in translational research because their demonstrable relevance to patient benefit is attractive to the media. Media attention increases the visibility of translational science, which in turn may help elevate its status at academic institutions.

It is very difficult to reward or promote a second-author investigator, no matter what his or her contributions are – even when they're very clear.

– NIH grants review program director

Activities to Emphasize and Increase Funding for Clinical and Translational Research and Team Science

- The NIH Clinical Center provides a place for investigators from all NIH Institutes to conduct and collaborate on clinical research. The Clinical Center not only enables the research, but pursues new ways of approaching scientific issues and simplifying processes that may serve as models elsewhere in the country. For example, a new, publicly available tool known as ProtoType helps investigators author protocols, project resource requirements, track performance, and merge clinical data with relevant basic science data.
- The NIH Clinical and Translational Science Awards (CTSA), part of the NIH Roadmap for Medical Research⁶² initiatives, are institutional awards intended to provide a true home for clinical and translational research science within academic health centers. It is expected that the manner by which clinical and translational research is incorporated or added at each grantee academic center (e.g., as a department, center, institute) will differ, but the intent is to provide a place where faculty can conduct original research, develop graduate programs and training curricula, and lead programs that integrate clinical and translational science across the institution's academic landscape. Applicant organizations will be able to develop novel and clinical translation methodologies, conduct pilot and collaborative translational and clinical studies, and implement biomedical informatics programs, among other activities. The Request for Applications (RFA) for this program is administered by the NIH National Center for Research Resources.
- In late 2005, NCI awarded six grants under the Strategic Partnering to Evaluate Cancer Signatures program to support team science projects on translating molecular signatures of tumors. The teams include investigators from the Clinical Cooperative Groups, Specialized Programs of Research Excellence (SPORes), cancer centers, NCI intramural laboratories, the National Laboratories, community hospitals, biotechnology companies, and individual academic institutions in the United States, Canada, and Europe.⁶³

- The Department of Defense (DoD) training mechanisms offered through the Congressionally Directed Medical Research Programs (CDMRP) strongly emphasize multidisciplinary postdoctoral fellowships as a way to influence research culture and inure investigators to collaborative efforts early in their careers. It was noted that this approach sometimes meets with resistance from peer reviewers for CDMRP grants whose orientation is more traditional.
- The American Society for Therapeutic Radiology and Oncology (ASTRO) recently has greatly increased grants for translational research and established a translational research committee. ASTRO includes the development of technology to detect and treat tumors in its definition of translational research.
- The NCI Cancer Center Support Grants (core grants) program is placing increasing emphasis on success in clinical translational research in evaluations for grant renewal. The SPORes have been and continue to be important stimuli for collaborative, translational research that recognizes the contributions of all participating disciplines.
- The M. D. Anderson Cancer Center promotion committee has begun to include participation in team science among the criteria for professional advancement. In addition, Faculty Achievement Awards that previously were given primarily to oncologists or surgeons now are being awarded to other patient care professionals, such as radiologists.
- For the past few years, ASCO has conducted a workshop to bring clinical research skills to community investigators. ASCO now is considering how the workshop can be expanded to a broader audience, and the possibility of increasing the linkage between its fellowship programs and community practice.
- The Cancer Center of the Carolinas is a private practice that has participated in the regional NCI Community Clinical Oncology Program (CCOP) for ten years. It is affiliated with the Greenville Hospital System (South Carolina), which has allocated facility space for use by Clemson University basic researchers who are funded by NCI and the National Kidney Foundation. The cancer center provides the clinical leadership to further develop basic science discoveries of the Clemson researchers, with center oncologists donating their time. In the 18 months preceding October 2005, the group launched four human trials. When the cancer center's private practice budget could no longer support all of the costs related to this research (e.g., pharmacy, staffing), the group secured supplemental support by also participating in trials sponsored by the U.S. Oncology Network and the Mary Crowley Research Network. This collaborative arrangement provides a model for increasing emphasis and funding for clinical research in the community.
- The American Association for Cancer Research (AACR) is discussing development of a team science award.
- NCI is working with the U.S. Surgeon General to launch a major public education effort on the benefits of participation in clinical trials. Community oncologists also play an important role in addressing this issue with their patients.



Suggested Priorities for the Next Two Years

Priorities for Modifying the Cancer Research Culture

- **Overcome academic barriers to appropriately crediting the work of co-principal and other investigators who participate in translational, clinical, and team science efforts so that they are not penalized in promotion and tenure decisions.** Pursuant to the January 2005 directive⁶⁴ from the Director of the Office of Science and Technology Policy in the Executive Office of the President, all Federal research funding agencies must allow more than one principal investigator to be designated on a project. However, the majority of academic institutions still do not value collaborative work as much as single investigator efforts in making promotion and tenure decisions.

Potential Partnerships, Collaborations, and Support

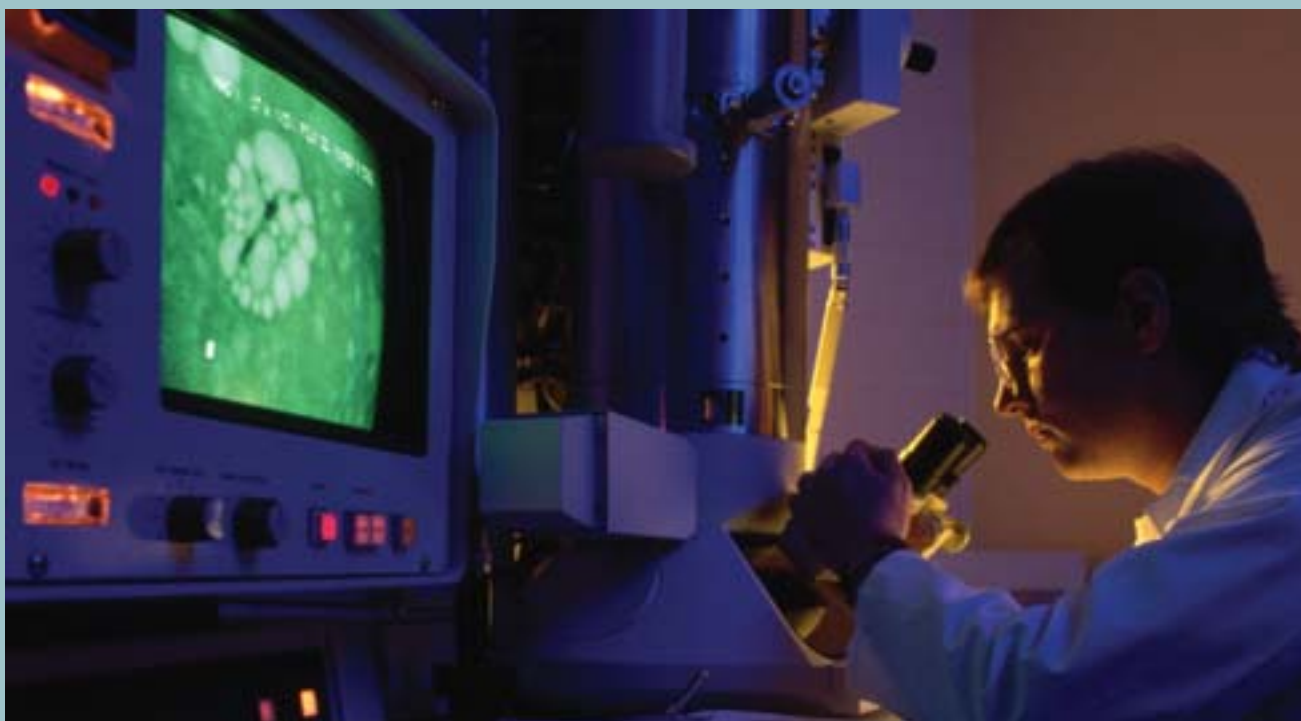
- Fortright support of translational, clinical, and team science by the leaders of individual medical schools is an essential ingredient in changing the current research hierarchy. Academic leaders should develop explicit appointment, promotion, and tenure criteria that address these types of research, including issues of co-authorship and internal allocation of grant dollars according to how the science actually is conducted. Academic medical center leaders also can demonstrate commitment to team science projects by allocating funds to pilot studies or other preliminary activities needed to organize large program project (NIH P01s) or other team science grants. The Association of American Medical Colleges (AAMC) Council of Deans should promote such actions among medical school deans and also encourage deans both individually and as a group to raise the visibility of these issues with university presidents.
- A formal accreditation or certification mechanism is needed to acknowledge excellence in clinical research that would provide an evaluation benchmark for promotion committees.

- The NIH tenure criteria and tenure review process may provide a model for other institutions. The criteria recognize team science, epidemiology, clinical medicine, biometry, and other research areas in addition to the more traditional basic science fields. The central tenure committee has subcommittees or panels to ensure that reviewers who are competent to judge areas of science that the central committee encounters less frequently are available to evaluate these proposals rigorously and fairly.
- The NCI SPORE program has been a successful model for facilitating team science and translation. Efforts should be made to build on that model rather than diminish it.
- Professional organization awards for team science accomplishments would help to resolve issues related to promotion and tenure decisions and send a message to the research community that discipline-specific professional groups are encouraging and valuing team science.
- Currently, the order in which co-authors are listed for certain articles may be determined randomly although all members of the team made significant contributions to the work. Scientific journal editors can devise ways of ensuring that true co-equals are recognized as such in published papers and that those with the most important contributions are distinguishable from other contributors when there are many authors (e.g., principal primary versus contributing authors). For example, principal authors can be highlighted and their leadership described in a footnote. Allowing more than one corresponding author could further emphasize the equal contributions of more than one individual. Consistency across journals in this area will make it easier for promotion and tenure committees to evaluate the accomplishments of specific investigators. Journals also can highlight translational and team science studies in their contacts with the press. Press attention to these types of studies helps to increase their visibility and importance at the investigators' home institutions.
- Increasing the visibility of team science successes in top tier journals will help change the research culture. Participants in or funders of successful team research efforts should report on the products of these projects more fully.

I think that universities – and medical schools in particular – need to be quite explicit in indicating the value of clinical research when it comes to promotion and tenure situations because in a university, you can have all the external rewards in the world, but if it's not valued in your own institution and doesn't help you advance your career and get proper recognition, then it diminishes the outside influence.

– *Medical school association executive*

- **Identify ways to increase involvement, recognition, and resources for academic and community pathologists, radiologists, nurse scientists, biostatisticians, and other professionals participating in multidisciplinary team research.** The current assumption that these scientists always are in a supporting or subordinate role to physician investigators, together with lack of payment for their participation, will continually undermine the potential and success of collaborative science.



Potential Partnerships, Collaborations, and Support

- The strengths of the intramural Veterans Administration (VA) Cooperative Studies program and its training programs (including those in health services research and research career development awards) should be studied to determine how they may be replicated in university settings to promote team science.
- The Children’s Oncology Group (COG) program in which nurse scientists mentor advanced practice nurses to develop research programs (including quality of life studies conducted in conjunction with Phase I and II trials) provides a model for increasing resources for and inclusion of non-physician researchers in multidisciplinary research.
- The public health and social sciences may provide models of collaboration that will be useful in promoting team science and changes in the research culture. Similarly, at the National Aeronautics and Space Administration, interdisciplinary team science is the norm and may provide a model that could be adapted to academic research environments. It was suggested that the industrial psychology literature may offer applicable insights on what makes teams work efficiently and well, key leadership qualities, and the types of research problems to which teams are best suited.

...we have a whole department of biostatisticians, but they don’t have any PI [principal investigator]. They don’t have any first author or corresponding author, but they play an important role in a P01 [program project] grant or in a SPORE [Specialized Program of Research Excellence] grant, and those people aren’t recognized.

