Executive Summary

With passage of the National Cancer Act of 1971 (P.L. 92-218), a promise was made to the American people – to conduct the full spectrum of research and related activities necessary to prevent, control, and cure cancers. The President's Cancer Panel, established by the National Cancer Act, is charged to monitor and evaluate the National Cancer Program (NCP) and to report at least annually to the President of the United States on impediments to the fullest execution of the program.

The tragic toll of cancer – in lives and productivity lost, diminished quality of life, family distress, and health care costs – is incontrovertible. Through national investments in cancer research and the efforts of dedicated scientists, health care providers, educators, and others, progress against some forms of cancer is being achieved. But other cancers remain intractable and new cancer cases are expected to increase markedly as the population ages and greater numbers of people reach the ages at which cancer risk rises significantly.

Testimony presented to the Panel in recent years touched upon myriad diverse yet interconnected problems affecting the speed at which the extraordinary discoveries in basic cancer research – particularly on the genetic and molecular underpinnings of cancer – are being developed into new interventions for cancer prevention, early detection, diagnosis, treatment, and supportive care. To explore these issues and barriers in greater depth, the Panel conducted four regional meetings between August 2004 and January 2005. Testimony was received from 84 academic, industry, and public sector basic, translational, clinical, and applied science researchers and administrators; community-based cancer care providers; specialists in drug and medical device development and commercialization; regulatory experts; public and private health care payors; statisticians; sociologists, professional and industry association representatives; media representatives, and patient advocates. Based on this testimony, this report describes and offers recommendations for overcoming major barriers that are limiting progress in translating research to reduce the growing burden of cancer, and suggests stakeholders with major responsibility for action.

To conquer cancer, many important tasks need to be accomplished, and these range from achieving critical insights in the laboratory all the way to delivering the right care in the community.

– Regulatory official

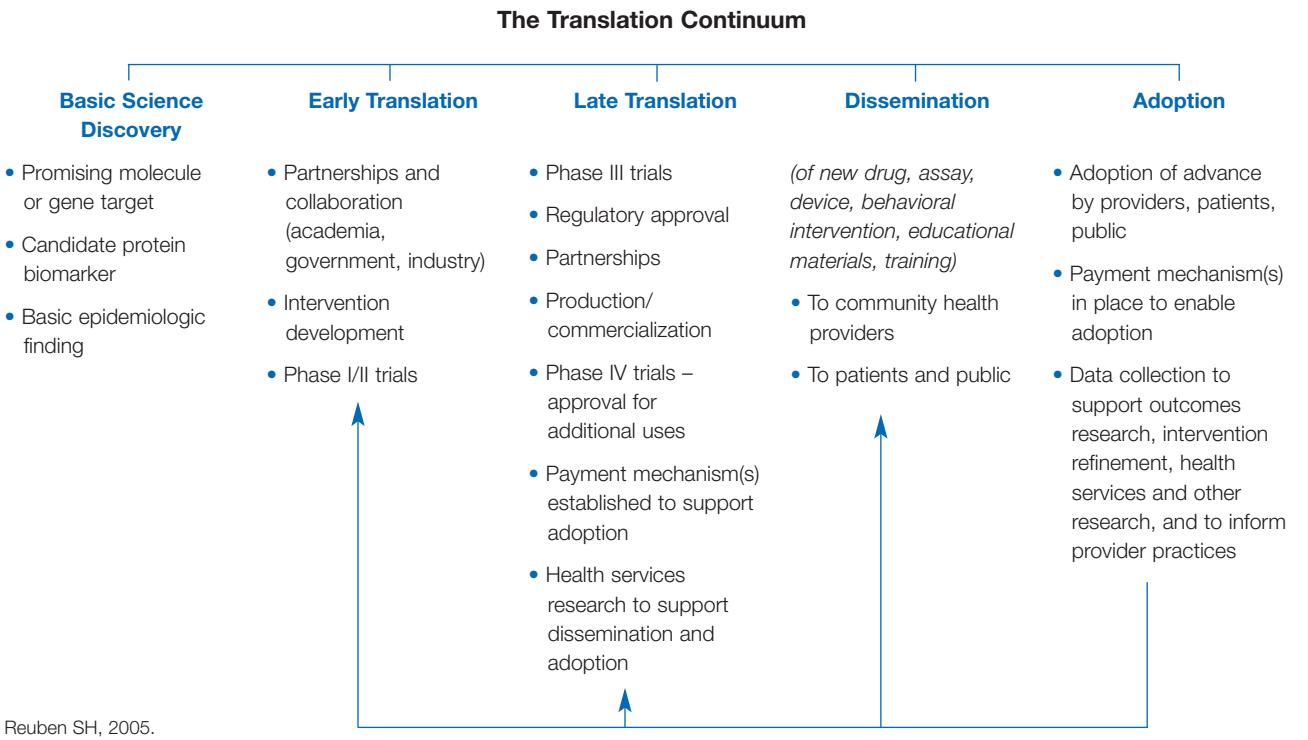
The Research Translation Continuum – Turning Discoveries into Cancer Care