– Cancer center research department chair

Priorities to Emphasize and Increase Funding for Clinical and Translational Research and Team Science

- **Explore innovative ways to leverage existing funding to provide greater support for clinical, translational, and team science.** Support is needed for those pursuing academic careers as well as those who choose careers in community practice. It is crucial that the latter group understand and appreciate the importance of clinical research, as they often comprise the effector arm of team science and clinical research projects in the community and have a vital role both in helping the public understand the value of participating in clinical research and referring patients to studies.

Potential Partnerships, Collaborations, and Support

- Collaborative efforts are needed to expand support mechanisms for translational and clinical researchers. For example, a career development package could be developed that includes funding from both Federal and private sources.
- Individual institutions and professional societies could change the criteria for one or more existing research recognition awards or prizes such that nominations would be open to groups rather than just single individuals. Such an action would be a cost-neutral way of increasing support and recognition for investigators who participate in team research.
- Hospital administrators should be involved in discussions of innovative ways to fund translational and clinical research, in which hospitals are important partners. Mutually advantageous partnerships may be possible that increase support for translational and clinical research.
- Partnerships between academic medical centers and industry (e.g., academically based Clinical Research Organizations that contract to conduct clinical trials for industry) currently exist that could serve as models for additional partnerships that increase resources for translational and clinical research. NIH or the Centers for Medicare and Medicaid Services may need to take a leadership role to facilitate such partnerships on a large scale.
- The public should be educated about the value of translational, clinical, and team research and engaged in advocacy to promote funding for this research. Awareness and education efforts should be coordinated among the many agencies and organizations (e.g., NCI, ACS, Lance Armstrong Foundation) now addressing aspects of this issue.
- A study section for clinical and translational research that encourages submissions of interactive, collaborative proposals by laboratory and clinical scientists could make efficient use of existing funds and advance the translation of promising basic science discoveries.
- By streamlining processes and related paperwork associated with Food and Drug Administration Investigational New Drug applications, informed consent requirements, and Health Insurance Portability and Accountability Act regulations, research could be conducted more efficiently. The enormous savings that would result could be used to support additional research.

Commitments Made – Team Science and the Culture of Research

Increasing Recognition

- The National Cancer Institute (NCI) will conduct informal consultations, focus groups, and surveys to identify additional forms of recognition that NCI could award that would be valued by investigators and their institutions.
- The American Society of Clinical Oncology (ASCO) is interested in partnering with other organizations to address issues related to academic translational or clinical research certification. In addition, ASCO indicated its willingness to participate in discussions of how attribution of individual researcher contributions in team science projects can be clarified and standardized in its publication, the *Journal of Clinical Oncology*, as well as in other medical journals.
- The *Journal of the National Cancer Institute* is eager to work with authors to find ways to acknowledge multiple key authors and the contributions of industry to research projects.
- The American Association for Cancer Research's *Journal of Clinical Cancer Research* is committed to working with others to develop unified criteria for authorship recognition that would be accepted by national membership organizations and medical schools.
- The National Institutes of Health (NIH) Clinical Center expressed willingness to work on developing criteria and a process for accrediting translational and clinical investigators.
- The Department of Defense (DoD) will investigate ways to recognize multiple principal investigators on research projects.
- The American Society for Clinical Pathology will consider extending the scope of its annual award for clinical research beyond individual investigators to include the work of research teams and will consider the need to develop certification mechanisms for translational scientists.

Improving Support

- The NIH Clinical Center will share its experience and products gained in developing informatics tools for researchers and training curricula for young investigators.
- Within the next two years, NCI will create a new Cancer Clinical Investigator Team Leadership Award for mid-level clinical investigators not currently holding principal investigator status on an NCI grant. The competitive award will provide funding equivalent to 10 to 20 percent salary support per year. Nominations will be solicited annually from cancer centers or other institutions carrying out NCI-funded clinical trials. The intent is to reward exceptional contributions that advance effective new treatments toward practice and embody collaborative team science ideals. NCI also is in the process of changing its review guidelines for awards supporting translational research investigators.

- ASCO will consider increasing emphasis on translational research and team science in its career development program, including creation of fellowships for those in clinical practice. ASCO also is discussing the possibility of advocating a policy of redistributing some income from patient care that would increase “protected time” for clinical investigators (i.e., that part of an individual’s time reserved for research pursuits as opposed to revenue-generating activities, typically supported by outside or dedicated institutional funding).
- The Veterans Administration provides protected time for investigators, and makes both career development and drug/technology industry partnership awards that promote team science. The agency is beginning to issue RFAs that combine laboratory, clinical, and health services research components.
- DoD will continue to support mechanisms for translational research and encourage team science through consortia and Center of Excellence awards.
- The American Society for Therapeutic Radiology and Oncology will continue to offer seed grants and career development awards and plans to establish an emerging technology committee that will bring together industry, academic radiation oncologists, and regulators early in the process of developing new technologies to encourage collaborative efforts and make the development process more efficient.
- The National Institute of Nursing Research will continue to work with NCI to enhance the involvement of research nurses and nurse scientists in the Community Clinical Oncology Programs.

Chapter 5



The Panel's report examined infrastructure-related barriers across the research translation continuum that are slowing the movement of basic research findings into the clinic for testing, and into community practice. Currently, a major barrier to progress is the relative dearth of translational and clinical researchers compared with the basic science workforce. This imbalance is a major factor contributing to the infrastructural bottleneck that now limits the translation of cancer-related discoveries. Since translational researchers must be trained in both basic and clinical sciences, their training typically is of longer duration than that of individuals pursuing basic or clinical science alone. Appropriate mentors and mechanisms to provide protected research time are in short supply. The Panel recognized that to speed new treatments and other interventions to patients, now and in the coming decades, these workforce issues must be addressed. Perhaps most urgently, steps are needed to attract and retain young investigators to translational and clinical research careers.

The Panel recommended:

2004-2005 Translation Report Recommendations — Workforce Infrastructure

To attract and retain young investigators to careers in translational and clinical research:

- Protected research time and mentoring must be provided earlier and potentially for a longer duration than is now the norm. Government training funds may be needed to enable academic institutions to provide this supportive environment.
- New or expanded student loan buy-back programs should be established to enable young investigators to pursue the additional training necessary for a career in translation-oriented research.
- Academic institutions should make special efforts to recruit and retain young scientists from underrepresented population groups. (Report Recommendation 5)

We should not underestimate the consequences of the coming years – problems with funding at NIH in terms of how students are going to make career decisions...the medical students who are in the system right now are out in the wards. Who are their immediate role models?...interns...residents...junior faculty – the ones who are going to feel the most intense pressure [to generate revenue]. So, unless we do something very effectively, we are going to have some real issues in terms of who is going to take care of the next generation of patients....who is going to teach the next generation of medical students, and who is going to do the research?

– *Clinical scientist association executive*

In October 2005, the Panel convened stakeholders from academic, governmental, and consumer organizations to discuss progress and next steps for addressing research translation workforce shortfalls.

The meeting participants emphasized that in addition to attracting young scientists from underrepresented groups, the clinical research workforce in total must be increased in size. Physician-scientists continue to be in short supply, although a study⁶⁵ suggests that their numbers have stabilized following a precipitous 22 percent decline between 1983 and 1998, due largely to targeted efforts initiated between 1998 and 2002 by the National Institutes of Health (NIH), academic centers, and the private not-for-profit sector. Until a new generation of clinical researchers is trained and becomes established as independent investigators, efforts are focusing on trying to attract into clinical research people trained in other disciplines. Participants maintained that investment in physician-scientist training should be increased, and that M.D.-Ph.D. programs should be expanded to include the social and behavioral sciences and informatics.

To attract medical students to research careers, they maintained, medical schools must expose students to clinical research early in their educational experience. In addition, it must be recognized that the incentives that attracted young scientists of the “baby boom” generation into research careers may no longer be appropriate, and incentives to recruit and retain young clinical researchers will have to accommodate these differences. Moreover, the gap between typical academic research and private practice incomes must be bridged if highly paid specialists are to be retained in clinical, translational, and team research careers. Typical “start-up packages” for clinical junior faculty (e.g., the mix of salary, protected time, access to resources, and other benefits) still tend to be less attractive than those offered to basic scientists.

...the start-up packages for faculty in clinical departments, particularly for faculty who want to do patient-oriented research, are woefully inadequate. I would put that squarely at the responsibility of the clinical departments, which in fact have not managed to set up constructive role models to address that issue.

– *Clinical scientist association executive*



The Panel's report emphasized the importance of protected time to the quality of clinical investigation, just as it is crucial to the quality of basic research. Unlike basic scientists, however, most clinical researchers are under significant pressure to support a large percentage of their salaries by generating patient care revenue. The result is the loss of time for contemplative thought and discussion that leads to innovation and high quality research. Meeting participants emphasized that the pressure on interns, residents, and junior faculty to generate revenue, frequent discussions about the uncertainty of funding, and the relegation of research activities, in many cases to off-duty hours, are both apparent and highly discouraging to medical students who are beginning to make career choices. If students are lost to possible research careers at this stage, developing additional postgraduate research training opportunities will be to little avail since there will be no students to take advantage of them.

In addition to ethnic and racial minorities, women were identified as an underrepresented minority in academic medicine and research. Although there now are more women in senior leadership positions than previously, many female scientists still leave academic medicine before they reach full professor or department chair levels.

The sections below highlight selected ongoing and new activities that support implementation of the Panel's recommendations, potential collaborations to accelerate implementation, and organizational commitments to progress in this area.

Progress Toward Implementation

Activities to Increase Protected Time and Mentoring

- The American Society of Clinical Oncology (ASCO) and the Association of American Cancer Institutes are engaged in discussions of options, including legislative action, to secure protected time for clinical investigators.
- Awards under the NIH RFA entitled “Training for a New Interdisciplinary Research Workforce,”⁶⁶ being launched as part of the NIH Roadmap for Medical Research initiatives may include linked Research Education Awards (R90) and Research Training Awards (T90).
- The institutional NIH Clinical and Translational Science Awards (CTSAs) also are part of the NIH Roadmap initiatives.⁶⁷ A principal purpose of the CTSAs is to “captivate, advance, and nurture a cadre of well-trained multi- and interdisciplinary investigators and research teams” in part through innovative graduate and postgraduate training curricula and career development.
- In February 2006, NIH announced the NIH Pathway to Independence Award,⁶⁸ a new opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. An initial one- to two-year mentored phase will allow investigators to complete and publish supervised research, and search for an independent research position; the second, independent phase will allow awardees who secure an assistant professorship or equivalent position to establish their own research programs. In Fiscal Year (FY) 2007, NCI will invest \$1.8 million in this initiative.
- A National Cancer Institute (NCI) training commission is taking an inventory of training activities at the Institute, on which \$280 million was spent in FY 2004. In 2006, the commission is focusing on gathering outcome measures for these activities.
- The June 2005 NCI Clinical Trials Working Group (CTWG) report included recommendations related to clinical and translational research-oriented training. A newly formed Translational Research Working Group is evaluating translational research across NCI and is expected to examine, among other issues, how research translation can be facilitated through training activities. It is expected to provide final recommendations to the NCI National Cancer Advisory Board in Winter 2006–2007.

Activities to Expand Loan Repayment Programs

- NCI participates in the NIH loan repayment programs; payments to extramural individuals through the program have increased from more than \$4 million in FY 2002 to about \$8 million in FY 2005, and intramural support totaled nearly \$6 million.

...some ethnic groups...are absolutely terrified of debt...so that, to me, means [we need] a different strategy than saying, “If you go into science, we’ll pay off your debt”....we’ve got to think more creatively than that...

– University chancellor

Activities to Recruit and Retain Translational and Clinical Scientists

In addition to the examples of training opportunities for translational and clinical cancer researchers noted in the Panel's report:⁶⁹

- The NIH Clinical Center has developed a curriculum for clinical investigators. Certificates are awarded to those who complete the program. In addition, the Clinical Center has partnered with a number of universities to develop clinical research training programs (e.g., a Master's program in clinical research at Duke University). Telecommunications are playing an important role in extending clinical research education. An introductory course on clinical research principles and practice had more than 700 enrollees in 2005; of these, more than half were not located at NIH and 200 were not in the United States.
- ASCO's program of young investigator and career development awards includes a joint program with the American Association for Cancer Research for young investigators focusing on clinical trial design.
- Recognizing that the lengthy timeline for peer review of grant applications can have negative effects on the efforts of investigators to establish and maintain independent research careers and on their career advancement, the NIH Center for Scientific Review is reducing the review timeline by approximately half.⁷⁰ The new process will be piloted beginning in February 2006 for young investigators and eventually will be extended to established investigators.
- The M. D. Anderson Cancer Center has established a new Ph.D. program in clinical research for physicians. The program is funded by a combination of Federal and institutional dollars.
- Since 1985, Howard Hughes Medical Institute (HHMI) has partnered with NIH on a Medical Research Scholars Program that enables medical students to spend a year away from medical studies to participate in research projects at NIH. HHMI sponsors a similar opportunity, the Medical Research Fellows Program, that enables students to conduct research in any academic or nonprofit research institution in the United States, excluding NIH. A new graduate student training partnership with the National Institute on Bioimaging and Bioengineering is designed to create an interface of physical, computational, mathematical, and biomedical sciences. HHMI also is now funding institutions to conduct training that improves graduate student understanding of medicine and/or to develop graduate training programs that lead to certificate, Master's, or Ph.D. programs in translational medicine.
- NCI's Cancer Prevention Fellowship Program is a three-year multidisciplinary program that includes one year of study toward an M.P.H. degree, followed by two years of prevention research at NCI, which can include research on cancer-related health disparities. Participants, who come from diverse fields (e.g., bench science, ethics, philosophy, clinical psychology, anthropology, nursing), have protected time for research and receive both scientific and career development mentoring. About 30 percent of the fellows are members of minority populations, about 15 percent are members of underrepresented groups, and about 70 percent are women. Recruitment has not been necessary because fellows frequently recommend the program to colleagues.

- NCI supports two major programs devoted to bringing underrepresented minorities into cancer research. The Continuing Umbrella of Research Experiences program provides funding to enable members of underrepresented minorities from high school through junior faculty to perform cancer research. The Minority Institution/Cancer Center Partnership initiative establishes partnerships between established cancer centers and minority-serving institutions to develop mentorship and collaborative interactions in an environment of equality and to improve the ability of both types of institutions to address issues that affect underrepresented populations. Together, the budget for these programs has grown by approximately 250 percent over the past five years.
- At Weill Medical College, Cornell University, last year's entering M.D.-Ph.D. class included seven women who, with the participation of an interested female faculty member, started the Female Association of Clinicians, Educators, and Scientists. The group has proven to be a motivating and empowering influence that is strengthening the program overall.
- The Harvard Medical School M.D.-Ph.D. program has created a new M.D.-Ph.D. track in the social sciences that may be emulated by other institutions. For the M.D. portion of their training, students may choose either the Harvard-MIT Health Sciences and Technology program or the regular medical school curriculum. The Ph.D. study may focus on biological or medical anthropology, economics, health policy, history of science, government, psychology, sociology, or statistics.
- Case Western Reserve University School of Medicine and the Cleveland Clinic have collaborated to establish a new medical school, the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University.⁷¹ The goal of the five-year curriculum is to educate physician investigators. Each student has both a clinical and research mentor and is required to complete a Master's level thesis.



Suggested Priorities for the Next Two Years

Priorities to Increase Protected Time and Mentoring

- **Provide greater assistance to junior faculty in identifying potential mentors. Consider other support mechanisms that may help enable initial career advancement.**

Potential Partnerships, Collaborations, and Support

- Academic institutions need to re-examine the mentoring processes in their faculty programs to better help young scientists identify appropriate mentors. Individuals from underrepresented and minority groups in particular may need such assistance when an appropriate mentor from the same group is not available.
- Additional assistance during early career development should be provided to female and underrepresented minority physician-scientists. For example, lack of child care options for the period spanning from graduate school to faculty appointment may be an important factor in the loss of women from science and a contributor to the scarcity of women in senior scientific positions.⁷² Industry models exist that may be adapted to the academic setting.

...mentoring of junior faculty, particularly minority junior faculty, continues to be a major challenge.... we had 75 people come out [to a session] on mentoring for underrepresented minorities. The kinds of questions young people were asking...were so fundamental in terms of how you find a mentor – particularly if there isn't an African American or Hispanic or whatever in your area – and what the strategies are. Young people need help with those strategies, and the faculty programs we put in place should look very carefully at how the mentoring process is going to take place...

– Academic medical center chancellor

- **Seek partnerships between Federal, voluntary health, and philanthropic organizations to help increase the number of physician-scientists.**
- **Medical schools should establish mentoring programs for M.D.-only students to ensure that they are exposed to clinical research and increase the possibility that they will pursue research in their postgraduate training and/or be receptive to participating in research in their medical practices.**

Priorities for Loan Repayment Programs

- **Develop creative mechanisms other than loan repayment programs to make careers in science financially feasible for young people.**

Potential Partnerships, Collaborations, and Support

- Anecdotal evidence suggests that some students (e.g., Hispanics/Latinos) are extremely hesitant to incur debt. Loan repayment programs, therefore, are not an effective incentive for these students, whereas work-study programs that keep them on campus and help avoid breaks in the continuity of their education may be more attractive. Focus groups with target student populations could uncover other factors influencing personal decisions about financing for education and training.

Priorities to Recruit and Retain Translational and Clinical Scientists

- **Intensify and modify recruitment activities to increase the number of physician-scientists.** According to recent Association of American Medical College exit interviews with graduating medical students,⁷³ approximately 15 percent (about 2,000 of 16,000 graduates per year) indicate that they would like research to be a significant part of their careers. Existing M.D.-Ph.D. programs enroll no more than 1,000 students per year.

Potential Partnerships, Collaborations, and Support

- Recruitment at all levels by academic centers and government agencies should target all socioeconomically disadvantaged groups, who represent a largely untapped pool of talent. However, numerous previous efforts to recruit and retain underrepresented individuals into medical study and science have failed.⁷⁴ Institutions hoping to attract members of these populations to scientific careers must understand their different perspectives and values. For example, in some groups, clinical practice is held in high esteem, while academic careers are not.
- Successful strategies for recruiting students into translational and clinical research should be identified and replicated. For example, some programs have established mechanisms to enable medical students to experience research while still in medical school; a number of “year out” programs (in which medical students take a year out to do research) exist that appear to be successful in increasing the number of physicians who include research as a substantial part of their careers. The number of these programs could be expanded.
- Programs could be structured to attract individuals who have completed medical school (e.g., enabling medical residents to also earn a Ph.D.).
- Medical schools could actively recruit undergraduates who may be open to pursuing an interest not only in medicine but in medical research.
- Attention should be paid to improving the undergraduate to medical school transition. Interested students could apply early and be admitted to medical school while still in college, or given admission preference. For those also interested in research careers, programs can be tailored that ensure exposure to translational and clinical research. NIH, voluntary organizations, and foundations may all have a role in devising creative ways to enhance this part of the pipeline to accelerate growth of the research workforce. Special effort should be made to involve schools with substantial minority populations.
- Admissions departments of medical schools should welcome the research interests of applicants, and tailor medical school programs for those interested in research. It was suggested that most medical schools, particularly their admissions departments, tend to discourage research interests.

So the real pipeline, folks, is in junior high school. When a kid is presented with, “Do I take algebra or not?” all too often, what happens – particularly among people of color – [is that] algebra will interfere with other activities, and that sets you down a pathway from which [educationally] you do not recover. As a basketball official of many years, I have spent many, many hours talking to young people. And I don’t talk to them about “setting picks”, I talk to them about taking pre-algebra.

– NIH research training official

- **Develop new or expanded training mechanisms in translational and clinical investigation and supportive fields.**

Potential Partnerships, Collaborations, and Support

- Medical schools should expose students to collaborative clinical science early and make clinical research an integral part of the medical school curriculum and experience. Students should have an understanding of how clinical research protocols may be implemented both in the academic center and in the community. In addition, medical school curricula should ensure that medical students are more familiar with advances in biology that will affect their success as physicians even if they do not pursue research.
- Participation in a degree-granting training program has been shown to be a strong predictor of an individual’s pursuit of a research career.⁷⁵ Individual medical schools could offer advanced degrees in clinical, translational, or team research and/or offer tuition savings (e.g., fifth year free) to attract more students into research career paths.
- Academic clinical departments need to improve early support for M.D.-Ph.D. graduates, particularly those who want to do patient-oriented research, and provide constructive role models to help retain young scientists in this research.
- Some of the K series of awards at NIH may be underutilized. These vary somewhat, but can provide supplement programs that may be used to attract underrepresented minorities to research activities. In addition, some postdoctoral students may resist entering multidisciplinary postdoctoral fellowships because they believe these programs will not help them obtain assistant professorships. Awards such as the NIH Pathway to Independence awards (see also p. 60) or the older K01 grants could be used to support senior multidisciplinary postdoctoral fellows for two to three years; under such a grant, upon appointment to an assistant professorship, additional grant funding is made available. The K22 program provides support in the first three years after an individual secures a junior faculty position. Individuals can apply before securing a position, and receive a Notice of Intent to Award, valid for one year. The program also is open to NIH intramural scientists who typically cannot apply for career development awards. These awards improve the competitiveness of candidates for junior faculty positions, since they will bring funds into the institution immediately.

...we have one model out there, the M.D.-Ph.D. program, where we create capacity within individuals. I wonder whether there's a way to expand translational research training...[such that] the end part of [an NIH training] K award...would require collaborative effort so that is learned earlier on in the [training] pathway.

– NCI official

- National Research Service Awards⁷⁶ could be made to M.D.-Ph.D. students. These fellowships may be awarded in any areas that fall within the missions of the NIH Institutes and Centers, and research training of physicians increasingly has been emphasized. By law, physicians who agree to undertake a minimum of two consecutive years of biomedical, behavioral, or clinical research training receive special consideration. The proposed training may be used to satisfy part of the degree requirements for a Master's, doctoral, or any other advanced research degree program.
- The institutional NIH Research Education Awards (R90) and Research Training Awards (T90), part of the NIH Roadmap for Medical Research initiatives, are intended to support efforts to develop and implement novel training programs focused on interdisciplinary science, including the physical, basic, behavioral, and social sciences. The results of these experiments should be evaluated for their possible replication or adaptation at other institutions.
- Training partnerships may be possible between academic centers and the pharmaceutical and biotechnology industries, which are accomplished at training clinical investigators, and with imaging companies. In addition, oil, chemical, and personal products companies may be interested in supporting prevention-oriented translational and clinical research. Conflict of interest is likely to be a minimal problem at early training levels.
- Training and career opportunities are needed for individuals who want to address behavioral, social science, and health services research issues related to cancer. Likewise, individuals with backgrounds in mathematics, physics, bioengineering, bioinformatics, and chemistry should be recruited into the faculties of medical schools, and physicians should be encouraged to pursue second degrees in these fields. A recent National Research Council report on research workforce issues⁷⁷ recommended increasing funding of the competitive NIH Medical Scientist Training Program by 20 percent and expanding its scope to include the clinical, health services, behavioral, and social sciences. Some of this program expansion could be funded through private philanthropy, but part of the funding would need to come from individual institutes at NIH.
- The translational research workforce needs training in current technology transfer concepts and methodology to better enable them to move discoveries beyond the laboratory to the point at which private investors will support their continued development.
- Regulatory reform related to currently cumbersome administrative activities such as adverse event reporting could result in substantial savings that could be used to support young investigators.