Research **translation** encompasses all of the processes involved in developing promising basic laboratory and epidemiologic discoveries into cancer-related drugs and biologics, medical devices, behavioral interventions, methodologies, and instruments, and making these readily available to all segments of the public with cancer and those at risk for cancer (Figure 1). Along this broad continuum, ***early translation*** generally refers to development activities that begin following a promising discovery in the laboratory or in basic epidemiology and continues to the point at which an intervention undergoes initial (Phase I/II) testing in the clinic or community. ***Late translation*** begins when an intervention demonstrates efficacy in a larger population, receives regulatory approval, if required, and is commercialized or produced so that it can be made available to the public. Late-stage translation also may include testing of approved agents or devices for new uses.

Late translation must be followed by ***dissemination*** of the intervention (including information, training, and resources) to providers and/or the public, and by ***adoption*** (sometimes called diffusion) – the uptake of new interventions into standard practice by providers or the acceptance of behavioral interventions by patients and the public. The adoption phase also should include post-marketing data collection to support intervention refinement; outcomes, health services, and other research; and provider practice pattern analysis. Without dissemination and adoption, the fruits of new knowledge never become a part of the health care available to the American people.

Across the translation continuum, the Panel identified complex barriers related to the current culture of research; regulatory issues; dissemination, education, and communication needs, public trust and community participation issues, and access to cancer information and cancer care.

Figure 1: Translating Research to Reduce the Burden of Cancer



Reuben SH, 2005.

Team Science and the Culture of Research

The current 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 priorities, the perceived desirability among institutions and individual investigators of conducting collaborative research, and resource allocations.

The growing complexity of cancer-related research, requiring collaboration among professionals with highly diverse skills and training, is sharply at odds with traditional, single investigator-oriented research approaches. Yet team science approaches clearly are proving to be the paradigm for achieving progress in translating basic science discoveries into useful interventions. Many of these efforts are large-scale collaborative projects to develop essential core resources needed to answer the most challenging scientific questions.

The [Human] Genome Project has spawned a new discipline in bioinformatics. What we need to now understand is the clinical significance of the information that we obtain. Population biologists would clearly play a key role, and medical economists….This is an example of an interdisciplinary or team approach that is quite different from the way science was conducted just in the recent past.

– Academic medical center researcher

Peer Review

Established peer review systems, particularly of the National Institutes of Health (NIH) and others modeled on the NIH system, tend to be biased toward proposals with a high probability of success and historically have been oriented strongly toward single investigator grants for basic and preclinical studies. In addition, the system favors established investigators over younger, less experienced scientists. As a result, novel, higher-risk proposals, those led by young investigators, and projects in translational and clinical science have been at a disadvantage in a system with limited funds and far more high quality proposals than can be funded. Recent reorganization of the NIH peer review system (including the focus and boundaries of study sections and efforts to include more clinical scientists as reviewers) as well as a growing recognition of the importance of research translation may improve the future success rate of collaborative, translational, and clinical cancer research proposals.

Other Disincentives to Collaboration

The academic research environment itself is a barrier to team science, since it rewards individual achievement rather than collaborative effort. Investigators are rewarded with promotions, compensation, tenure, laboratory or clinic space, staffing, and prestige depending on their success in bringing grant and contract revenue into their institutions. Success also is measured by the number of papers published in scientific journals on which an investigator is the lead author. These incentives also discourage collaboration, since collaborative efforts may decrease the amount of funds coming into the institution and until very recently, only one individual could be designated the principal investigator on a grant. Moreover, translation-oriented research is not the principal focus of the most prestigious journals, and papers reporting translational studies may be difficult to get

published. Even within individual academic institutions, collaboration is impeded by rigid departmental boundaries that limit communication among scientists in different disciplines, even though all may be engaged in cancer-related research.