- **Consider system changes that could help attract new talent to translational and clinical research.**

Potential Partnerships, Collaborations, and Support

- Many basic scientists hold academic positions in clinical departments of medical schools; in some instances this situation has limited M.D.s to patient care and prevented them from having a research program. However, these basic scientists may represent an untapped reservoir of talent for advancing translational research in such settings. A substantial number of Ph.D. basic scientists are interested in doing translational research, but little infrastructure and support exists to help them do so and establish a successful career path as an independent investigator. One possibility to improve this situation is to develop a mechanism similar to the NIH K01 grant specifically for Ph.D.s interested in translational research.
- Establishing a peer review system for translational patient-oriented research could help draw more basic scientists into this area of research.

Commitments Made – Workforce Infrastructure Issues

- The American Association of Cancer Research welcomes opportunities to partner with other organizations to provide clinical research training, as it has done previously with the American Society of Clinical Oncology.
- The Howard Hughes Medical Institute is interested in partnering with the National Institutes of Health and other organizations to develop new approaches to workforce issues, such as shortening the time it takes a new clinical investigator to obtain his or her first R01 grant.
- The University of Texas System medical schools have numerous linkages with undergraduate schools and will consider developing a way to track undergraduates who have an interest in science and medicine, with a view to developing programs for these students.
- The National Cancer Institute Division of Cancer Prevention has partnerships with the governments of the Republic of Ireland and Northern Ireland and with some pharmaceutical companies that support prevention studies. The Division will explore potential partnerships with private industry to support translational science training that includes prevention-related issues.
- The National Association of M.D.-Ph.D. Programs will consider how to become more involved in training medical students who do not want a Ph.D. but are interested in learning about research. The Association will work more closely with high school, college, and medical school advisors to help them understand the need for physician-scientists and the types of preparation and intellectual curiosity that contribute to individual success.
- Emory University is modifying its medical school curriculum to better expose students to translational research. The university also is considering creation of a Ph.D. program in translational research and possible awards for outstanding translational investigators or translational science.

Chapter 6



The Panel's report on barriers impeding the translation process emphasized that unless new cancer treatment, prevention, and health services interventions and technologies are effectively disseminated to health care providers and the public – and become part of the care available to all Americans – the national investment in cancer-related research will be squandered, and the national cancer burden undiminished. Yet much remains to be learned about the most effective ways to reach diverse audiences, motivate lasting behavior changes, and improve cancer care provided by individual practitioners and the health care system as a whole. Community participation in research, intervention design, communication strategies, program implementation, and evaluation increasingly is recognized as an indispensable key to successfully moving discoveries into practice.

In October 2005, the Panel convened Federal, state, voluntary, and private sector stakeholders and representatives from the public health, community-based and health services research, patient advocacy, social work, training, health care financing, oncology, and primary care fields to discuss how best to advance implementation of the following recommendations:

2004-2005 Translation Report Recommendations — Dissemination and Community Participation

1. A lead agency for cancer-related dissemination activities should be designated and provided with the budget and authority to carry out this crucial function. (Report Recommendation 14)
2. The National Cancer Institute should significantly increase funding for research and implementation activities to improve dissemination and adoption of cancer research advances. As part of this effort, Comprehensive Cancer Centers should be required and funded to take an active role in disseminating new cancer-related interventions into their communities/regions and facilitating their adoption by community cancer care providers, including non-physician personnel. (Report Recommendation 15)
3. Clinical and prevention research funders should require community participation early in protocol design and in research implementation. (Report Recommendation 17)
4. Existing community-based participatory research models should be evaluated to determine the potential for adopting them in other geographic areas and populations. (Report Recommendation 20)

Meeting participants considered whether the dissemination process would benefit from a “whole systems management”⁷⁸ approach that includes both top-down and bottom-up strategies. A key to this approach is the development of relationships between key stakeholders that transcend any one project. In this respect, the single project, short-term perspective that prevails in much of scientific activity has been a barrier to more effective translation and dissemination. Established relationships improve system capacity to respond quickly when there is a need, for example, to disseminate new information about a drug or address a new issue in community practice or a specific patient population. However, meeting participants highlighted an important gap in the translation continuum: a lack of funding to implement dissemination strategies or interventions that research has shown to be effective. Federal research support can be used to develop community-based interventions but usually is not available to move proven interventions into the community because dissemination is not considered a research activity. Some dissemination activities, primarily education and awareness efforts, are funded by the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA), which funds several types of community-based health centers.

...we need to make sure that the vast majority of people who graduate from medical school [but] are never going to do clinical research personally understand its value and its import, or they won't be referring patients, because they will be the intake valve for patients for all sorts of clinical studies.

– Medical school association executive

Community-based participatory research (CBPR) is a proven tool for involving communities in research activities, but has had relatively limited application to date in cancer-related research. Discussants maintained that CBPR will not flourish as a dissemination tool for cancer knowledge and interventions until investigators can earn tenure by conducting this type of research. For this goal to be reached, dissemination research must be acknowledged as valid scientific work. Currently, most of the people conducting community-based dissemination research are adjunct professors or affiliated with community-based organizations or state health departments. Their research protocols are less likely to be used as models by others and their contributions to studies conducted by tenured faculty often go unrecognized. It was further noted that information dissemination is essential in bringing together researchers from different fields and engaging community providers in research activities. Therefore, dissemination should be included in discussions of how to encourage team science.

Meeting participants emphasized that education is an underlying challenge to effective dissemination and community participation. For example, to improve clinical trials participation, both providers and the public need to be educated about the value and accomplishments of clinical research. Patients are more likely to be open to participating in clinical research if they understand its value and potential personal benefit before they are coping with the stress of a new cancer diagnosis. Basic fears, myths, and misconceptions

This [dissemination] is not going to happen until you can get tenure by doing community-based participatory research.

– Public health association executive

about clinical trials remain entrenched even among well-educated individuals. Chapter 1 of this report describes patient, provider, and medical student education needs specific to implementing treatment summaries and follow-up care plans for cancer survivors. This chapter addresses a broader range of ideas for strengthening translation-oriented dissemination research, dissemination activities, and communities' involvement in them.

Progress Toward Implementation

Meeting participants described: (1) cancer-related dissemination activities of their organizations, (2) progress related to increasing emphasis on and support for dissemination research and activities, and (3) progress in strengthening community involvement in research.

Identified Dissemination Activities

- The National Cancer Institute (NCI) has updated its *Facing Forward* series of publications, and in collaboration with the American Cancer Society (ACS), disseminated them nationally to ACS offices. It does not appear, however, that the documents are being provided or made part of patient discharge discussions.
- In 2005, the Association of Oncology Social Work and National Association of Social Workers (NASW) launched a free online course, *Cancer 101*, for all social workers to acclimate them to psychosocial issues common in cancer and enable them to better help survivors directly and provide referrals to available resources. Social workers in schools who encounter the children of parents diagnosed with cancer and those in employee assistance programs who deal with long-term survivors in the workplace were audiences of special interest. The program also is intended for a range of community practitioners, including physicians and nurses. In the first six months that it was available online, 15,000 social workers completed the course. NASW has developed a version of the course for patients, and also conducts face-to-face training at its 56 annual conferences conducted in conjunction with state chapter meetings.
- The Wellness Community, a community-based nonprofit organization that provides free support services to cancer patients in 22 centers throughout the United States, has developed a comprehensive patient education program called *Frankly Speaking About New Discoveries in Cancer* and has distributed approximately 20,000 copies of the program information kit. The program addresses both medical and psychosocial aspects of the cancer experience. The organization also provides a professionally facilitated, Web-based support group. All of its programs are based on peer-reviewed published research. The Wellness Community has begun to offer its programs in a number of NCI-designated Comprehensive Cancer Centers, other cancer centers, and hospitals, which have been receptive to its evidence-based interventions. In addition, the Wellness Community has contracted with other groups to replicate its models in areas such as Parkinson's disease and substance abuse.
- The National Comprehensive Cancer Network, an alliance of 19 major academic cancer centers in the United States, has developed a complete library of clinical practice guidelines addressing total diagnostic work-up and management (including supportive care, prevention, detection, and screening) that in the aggregate apply to about 98 percent of all cancer patients. The guidelines are meant for use by providers, patients, caregivers, and insurers. In addition to being freely available on the Internet,⁷⁹ the guidelines are provided in a variety of other formats for diverse audiences. Since the guidelines were posted online in 2002, visits to the guidelines site have increased from 306,000 to more than five million visits per year. Updated at least annually, the guidelines are an important tool for informing various health care constituencies and the public about quality cancer care.



- The American Public Health Association maintains a searchable disparities database that includes information on a number of cancer prevention and cancer care programs.
- The Asian American Network for Cancer Awareness, Research, and Training, part of the NCI-funded Community Network Program, and ACS have launched the Asian and Pacific Islander Cancer Education Materials Web tool, a searchable online database of Asian-language cancer materials designed to help health care providers locate appropriate cancer education materials for Asian patients with limited English proficiency. Materials are available in 11 Asian and Pacific Islander languages.⁸⁰
- The Lance Armstrong Foundation (LAF) is establishing a national network of survivorship centers located in NCI-designated Comprehensive Cancer Centers. Each center will partner with at least three community-based organizations to create a new paradigm of survivorship care and information dissemination (see also p. 11). LAF also is a founding partner in the Education Network to Advance Cancer Clinical Trials, which is promoting community awareness of the benefits of clinical research.
- ACS collaborates with other professional organizations to update screening guidelines and disseminate the information through its Web site and local programs. In addition, ACS operates a National Cancer Information Center that has a clinical trials matching service available to patients and physicians.
- NCI conducts the Health Information National Trends Survey (HINTS)⁸¹ that monitors the public's perceptions and beliefs about cancer and how they seek cancer information. The survey data are disseminated in a publicly available database that helps inform health communication interventions. The survey was conducted most recently in December 2005.

...we need to be thinking about dissemination to community practitioners – be they physicians, nurses, community social workers – who are then able to help the people that they see in their own settings to be acclimated and referred to the right resources or be better equipped to actually provide the service themselves.

– *Oncology social work association executive*

- The U.S. Preventive Services Task Force, administered by the Agency for Healthcare Research and Quality (AHRQ), is an independent panel of experts in primary care and prevention that systematically reviews evidence and develops recommendations for clinical preventive services. It publishes an annual *Guide to Clinical Preventive Services*.⁸² The *Guide* is widely distributed and accepted as the standard of care for cancer screening. A complementary independent group appointed by the Director of the Centers for Disease Control and Prevention (CDC), the U.S. Task Force on Community Preventive Services, produces the *Guide to Community Preventive Services (Community Guide)*,⁸³ which includes recommendations on population-based interventions to promote health and prevent disease, injury, disability, and premature death.

Progress Related to Increased Emphasis on and Support for Dissemination Research and Implementation

- In the past two years, the number of collaborations related to dissemination and diffusion (i.e., adoption of interventions or new knowledge) has increased dramatically. As governmental and non-governmental organizations have struggled to cope with shrinking or flattening budgets, the need to leverage limited funding through partnerships has become an imperative. In numerous instances, NCI, CDC, AHRQ, ACS, the Legacy Foundation, C-Change, and other organizations have set aside traditional barriers to collaboration to blend resources, ideas, and energy to accomplish common goals. The content to be disseminated and the characteristics of target audiences has determined the combinations of partners needed to implement specific dissemination activities.

I really see two priorities for the future...[first,] we all need to commit to continuing to educate the public and our constituents about research in general, clinical trials, cancer, and healthy lifestyles. Secondly, I think – again from the private funders’ perspective – we need to build in some incentives for researchers to discuss dissemination in their research plans.

– Advocacy foundation executive

- The NCI Cancer Center Guidelines,⁸⁴ revised in 2004, now permit comprehensive cancer centers to establish dissemination research programs as part of their infrastructure; however, as of October 2005, only one program had been established (University of North Carolina Lineberger Comprehensive Cancer Center). Dissemination activities remain unfunded at the cancer centers.
- Exploratory discussions have begun at NCI on the possibility of creating a community-based cancer centers program designed to disseminate knowledge where it is needed most. The new program would bring molecularly targeted therapies and other advances to cancer patients treated in community settings, who comprise more than 80 percent of all people with cancer. Ideally, these centers would bring private practice physicians together in multidisciplinary groups and facilitate collaboration with community hospitals.
- NCI also is considering additional ways to integrate dissemination into the existing cancer centers infrastructure. Ideas include creating partnerships with additional community organizations and cancer centers not yet NCI-designated, and using P60 grants to pay for dissemination activities.

- NCI's Special Populations Networks (SPN) were reconstituted in 2005 as the Community Networks Program. Approximately 25 grantees are building on the SPNs' experiences to continue and expand CBPR programs tailored to the needs of minority and other underserved populations in their communities. The grants are five years in duration.
- In October 2005, the National Institutes of Health (NIH) re-issued a Program Announcement on dissemination and diffusion research.⁸⁵ A special study section will be created to review grant proposals received in response to the announcement.
- ACS provides limited funding to communities to implement dissemination activities shown to be effective through dissemination research.

Progress in Strengthening Community Participation in Research

- The Cancer Center of the Carolinas, a Community Clinical Oncology Program (CCOP)-participating private oncology practice, has partnered with the Greenville Hospital Association and Clemson University to develop and launch clinical trials in the community oncology setting (see also p. 49).
- NCI- and AHRQ-supported Practice-based Research Networks (PBRNs) have provided an infrastructure for involving the community in research design and implementation for about 20 years. Approximately 100 PBRNs exist across the country; a few have emphasized cancer prevention and control. Only recently, however, have NCI and other agencies begun to include them in Requests for Applications. In addition, CDC and NCI jointly fund Prevention-based Research Networks that focus on dissemination research specific to cancer prevention.
- The June 2005 NCI Clinical Trials Working Group report recommended more active involvement of the community in protocol development and review.



Suggested Priorities for the Next Two Years

Priorities for Advancing Dissemination Research and Activities

Meeting participants concurred that designating a single lead agency to oversee all dissemination research and activities would be more likely to create a cumbersome bureaucracy than solve the problem of how to inform organizations of each others' activities and provide a mechanism for accountability as to the effectiveness and efficiency of diverse activities. While the need for coordination was acknowledged, participants favored partnerships, collaborations, and resources tailored specifically to the material to be disseminated and its audience(s). Targeted efforts such as these appear to be increasing in frequency. The need to clearly define roles at the outset of such collaborations was underscored.

Participants identified the following priorities for advancing dissemination research or activities:

- **Strengthen the evidence base for dissemination science.** Ideally, dissemination is a two-way process that includes both translating research into practice and sharing knowledge gained through practice to further inform research. A recent AHRQ review⁸⁶ conducted for NCI on the state of dissemination science showed that knowledge about effective dissemination methods remains extremely limited. Dissemination research must be expanded to keep up with the rapid growth of scientific knowledge. Identifying effective interventions will help direct scarce resources.

Potential Partnerships, Collaborations, and Support

- A partnership between AHRQ, NCI, CDC, and ACS could be established to provide funding for research projects and interdisciplinary scholarship that includes both academic specialists and business experts in areas such as social marketing.
- NCI, CDC, AHRQ, the Centers for Medicare and Medicaid Services (CMS), and HRSA should collaborate to address dissemination needs related to one or two key issues. Over a two-year period, the agencies should develop, implement, and evaluate (based on pre-defined outcome measures) practical intervention models on the selected issues (e.g., colonoscopy), followed by a conference to disseminate findings. Interventions shown to be effective would inform resource allocations.
- The NIH Roadmap for Medical Research initiative, with its trans-NIH approach, offers a model for the kind of integrated infrastructure needed to support dissemination research.
- Private funders could provide incentives in the form of grants for institutions to include dissemination in their research plans.
- New CMS coverage policies that provide reimbursement for specific procedures in order to collect data needed to evaluate effectiveness offer a mechanism for controlled and perhaps accelerated diffusion of new treatments and technologies.

- **Explore options for registering and monitoring dissemination research and activities to avoid redundancy, assess their effectiveness, and report on the state of dissemination science.**

Potential Partnerships, Collaborations, and Support

- Cancer Control PLANET,⁸⁷ a collaborative dissemination effort involving NCI, CDC, AHRQ, ACS, HRSA, and the Substance Abuse and Mental Health Services Administration, could be expanded to serve as a national database for cancer-related dissemination research and activities. Like PLANET, the Cancer Prevention Network focuses on evidence-based interventions and offers another potential model for cataloguing dissemination efforts and research.

The review that was done by AHRQ for the [National] Cancer Institute showed just how little we really know about effective dissemination methods....if we're going to be effective at dissemination, we need to stop using just *ad hoc* intuitive approaches and really make this an area of scientific focus.

– Dissemination research program director

- NCI and/or CDC could take the lead in assembling a working group or other body that would be tasked with monitoring, coordinating, and identifying dissemination research and implementation gaps. This could take the form of an annual review and report similar to AHRQ annual reports on quality of care and health disparities.^{88,89} Funding, probably in the form of grants, would be required to support this activity. Federal and state agencies, nonprofit organizations, and academic and other institutions involved in dissemination research and activities could jointly support this effort.
- Incentives for organizations to contribute to the database and participate in monitoring could take several forms, e.g., modest funding to support bringing groups together to facilitate collaboration, access to information about potential collaborators, positive publicity resulting from having the organization's research and information dissemination activities described in an annual report or in some other manner.
- **Identify new ways to bridge the gap between successful dissemination intervention research and the actual implementation of information dissemination strategies, and prevention, cancer control, therapeutic, and supportive interventions in the community.**

Potential Partnerships, Collaborations, and Support

- Cancer centers need both institutional commitment and funding to support staff dedicated to implementing interventions in the community. A possible funding option is core grant funding such as is now available for dissemination research. Although dissemination research activities and dissemination service activities of cancer centers should be integrated in practice, funding and review procedures often require that they be kept separate. Review criteria should take into consideration that dissemination services provide an infrastructure for dissemination research activities.

- Many community oncologists are interested in becoming involved in disseminating new knowledge and clinical advances, but may require some funding support. Solutions to this problem are likely to vary by region, and may require innovative mechanisms to support new efforts. Private funders such as LAF can play a role in providing incentives for dissemination through grants and other mechanisms.
- Public and private health care payors should be included in discussions of research dissemination; coverage policies often are the critical barrier between dissemination and adoption.
- Others who could contribute to discussions of dissemination issues include non-cancer related community-based organizations, employers, and policymakers, particularly those who have been resistant to applying evidence on effective cancer prevention, control, and treatment strategies (e.g., tobacco excise tax increases).

I don't think we fully appreciate how constrained the categorical nature of our funding and of our thinking is. It causes fragmentation. What we need now is integration....[we need] the infrastructure and incentives for relationships, and then focusing on cancer but doing that within a larger context about health...

– Primary care researcher

Priorities for Improving Community Participation

- **Improve community participation in research through focused public education about cancer and cancer research.**

Potential Partnerships, Collaborations, and Support

- Genetic and lifestyle factors often put people at risk for more than one disease condition. From a communications perspective, therefore, most individuals are part of more than one health information target audience. ACS, the American Diabetes Association, and the American Heart Association previously collaborated with the Ad Council on a three-year public health campaign called “Protect Yourself”⁹⁰ that encourages people to modify risk-elevating behaviors. These and other health organizations should collaborate similarly to jointly sponsor activities targeting risk factors (e.g., tobacco, obesity, physical activity) common both to cancer and other diseases. Cancer prevention and control messages should be embedded in broader chronic disease prevention and control approaches. Consistent information about dietary guidelines and other health-promoting behaviors would help reduce public confusion about how to protect and improve health.
- The print, broadcast, and Web-based media should be involved in discussions of how to: (1) educate the public and providers about the value and process of clinical research to help dispel persistent fears and myths about research and (2) best incorporate all of the sources (e.g., pharmacists, cancer survivors, patient support telephone help lines) that people seek out for health information. Care must be taken to devise communications for those on both sides of the “digital divide” (i.e., those with and without Internet access). Social marketing principles and data from HINTS should help inform these discussions.

- Researchers have an obligation to provide clear and accurate information about new discoveries to the media to avoid unrealistic expectations and confusion. Sensationalized reports defeat efforts to build public trust in research and the health care system and cause the public to doubt the reliability of all health information.
- Patient advocacy groups and survivors have no motives for profit or other personal gain and therefore have a level of credibility with the public that does not exist in the health care system or in academic research. They could be involved more fully to carry cancer education and other health messages to the public.
- **Identify effective community-based participatory research (CBPR) models and other strategies for involving the community in collaborative research and dissemination efforts.**

Potential Partnerships, Collaborations, and Support

- Case studies or other descriptions of effective CBPR models from both the funders' and grantees' perspective would help funders construct new approaches to supporting this research. The CDC/NCI-funded Cancer Prevention and Control Research Networks⁹¹ underway in eight different settings nationwide offer one such model. Much of the cancer-related CBPR to date has originated at a cancer center with outreach to the community. By contrast, a project in Savannah, Georgia is developing with a starting point in the community. Private practitioners and a local hospital are establishing a collaboration to conduct rural cancer prevention programs in partnership with local churches; it is anticipated that the programs also will be linked to a comprehensive cancer center. Collaborative funding arrangements of successful models should be studied.

...it's really important not to see the community as only physicians or only hospitals, although they are a critical part of the community. But particularly for reaching underserved populations, we know that churches, community organizations – there's a whole range of organizations that need to be a part of the mix – and if we only focus on one part of them then we're going to lose our opportunity to have impact.

– Dissemination researcher

- Cancer centers could work toward developing PBRNs of community oncologists and others who provide care to people with cancer. Rather than just being asked to help recruit patients to clinical trials, these providers would become functioning extensions of the cancer center who also may participate in research. Experience in developing primary care-oriented PBRNs has shown that they can be established with a small budget and have generated a culture of evidence-based quality improvement among participating providers.
- Comprehensive cancer centers have a role to play in promoting community participation but may not necessarily be the central component of efforts to disseminate information and state-of-the-art care into the community. Community health providers, local ACS and CDC cancer prevention and control programs, schools of public health, local policymakers, community-based organizations, advocates, churches, school systems, and worksites are examples of other important players in dissemination that together can reach and involve the whole community.

- If communities (e.g., advocacy groups, patients/survivors and their families, community providers and organizations, social workers) were involved at the concept design and review stage of research rather than later during protocol design and review, their perspectives could help investigators avoid barriers to success and streamline the research process. Their contributions also would be of value even earlier, when questions to be researched are developed.
- Academic investigators may assume that practicing clinicians understand research design and the research process to a greater extent than often is the case. Community physicians may be concerned that they will lose patients, or that their patients may receive placebos; such concerns must be addressed to engage these providers more fully in research. Established CBPR-based networks could be queried to identify successful models for overcoming these concerns.

Commitments Made — Dissemination and Community Participation

Organizational representatives at the meeting made the following commitments to advance dissemination research and activities and enhance community participation:

Research Support

- The National Cancer Institute (NCI) will continue to conduct the Health Information National Trends Survey that monitors the public's perceptions and beliefs about cancer and how they seek cancer information. The survey data are an important tool in the development of dissemination and diffusion interventions.
- The American Cancer Society (ACS) will expand the scope of its funding to new investigators, currently targeting clinical, policy, and behavioral research, to include dissemination research and related policy research.
- NCI plans to expand support for health services research that supports research translation, and in collaboration with the Centers for Disease Control and Prevention, the Lance Armstrong Foundation (LAF), ACS, the Intercultural Cancer Council, and other organizations, will continue its support of the Comprehensive Cancer Control Leadership Institutes⁹² that promote state-level cancer control programs.
- The Association of Schools of Public Health will be asked to address translational research, dissemination, and community involvement both specific to cancer and as they relate more broadly to health.
- At its next national meeting, the American Association of Healthcare Consultants will discuss the issues associated with the Panel's recommendations and consider how the Association can help the Panel in the future.