The academic research culture, and its structures, practices, and reward systems must be changed to remove these major obstacles to collaborative, multi- and transdisciplinary research.

Infrastructure Required for Research Translation

The existing translational research infrastructure is inadequate to support the work that must be done to develop new knowledge into beneficial interventions and deliver them in the community. Major barriers to progress involve the current organization of the clinical trials system, workforce issues, and a lack of key research resources.

The Clinical Trials System

Despite increasing research and development investments, the annual number of new drug approvals is declining, a major source of frustration among public and private sector researchers and policymakers. It often does not become clear that a new compound is of little or no benefit – or is no better than existing therapies – until large Phase III trials are well underway. By this time, most development costs already have been incurred. Moreover, cancer drugs tend to have a higher late trial failure rate than new drugs for other diseases – more than 50 percent. Ways must be found to identify earlier the chemical and biological compounds with clear anti-tumor activity or impact on critical genetic and molecular pathways associated with carcinogenesis, tumor progression, or metastasis.

The clinical trials system in the United States must be simplified and made more cohesive, efficient, and effective without compromising the safety of study participants. It was suggested that for any clinical trials system to be successful, it must: (1) have a mandate and a philosophy that embraces clinical trial enrollment as a central precept, (2) offer provider incentives and recognition associated with doing the extra work involved in trial participation, (3) have stable resources, (4) have a structure that provides a broad base of opportunity for participation by community providers and patients, and perhaps, (5) employ navigators to help patients through the system.

A number of efforts are underway to overhaul the national clinical trials system. Both NIH and the National Cancer Institute (NCI) are exploring strategies to streamline and improve their extramural and intramural clinical trials systems. A joint initiative of cancer center and oncology professional associations is working to devise a system for smaller, “smarter” trials that will take advantage of emerging technologies and use human resources more productively to expedite research translation. A more sweeping proposal would join public, private, and nonprofit stakeholders – including researchers, research sponsors, regulators, health care consumers, health care purchasers, physicians, and non-physician health professionals – to establish a single, integrated national clinical trials enterprise that could overcome obstacles now slowing translation.

…the administrators in research institutions squeeze the time allocations for research and force investigators to identify sources of income to help pay their salaries…there are fewer young researchers being funded through the [NIH] R01 mechanism, and this is likely to reach crisis proportions unless there is some redirection of the funding to allow [them] to gain research support and not leave the field.

– Nonprofit cancer organization executive

The Research Translation Workforce

Compared with the basic science workforce, there is a dearth of translational and clinical researchers. This workforce imbalance is a major factor contributing to the infrastructural bottleneck that now limits the translation of cancer-related discoveries. Translational researchers must be trained in both basic and clinical science, and therefore, often require a longer training period than does an individual pursuing either basic or clinical science alone. These physician-scientists are in short supply and are dwindling in number – now only two percent of the physician workforce nationwide. Few training programs exist that are designed specifically to develop this special mix of skills and knowledge.

In addition, translational and clinical researchers have relatively few opportunities to secure "protected time" (i.e., salary support that relieves them of revenue-generating activities so that they can pursue research projects). Appropriate mentors within the academic setting also are scarce. With grant funding for translational and clinical research more limited than for basic research, some talented young investigators are choosing careers in other scientific areas. Expanded educational loan repayment programs may be a tool to help young physicians to pursue translational and clinical cancer research careers. Support also is inadequate for other essential components of the translation workforce, including health services researchers, research and oncology nurses, radiologists, statisticians, data managers, sociologists, behavioral medicine specialists, oncology social workers, community primary and ancillary care providers, health communication specialists, and others whose contributions across the translation continuum are critical if research advances are to reach the public. Many of these personnel are too few in number to meet the need for their skills, and in some cases, their services may not be reimbursable, creating a barrier to their participation in research-related activities.

Research Resources

Numerous public initiatives have been implemented to expand and refine research resources that support basic science discovery. Funding for shared resources supporting translational activities, however, has been far less robust, with relatively little support coming from the private and nonprofit sectors. Some publicly funded translation-oriented programs exist, but are too few in number and too small to support the research needed to turn promising discoveries into better cancer prevention and cancer care. Other research resources needed to speed translation include:

- Interoperable bioinformatics systems with standardized formats and datasets.
- More robust cancer surveillance data.
- Coordinated, linked biorespositories with standardized information on specimens.
- Validated biomarkers of carcinogenesis and treatment response, and biomarkers to identify disease subgroups and predict prognosis.
- Enhanced applied and health services research capacity.
- Interoperable electronic health record systems.