- The Agency for Healthcare Research and Quality (AHRQ) will continue to seek partnerships with other agencies and organizations to promote research translation. AHRQ will share its extensive expertise in synthesizing evidence provided by research partners into readable reports that can be used to translate knowledge into action, its experience in establishing community Practice-based Research Networks, and its work to date related to setting health information technology standards as a way to enhance information dissemination to clinicians and patients.
- The Association of State and Territorial Chronic Disease Program Directors will disseminate information about community participation in research to its members.
- The North American Primary Care Research Group committed to increasing its role in advocacy and disseminating knowledge on how to conduct community-based participatory research.
- The Federation of Practice-Based Research Networks will endeavor to place a higher priority on dissemination research and will work with AHRQ on merging practice-based research with community-based participatory research.
- LAF is committed to exploring new mechanisms for funding community-based participatory research through its survivorship center network and other research and community programs.
- The Association of American Cancer Institutes is committed to ensuring that cancer centers act as change agents within their universities on issues such as hiring, recognition, and tenure for investigators who participate in community-based research.
- The Dana Farber Cancer Institute is committed to dissemination research through its participation in the Cancer Prevention and Control Research Network.
- The American Public Health Association (APHA) will work with the editors of the *American Journal of Public Health* to increase publication of articles focusing on dissemination and participatory research. Further, APHA will more aggressively disseminate its literature on community-based participatory research and investigate ways to highlight these areas during its annual meetings.

Dissemination Activities/Community Participation

- The Wellness Community is committed to providing its comprehensive educational program to assist cancer and other health organizations in educating patients about new discoveries in cancer and clinical trials.
- ACS would be willing to contribute funding to convene a meeting of non-governmental organizations to discuss dissemination activities and ways to increase community participation in research. ACS also will continue to play a role in collaborative dissemination projects using its established dissemination channels.
- The National Comprehensive Cancer Network, in collaboration with other groups, is committed to translating its guidelines into measures of quality and performance, templates for public reporting of performance data, and models for pay-for-performance policies.

- NCI will continue in its role as a committed partner with the diverse organizations working to promote dissemination and community participation in cancer research. These topics are the focus of active conversation within the Cancer Centers program.
- The Community Oncology Alliance will continue its focus on maintaining access to high-quality, evidence-based, affordable, community-based cancer care.
- Patient Advocates In Research (PAIR) will continue to share information with the many advocacy organizations that are represented among its members. PAIR is always seeking opportunities to provide education and training assistance; the Specialized Programs of Research Excellence and Cooperative Groups present excellent opportunities for such collaboration.
- The Texas Department of State Health Services will continue to disseminate and implement evidence-based cancer control practices and will invest part of its program implementation funding for evaluation. Evaluation results will be shared to contribute to the dissemination research and intervention evidence base.
- The CEO Roundtable on Cancer will disseminate information about the return on investment that results from implementing evidence-based screening and early detection services to increase the number of companies that adopt these benefits into their employee health insurance programs.
- LAF will continue to improve methods for educating its constituents about research, clinical trials, and cancer survivorship.
- APHA will be seeking partners for a grassroots initiative to ensure that all American families and communities are able to protect themselves from preventable health threats; this initiative will include emphases on wellness and cancer screening programs.
- The National Association of Social Workers is committed to educating social workers about cancer, genetics, and pain control so that they can remain effective in their practices and function optimally as partners and collaborators in research and dissemination activities.

PART IV



In 2005, the President's Cancer Panel elected to revisit key recommendations from each of its two most recent annual reports to assess progress and the pace of change in essential areas of cancer research and care. A total of 75 stakeholders from government, academia, industry, the nonprofit sector, the advocacy community, and community-based health, social service, and other provider organizations participated in dynamic roundtable discussions of the selected recommendations. These productive discussions both facilitated communication among stakeholders about recent activities and generated numerous possibilities for new approaches and partnerships to address identified problems and priorities. It is the Panel's hope that these activities and ideas, catalogued in this report, will be used by diverse cancer constituencies to establish new partnerships for action and expand ongoing activities.

At the same time, the meetings illuminated both uneven progress and in some cases, disturbingly diminished expectations for change related to specific survivorship and research translation concerns. These real and perceived limitations, almost without exception, could be traced directly to the impact of one or more longstanding, overarching issues. The paragraphs below discuss these persistent barriers to progress, followed by conclusions specific to the survivorship- and translation-related recommendations addressed at the meetings.

Overarching Issues

Four themes suffused the discussions at the Panel's meetings, regardless of the specific topic at hand. None are new; the Panel has addressed each in numerous previous reports. Yet these pervasive issues are of more pressing concern with each passing year as the American population ages, the total number of cancer cases increases as a function of age-related risk, and health care costs continue to spiral upward while insurance benefits and research dollars shrink.

Fiscal Constraints

For the first time in more than 70 years, the U.S. cancer death rate declined slightly, even though the number of new cancer cases continued to increase.⁹³ Albeit small, this success in reducing cancer mortality reflects the impact of research advances, including earlier cancer detection methods, better diagnostic tools, and better treatments. This momentum must not be lost. Current fiscal constraints affecting cancer research and cancer care derive from three detrimental trends: declining Federal research budgets, the potential for escalating mandatory contributions from the NCI budget to broad NIH initiatives, and increasingly meager insurance reimbursements by public and private health care payors. This situation cannot help but have a negative impact on the twin goals of making cancer a disease people can live with, rather than die from, and rendering cancer a largely preventable disease.

The debilitating impact of scarce funding could be traced throughout the Panel's meetings. Oncology professionals noted that reimbursement seldom is available for the considerable time and costs associated with developing and discussing the detailed treatment summaries and follow-up care guidance needed by newly discharged cancer patients. Creative ideas for improving cancer information and care services were immediately met with questions about where the necessary funding would come from.

In addition, the Panel's 2004–2005 report on research translation highlighted the escalating threat to continued progress against cancer due to fiscal realities related to the drug patent, development, approval, and marketing processes. The cost of bringing a drug to the marketplace currently exceeds \$800 million,⁹⁴ and the number of new cancer drug approvals is low.⁹⁵ Even if used to treat common cancers, the potential market for any new cancer drug is small compared with medications for hypertension, diabetes, or heart disease management. Moreover, our success in identifying subgroups of common cancers that require different treatments actually is further shrinking the markets for individual anticancer drugs and industry's interest in developing them.

Of equal concern, as older cancer drugs (e.g., cisplatin) that are the mainstay of many current treatments lose patent protection and their profitability, some pharmaceutical companies are electing to cease production of these essential agents, potentially leading to short supplies of life-saving medications. The Panel reiterates its contention that to encourage new cancer drug development and ensure adequate supplies of mainstay treatments, cancer should be designated an orphan disease,⁹⁶ thereby enabling drug developers and manufacturers to obtain support to offset specific elements of cost and extend patent protection for approved agents.

The myriad ramifications of scarce funding for critical cancer research and cancer care activities are cause for urgent concern. Even if these problems are addressed, all stakeholders involved in cancer research and cancer care must seek out and seize every opportunity to work collaboratively and efficiently to make the most of available resources.

Health Care Coverage

People who have had cancer need lifelong care to monitor for and treat late effects of cancer therapies, recurrences, and second cancers, and to address psychosocial, nutritional, rehabilitation, and other needs that may arise years after treatment ends. More than 10 million people in this country are living with a history of cancer; in 2006, nearly 1.4 million new cancer cases will be diagnosed.⁹⁷ According to the most recent available estimate, 45.8 million people in the United States lack health insurance of any kind,⁹⁸ and many millions more are underinsured for the costs of initial and ongoing cancer care. Employer-sponsored employee and retiree health benefits are declining in terms of the numbers of people covered, the scope of benefits, and increased premium, deductible, and copayment cost-shifting onto insureds.⁹⁹ Medicaid budget cuts scheduled over the next five years are very likely to put targeted, individualized cancer care – or even standard care – further out of the reach of the nation's poor and widen disparities in cancer care and outcomes already experienced by poor and underserved individuals. In addition, the existing health care system continues to focus on acute care rather than disease prevention and the benefit to national productivity that accrues from maintaining individual wellness.

The Panel has strongly recommended a renewed effort to craft national comprehensive health care reforms, and reiterates this recommendation here. In the Panel's view, incremental remedies, including those currently proposed (e.g., Health Savings Accounts/high-deductible consumer-directed health plans), are not and will not be adequate to address fundamental health system problems and may even have the effect of reducing coverage by increasing out-of-pocket costs, particularly for those least able to afford them.

Education and Communication

Education and communication needs permeate nearly every cancer research and care issue. Though critical for success across the research and care continuum, education and communication activities often get short shrift and small budgets.

The need to improve public understanding about cancer and the importance of cancer research is virtually undisputed. For example, cancer myths and misconceptions (e.g., that exposing cancer to air can cause it to spread, that research participants are “guinea pigs”) continue to flourish. Nearly half of U.S. adults who participated in a recent national survey believe they have little or no control in reducing their risk of cancer.¹⁰⁰ To counter discrimination still experienced by some cancer survivors, employers, lenders, and insurers (including health, life, and disability coverage providers) must be informed of the longevity and renewed productivity most survivors can now expect due to research advances. People diagnosed with cancer and their caregivers need immediate access to accurate information about treatment options and available resources. Likewise, survivors need reliable, up-to-date information sources to stay abreast of research and care advances relevant to their individual situations.

For the public to benefit from research advances, new knowledge, technologies, and resources must be disseminated rapidly to the provider community, with follow-up information and communication to encourage new intervention adoption. In addition, health and ancillary care providers of all types need ongoing education about cancer as a disease, and about the importance of early detection, the value of clinical trials, and survivorship issues. This information is critical if providers are to make appropriate

treatment recommendations and referrals (including to clinical trials); explain treatment options, informed consent, and other issues to patients; and coordinate patient care effectively.

Information and communication needs in the research community also are diverse. For example, researchers involved in drug or medical device development must understand regulatory requirements and communicate effectively with regulators, funders, and insurers. Effective communication with patients and family members about specific clinical trials and informed consent for treatment or research use of tissue or other biologic samples is crucial. In addition, researchers from different disciplines and institutions must be able to communicate and share data as needed to best design and carry out research projects.

The unanticipated consequences of privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) remain a significant continuing impediment to data sharing, cancer care provision, research, and other communications. Electronic health records development and use, health provider-patient/caregiver communication, restrictions on researchers' ability to use stored tissue samples or to contact survivors to inform them about new findings or treatments – all are affected adversely by HIPAA. The Panel has called for an evaluation of HIPAA-related barriers to guide whatever legislative or regulatory changes may be needed to alleviate them, and urges that this evaluation be undertaken and completed with all possible speed.

Coordination

The Panel has commented frequently on the need for coordination of National Cancer Program activities. The need for coordination emerged again strongly at the Panel's meetings, however, the form such coordination should take was repeatedly at issue. Many meeting participants maintained that any centralized coordinating function would create an additional layer of bureaucracy comprised principally of individuals whose scope of knowledge could not possibly encompass all of the relevant research- and care-related issues. Targeted, subject-specific partnerships and collaborations were viewed as the preferable approach.

It continues to be the Panel's observation, however, that this piecemeal approach often produces uneven results, and further, that collaborative efforts often are preceded by redundant and/or incompatible activities that can waste limited resources and create proprietary stances that later may be difficult to relax. In the Panel's view, the diverse stakeholders within the cancer community have the responsibility, if they do not want centralized coordination, to find more effective and efficient ways to communicate about ongoing and planned activities, and to work together earlier and more cohesively to address issues across the cancer research and cancer care enterprises.

Progress on Survivorship Issues

Among the recommendations contained in *Living Beyond Cancer: Finding a New Balance*, the Panel was particularly interested in assessing progress toward providing treatment summaries and follow-up care plans to all cancer survivors, expanding the body of research on adolescents and young adults with cancer, and improving access to care and insurance coverage for health care services needed by survivors.

The most robust progress was apparent in partnerships and programmatic initiatives to increase public and health provider awareness of survivorship issues and to empower cancer patients/survivors with available knowledge about possible late effects of cancer treatment, sources of information and support, and tools to help maintain their personal health records and protect their health. Efforts to date to develop a standard treatment summary template have been substantial, but collaboration is needed among those who thus far have worked on this issue.

Lack of a solid knowledge base to support follow-up care guideline development for the many types of cancer and individual patients' circumstances remains a barrier to progress in this area. However, while this evidence base is being strengthened, follow-up care plans must nonetheless be provided, based on best practices and the best available expert opinion.

Research on adolescents and young adults diagnosed with cancer continues to lag far behind the study of other age groups. Given that cancer survival rates for this population have not improved appreciably for more than two decades, this dearth of knowledge is particularly alarming. The Panel is optimistic that forthcoming recommendations from the recent review of research in this population will help stimulate and focus the national research agenda on cancer in this age group.

Survivors of all ages continue to suffer from limited access to medical, psychosocial, and supportive care they need following cancer treatment, including in some cases, prosthetic and fertility-related services. For many survivors, needed services are not available where they live and they cannot travel to reach them. For even more survivors, available services remain out of reach due to lack of insurance coverage for needed care and/or inability to pay for care out-of-pocket.

Progress Related to Research Translation

Among the recommendations in *Translating Research into Cancer Care: Delivering on the Promise*, the Panel revisited core issues related to team science and the current culture of research, building and retaining the translational and clinical research workforce, and the dissemination of research advances and new interventions.

The Panel expected to find little progress toward implementing its research translation-related recommendations since only a short period of time had elapsed since the report's publication. However, meeting participants reported several new initiatives and partnerships that can be expected over time to influence the culture of research to more fully embrace and value team science and other collaborative cancer research. These include revising grant award criteria to place a higher priority on team efforts, establishing team science recognition awards, and exploring ways to improve attribution for individual contributions to team projects. Steps such as these should raise the visibility and perceived value of collaborative translational and clinical research at individual institutions and dissipate current hiring, promotion, and tenure barriers that now discourage participation in these types of research.

The promise of basic science discoveries in cancer will never be realized if we lack the cadre of translational and clinical researchers whose work turns these discoveries into better care for people with cancer. It is equally crucial to recruit young scientists to careers in translational and clinical research and to retain them in science once they have

completed training by ensuring that a viable career path exists. These investigators need greater support and protected time across their career trajectory, particularly to relieve the increasing pressure on them to generate patient care revenue. Recruiting and retaining individuals from minority and underrepresented groups, including women, may require special initiatives.

The Panel was encouraged by new commitments by the National Institutes of Health to strengthen support for young investigators despite declining budgets. Similarly, other research institutions, professional societies, and foundations are providing a range of career development and new investigator awards; more are needed. Some institutions are developing innovative M.D.-Ph.D. programs, and the number of physician-scientists appears to be stabilizing after a period of significant decline. Meeting participants emphasized, however, that the scientific community must reach back to the undergraduate population to nurture early interest in a research career. Further, it was recognized that crucial academic decisions affecting later career choices are made as early as the middle school years.

Dissemination research is a nascent science, but its utility for reaching public and health provider audiences with new cancer knowledge and interventions appears to be gaining recognition. For example, the National Cancer Institute's Comprehensive Cancer Centers may now apply for support of a dissemination research program as a supplement to the center's core grant; one such program has been funded. Dissemination activities, however, remain almost entirely unfunded at the cancer centers and in large measure continue to be conducted in a fragmented fashion by foundations and underfunded Federal, state, and community-based agencies. Information and advocacy organizations focused on chronic diseases with similar risk factors (e.g., cancer, heart disease, diabetes) should join forces to meld similar disease prevention, management, and wellness messages into a broader approach that crosses disease boundaries. Such an approach could leverage resources and expertise and reduce public confusion about health-related information. At a higher level, however, the continuing lack of leadership and support for both dissemination research and dissemination activities must be addressed.

Summary

The Panel believes progress has been made toward resolving some of the issues described in its recent reports, but a great deal remains to be accomplished. Many of these findings apply not only to cancer research and cancer care, but to biomedical research in general and the entire health care system. Therefore, to maintain progress and advance the pace of change in the current challenging health care and economic environments, all of us who strive to improve the lives of people with cancer, their families, and others at risk for cancer must bring to bear the maximum measure of our creativity, skills, resources, and dedication for their benefit.

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President's Cancer Panel Meetings

2005

Washington, DC

Participants

MEETING DATE: AUGUST 25, 2005

Name	Affiliation
Lance Armstrong	President's Cancer Panel Lance Armstrong Foundation
Jules Berman, M.D., Ph.D.	National Cancer Institute
Mark Clanton, M.D., M.P.H.	National Cancer Institute
Kenneth Cowan, M.D., Ph.D., F.A.C.O.G., F.A.C.P.M.	National Cancer Advisory Board
Robert Croyle, Ph.D.	National Cancer Institute
Georgia Decker, M.S., R.N., C.S.-A.N.P., A.O.C.N.	Oncology Nursing Society
Roger Herdman, M.D.	Institute of Medicine
David Johnson, M.D., F.A.C.P.	American Society of Clinical Oncology
Margaret Kripke, Ph.D.	President's Cancer Panel The University of Texas M. D. Anderson Cancer Center
Joel Kupersmith, M.D.	Department of Veterans Affairs
LaSalle D. Leffall, Jr., M.D., F.A.C.S.	President's Cancer Panel, Chair Howard University College of Medicine
David Poplack, M.D.	Texas Children's Hospital
Abby Sandler, Ph.D.	President's Cancer Panel, Executive Secretary National Cancer Institute
John Seffrin, Ph.D.	American Cancer Society
Mitch Stoller	Lance Armstrong Foundation
Ellen Stovall	National Coalition for Cancer Survivorship
Doug Ulman	Director's Consumer Liaison Group
Burt VanderLaan, M.D.	America's Health Insurance Plans
Maureen Williams, B.A.	Health Resources and Services Administration
Rodger Winn, M.D.	National Quality Forum Cancer Project

MEETING DATE: AUGUST 26, 2005

Name	Affiliation
Karen Albritton, M.D.	Dana Farber Cancer Institute
Lance Armstrong	President's Cancer Panel Lance Armstrong Foundation
Alan Balch, Ph.D.	Friends of Cancer Research
Lindsay Nohr Beck	Fertile Hope
Archie Bleyer, M.D.	St. Charles Medical Center
Robert Comis, M.D.	Coalition of Cancer Cooperative Groups
Brenda Edwards, Ph.D.	National Cancer Institute
Ronit Elk, Ph.D.	American Cancer Society
Brandon Hayes-Lattin, M.D.	Oregon Health & Science University
Sandra Horning, M.D., F.A.C.P.	American Society of Clinical Oncology
Eugenie Kleinerman, M.D., B.A.	The University of Texas M. D. Anderson Cancer Center
Margaret Kripke, Ph.D.	President's Cancer Panel The University of Texas M. D. Anderson Cancer Center
LaSalle D. Leffall, Jr., M.D., F.A.C.S.	President's Cancer Panel, Chair Howard University College of Medicine
Gail McGrath	Patient Advocate Foundation
Anna Meadows, M.D.	Children's Hospital of Philadelphia
Andy Miller, M.H.S.E., C.H.E.S.	Lance Armstrong Foundation
Kevin Oeffinger, M.D.	Memorial Sloan-Kettering Cancer Center
Kutluk Oktay, M.D.	Cornell University
Eddie Reed, M.D.	Centers for Disease Control and Prevention
Julia Rowland, Ph.D.	National Cancer Institute
Abby Sandler, Ph.D.	President's Cancer Panel, Executive Secretary National Cancer Institute
Scott Saxman, M.D., F.A.C.P.	National Cancer Institute
Doug Ulman	Director's Consumer Liaison Group
Katherine Walsh-Burke, M.S.W., Ph.D.	Association of Oncology Social Work
Susan Weiner, Ph.D.	The Children's Cause for Cancer Advocacy
Brock Yetso	Ulman Cancer Fund for Young Adults

MEETING DATE: OCTOBER 24, 2005

Name	Affiliation
Olaf Andersen, M.D.	National Association of M.D.-Ph.D. Programs
Georgia Decker, M.S., R.N., C.S.-A.N.P., A.O.C.N.	Oncology Nursing Society
James Doroshow, M.D.	National Cancer Institute
Emil Freireich, M.D.	Association for Patient Oriented Research
William Galey, Ph.D.	Howard Hughes Medical Institute
John Gallin, M.D.	National Institutes of Health
William Hait, M.D., Ph.D.	The Cancer Institute of New Jersey
Martha Hare, Ph.D., R.N.	National Institute of Nursing Research
Janet Harris, A.N., R.N., Ph.D.	Department of Defense
Ernest Hawk, M.D., M.P.H.	National Cancer Institute
Sandra Horning, M.D., F.A.C.P.	American Society of Clinical Oncology
Mien-Chie Hung, Ph.D.	The University of Texas M. D. Anderson Cancer Center
Barnett Kramer, M.D., M.P.H.	Journal of the National Cancer Institute
Margaret Kripke, Ph.D.	President's Cancer Panel The University of Texas M. D. Anderson Cancer Center
Joel Kupersmith, M.D.	Department of Veterans Affairs
Thomas Lawley, M.D.	Association of American Medical Colleges
Theodore Lawrence, M.D., Ph.D.	American Society for Therapeutic Radiology and Oncology
LaSalle D. Leffall, Jr., M.D., F.A.C.S.	President's Cancer Panel, Chair Howard University College of Medicine
Fred Rodriguez, Jr., M.D.	American Society for Clinical Pathology
Abby Sandler, Ph.D.	President's Cancer Panel, Executive Secretary National Cancer Institute
Antonio Scarpa, M.D., Ph.D.	National Institutes of Health
Kenneth Shine, M.D.	The University of Texas System
Joseph Stephenson, Jr., M.D.	Cancer Center of the Carolinas
Lawrence Tabak, D.D.S., Ph.D.	NIH Roadmap, Interdisciplinary Research Teams of the Future Working Group
Douglas Weed, M.D., M.P.H., Ph.D.	National Cancer Institute

MEETING DATE: OCTOBER 25, 2005

Name	Affiliation
Georges Benjamin, M.D., F.A.C.P.	American Public Health Association
Thomas Burish, Ph.D.	American Cancer Society
Elizabeth Clark, Ph.D., A.C.S.W., M.P.H.	National Association of Social Workers
Deborah Collyar	Patient Advocates In Research
Robert Croyle, Ph.D.	National Cancer Institute
H. Shelton Earp, M.D.	Association of American Cancer Institutes
Karen Emmons, Ph.D.	Dana Farber Cancer Institute
Ernest Hawk, M.D., M.P.H.	National Cancer Institute
Philip Huang, M.D., M.P.H.	Texas Department of State Health Services
Leonard Kalman, M.D.	Community Oncology Alliance
Suzanne Kho, M.S.Ed.	Lance Armstrong Foundation
Margaret Kripke, Ph.D.	President's Cancer Panel The University of Texas M. D. Anderson Cancer Center
David Lanier, M.D.	Agency for Healthcare Research and Quality
LaSalle D. Leffall, Jr., M.D., F.A.C.S.	President's Cancer Panel, Chair Howard University College of Medicine
William McGivney, Ph.D.	National Comprehensive Cancer Network
John Niederhuber, M.D.	National Cancer Institute
Edwin Parkhurst, M.B.A., F.A.A.H.C., C.H.E.	American Association of Healthcare Consultants
Barbara Rimer, Dr.P.H.	University of North Carolina School of Public Health
Abby Sandler, Ph.D.	President's Cancer Panel, Executive Secretary National Cancer Institute
Kurt Stange, M.D., Ph.D.	North American Primary Care Research Group
Kim Thiboldeaux	The Wellness Community
Andrew von Eschenbach, M.D.	National Cancer Institute

AACI	Association of American Cancer Institutes
AACR	American Association for Cancer Research
AAMC	Association of American Medical Colleges
AARP	formerly the American Association of Retired Persons
ACoS	American College of Surgeons
ACS	American Cancer Society
AHIP	America's Health Insurance Plans
AHLTA	Armed Forces Health Longitudinal Technology Application
AHRQ	Agency for Healthcare Research and Quality
AOSW	Association of Oncology Social Work
APHA	American Public Health Association
ASCO	American Society of Clinical Oncology
ASRM	American Society for Reproductive Medicine
ASTRO	American Society for Therapeutic Radiology and Oncology
AYA	Adolescent and Young Adult
CBPR	Community-based Participatory Research
CCOP	Community Clinical Oncology Program
CCSS	Childhood Cancer Survivor Study
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CHC	Community Health Center
CMS	Centers for Medicare and Medicaid Services
COG	Children's Oncology Group
CTSA	Clinical and Translational Science Award
CTWG	Clinical Trials Working Group
DoD	Department of Defense
EHR	Electronic Health Record
FDA	Food and Drug Administration
HHMI	Howard Hughes Medical Institute
HHS	Department of Health and Human Services
HINTS	Health Information National Trends Survey
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
IOM	Institute of Medicine
IRB	Institutional Review Board
IT	Information Technology
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JCO	Journal of Clinical Oncology
LAF	Lance Armstrong Foundation
MIT	Massachusetts Institute of Technology
NASW	National Association of Social Workers
NCCN	National Comprehensive Cancer Network
NCCS	National Coalition for Cancer Survivorship
NCI	National Cancer Institute

NCP	National Cancer Program
NCQA	National Committee for Quality Assurance
NIH	National Institutes of Health
NINR	National Institute of Nursing Research
NQF	National Quality Forum
OCS	Office of Cancer Survivorship
ONCHIT	Office of the National Coordinator for Health Information Technology
ONS	Oncology Nursing Society
PA	Program Announcement
PAF	Patient Advocate Foundation
PAIR	Patient Advocates In Research
PBRN	Practice-based Research Network
PCP	President's Cancer Panel
PLANET	Plan, Link, Act, Network with Evidence-based Tools
PRG	Progress Review Group
RAID	Rapid Access to Intervention Development
RFA	Request for Applications
SCHIP	State Children's Health Insurance Program
SEER	Surveillance, Epidemiology, and End Results
SPN	Special Populations Network
SPORE	Specialized Program of Research Excellence
UCF	Ulman Cancer Fund for Young Adults
VA	Department of Veterans Affairs

Appendix C Suggested Priorities for Advancing Change Selected Recommendations of the President's Cancer Panel 2003–2005

Recommendations from *Living Beyond Cancer: Finding a New Balance*

Suggested Priorities

Treatment Summaries and Follow-Up Care Plans

1. Upon discharge from cancer treatment, including treatment of recurrences, every patient should be given a record of all care received and important disease characteristics. This should include, at a minimum:
 - Diagnostic tests performed and results.
 - Tumor characteristics (site(s), stage, and grade; hormonal status; marker information).
 - Dates of treatment initiation and completion.
 - Surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, gene, or other therapies provided, including agents used, treatment regimen, total dosage, number and title(s) of clinical trial(s) (if any), indicators of treatment response, and/or toxicities experienced during treatment.
 - Psychosocial, nutritional, and other supportive services provided.
 - Full contact information for treating institutions and key individual providers. (Report Recommendation 1a)
2. Upon discharge from cancer treatment, every patient should receive a follow-up care plan considering evidence-based standards of care. This should include, at a minimum:
 - A description of recommended cancer screening and other periodic testing and examinations, as well as the schedule on which they should be performed.
 - Information on possible late and long-term effects of treatment and symptoms of such effects.
 - Information on possible signs of recurrence and second tumors.
 - Information on the possible future need for psychosocial support.
 - Specific recommendations for healthy behaviors (e.g., diet, exercise, sun and virus protection, smoking cessation).
 - Referrals to specific follow-up care providers, support groups, and/or the patient's primary care provider.
 - A listing of cancer-related resources and information (Internet-based sources and telephone listings for major cancer support organizations). (Report Recommendation 1b)

- **Gain consensus on and implement with all possible speed an initial uniform treatment summary template.**
- **Conduct research to build the evidence base for follow-up care guideline development and to determine whether treatment summaries and follow-up care plans lead to improved patient outcomes.**
- **Accelerate efforts to develop and disseminate survivorship follow-up clinical care guidelines based on the best available evidence (including best practices and expert opinion) until the evidence base is further developed through targeted outcomes and related research.**
- **Establish interoperable media and related standards for electronic health records (including standard terminology for data reporting) so that treatment summaries and follow-up care plans will be comparable and accessible regardless of the format in which they are provided (e.g., CD/DVD, paper, Internet).**
- **Address data access issues, including but not limited to those related to the privacy provisions of the Health Insurance Portability and Accountability Act of 1996.**
- **Secure provider reimbursement through the Centers for Medicare and Medicaid Services and other public and private insurers for preparing and presenting treatment summaries and follow-up care plans to patients.**
- **Develop and provide education to patients, the public, health care providers, and medical students.**

Adolescents and Young Adults

1. A working group comprised of representatives from the public agencies and private organizations with established surveillance databases should be convened to determine what additional data collection, infrastructure, and related funding would be required to better capture treatment and survival data on adolescent and young adult cancer survivors. (Report Recommendation 11a)
2. The National Cancer Institute and other cancer research sponsoring agencies should increase the priority of and funding for research on the issues of cancer survivors diagnosed as adolescents or young adults. Studies of biologic differences in cancer type and host factors, and of late effects of cancer and cancer treatment in this population should be emphasized to improve the knowledge base and inform the design of treatment, prevention, and quality of life interventions designed to benefit this population. (Report Recommendation 11b)
3. Further research should be conducted to determine what fertility preservation options are possible for children and young adolescent cancer patients. (Report Recommendation 6c)

- **Build a comprehensive database on all adolescent and young adult (AYA) cancer survivors.**
- **Improve the delivery infrastructure for and communication with AYA survivors to encourage continued contact with the health care system and make it possible to collect data on their long-term outcomes.**
- **Conduct research in the following priority areas:**
 - **Host factors and the biology and pathogenesis of tumors in the AYA age group.**
 - **Whether specific types of follow-up care and surveillance for AYAs with cancer improve outcomes, the cost-benefit of follow-up in terms of quality of life and overall survival, and the incidence of second cancers beyond age 40 among adolescents treated with radiation and chemotherapy.**
 - **Measures to identify survivors at high risk for late effects due to genetic predisposition or other factors.**
 - **Psychosocial factors and their influence on access to care and adherence to recommended care.**
- **Establish a separate National Institutes of Health study section, or modify the mix of reviewer expertise in existing study sections, to help ensure fair and informed evaluation of survivorship research proposals.**
- **Conduct research to develop improved fertility preservation options for children, adolescents, and adults of reproductive age.**
- **Develop mechanisms to ensure that children and adolescents with cancer, their caregivers, adults of reproductive age, and oncologists are aware of opportunities for fertility preservation.**

Insurance and Access

1. Adequate reimbursement for prosthetics must be provided and it must be recognized that: (i) many such items must be replaced periodically and (ii) access to prostheses is an integral part of psychosocial care for cancer. (Report Recommendation 7b)
2. Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment. (Report Recommendation 6d)
3. Coverage should be provided routinely for psychosocial services for which there is evidence of benefit both during treatment and post-treatment as needed. (Report Recommendation 7c)
4. Public and private insurers should provide reimbursement for risk assessments, surveillance, and other follow-up care for cancer survivors, including care provided by appropriately trained non-physician personnel. (Report Recommendation 7d)
5. Existing follow-up care clinic models should be evaluated and compared to ascertain their impact on survivor outcomes and their cost effectiveness. (Report Recommendation 7e)

- **Work collaboratively for the legislative, regulatory, and health care financing changes needed to make comprehensive quality care a reality for survivors.**
- **Increase the health insurance coverage rate of the young adult population to improve the likelihood that individuals diagnosed with cancer will have coverage for treatment costs and subsequently will not be subject to preexisting condition exclusions.**
- **Explore creative mechanisms for providing needed services outside of traditional insurance mechanisms.**
- **Standardize data collection to the extent possible so that data can be shared and studies of specific interventions or follow-up care programs more broadly will have greater statistical power.**

Team Science and the Culture of Research

1. The existing culture of cancer research must be influenced to place more value on translational and clinical research. To effect this culture change, a task force representing key stakeholders in academic research should be convened to examine and modify existing reward systems (e.g., compensation, promotion/tenure, space and resource allocation, prestige) to encourage collaborative research and ensure that all contributors (including but not limited to pathologists, radiologists, and research nurses) benefit from participating in these activities. (Report Recommendation 1)
2. Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research. (Report Recommendation 2)

- **Overcome academic barriers to appropriately crediting the work of co-principal and other investigators who participate in translational, clinical, and team science efforts so that they are not penalized in promotion and tenure decisions.**
- **Identify ways to increase involvement, recognition, and resources for academic and community pathologists, radiologists, nurse scientists, biostatisticians, and other professionals participating in multidisciplinary team research.**
- **Explore innovative ways to leverage existing funding to provide greater support for clinical, translational, and team science.**

Workforce Infrastructure

To attract and retain young investigators to careers in translational and clinical research:

- Protected research time and mentoring must be provided earlier and potentially for a longer duration than is now the norm. Government training funds may be needed to enable academic institutions to provide this supportive environment.
- New or expanded student loan buy-back programs should be established to enable young investigators to pursue the additional training necessary for a career in translation-oriented research.
- Academic institutions should make special efforts to recruit and retain young scientists from underrepresented population groups. (Report Recommendation 5)

- **Provide greater assistance to junior faculty in identifying potential mentors. Consider other support mechanisms that may help enable initial career advancement.**
- **Seek partnerships between Federal, voluntary health, and philanthropic organizations to help increase the number of physician-scientists.**
- **Medical schools should establish mentoring programs for M.D.-only students to ensure that they are exposed to clinical research and increase the possibility that they will pursue research in their postgraduate training and/or be receptive to participating in research in their medical practices.**
- **Develop creative mechanisms other than loan repayment programs to make careers in science financially feasible for young people.**

		• Intensify and modify recruitment activities to increase the number of physician-scientists. • Develop new or expanded training mechanisms in translational and clinical investigation and supportive fields. • Consider system changes that could help attract new talent to translational and clinical research.
Dissemination and Community Participation 1. A lead agency for cancer-related dissemination activities should be designated and provided with the budget and authority to carry out this crucial function. (Report Recommendation 14) 2. The National Cancer Institute should significantly increase funding for research and implementation activities to improve dissemination and adoption of cancer research advances. As part of this effort, Comprehensive Cancer Centers should be required and funded to take an active role in disseminating new cancer-related interventions into their communities/regions and facilitating their adoption by community cancer care providers, including non-physician personnel. (Report Recommendation 15) 3. Clinical and prevention research funders should require community participation early in protocol design and in research implementation. (Report Recommendation 17) 4. Existing community-based participatory research models should be evaluated to determine the potential for adopting them in other geographic areas and populations. (Report Recommendation 20)		• Strengthen the evidence base for dissemination science. • Explore options for registering and monitoring dissemination research and activities to avoid redundancy, assess their effectiveness, and report on the state of dissemination science. • Identify new ways to bridge the gap between successful dissemination intervention research and the actual implementation of information dissemination strategies, and prevention, cancer control, therapeutic, and supportive interventions in the community. • Improve community participation in research through focused public education about cancer and cancer research. • Identify effective community-based participatory research models and other strategies for involving the community in collaborative research and dissemination efforts.



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