Although initiatives are underway, principally in the public sector, to enhance capacity in each of these areas, substantially increased funding and effort will be required to develop the resources needed to fully support research translation.

Regulatory Issues Affecting Translation

Nearly every aspect of cancer-related research and drug development is controlled by myriad Federal and state regulations. These regulations have been developed over the past few decades principally to protect the public from harm due to financial conflicts of interest in the research and pharmaceutical communities, inadequate patient protection in research studies, unsafe drugs and devices, and invasions of privacy. But many of the current regulations, though well-intentioned, are having unintended consequences that are impeding the pace at which new discoveries in basic science can be developed into interventions and delivered to the public.

…the lack of sound policy is presenting real barriers in the fight against cancer – in particular, innovation policy, including research funding and procurement; regulatory and reimbursements challenges; intellectual property as it results particularly in gene patents; the setting of standards, particularly in information technology and health care; and proactive policy in areas of genetic privacy and nondiscrimination.

– Biotechnology company executive

Further, the regulatory structure related to clinical trials in many ways thwarts efforts to create the most efficient, effective, and least costly cancer clinical trials system. In particular, regulations related to multi-institutional trials have become so complex that they are a significant obstruction to progress. Coordinating multiple grant participants, Institutional Review Boards (IRBs), and Federal and state regulations is a costly undertaking that often delays trials and in some cases, prevents important trials from being conducted at all.

Institutional Review Boards and Human Research Subject Protections

Ideally, the IRB process should be streamlined such that a single scientific review and single IRB review meet the needs of all stakeholders. Using a central IRB for multisite trials, or alternatively, using nationally agreed-upon IRB standards, are possible options for solving some of the current problems. Standardized reporting requirements and formats for adverse events occurring during clinical trials also are needed.

Intellectual Property, Patents, and Conflict of Interest

Several issues in this area are impeding translation and have become more complex as greater numbers of patents are granted for biomedical discoveries that previously would have resided in the public domain, as large-scale projects require the use of many patented products, and as industry-academic partnerships have increased. Perhaps most importantly, strident protection of intellectual property rights, patents, and licensing arrangements make it exceedingly difficult to test combination therapies of drugs not yet approved by the Food and Drug Administration (FDA), despite wide recognition that combination therapies targeting multiple cancer pathways have the best chance of success. In addition, as subtypes of common cancers are identified, each requiring different treatment, the market for individual cancer drugs is shrinking, along with private industry's interest in developing them. Options identified to address these issues include a standard patent exclusion for research purposes, standard contract clauses governing collaborative drug and device development efforts, modifications to the periods of exclusivity now provided by current patent law, greater government involvement in early drug development, and designating all cancers as "orphan" (low incidence) diseases eligible for special drug development assistance under the Orphan Drug Act of 1983.

Conflict of interest, intellectual property, and patent issues can be managed successfully with strict disclosure rules and firm enforcement, but cannot be eliminated. Some drugs, biologics, and devices for which early translation tasks were supported by public funds may require "gap funding" from nonprofit or other sources to continue their development to the point that the private sector will risk the significant funding needed to commercialize them.

Food and Drug Administration

Suggested changes in the FDA process and interface of medical product reviewers and academic and private cancer drug and device developers were to: (1) enable developers to meet earlier in the translation process with FDA officials to discuss the types of trials and data that will be required for approval, (2) accelerate FDA efforts to develop product review tools that keep pace with scientific advances, (3) develop an improved mechanism to enable FDA to share clinical trials information with the academic community that both accommodates the proprietary environment and does not compromise the approval process, (4) encourage the rapid development of regulations to guide the development and approval of chemopreventive agents and combination drug trials, and (5) support the FDA-NCI partnership to streamline the clinical evaluation process and identify biomarkers and other surrogate endpoints for use in assessing the efficacy of new agents in clinical trials.

Centers for Medicare and Medicaid Services (CMS)

The potentially chilling impact on drug development and community oncology services availability due to Medicare reimbursement changes under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was discussed at length at the Panel's meetings, and such changes should be monitored closely as various provisions of the MMA are implemented.

CMS will become more involved in collecting data on "off-label" uses (i.e., uses other than those approved by the FDA) of cancer drugs and cancer care technologies, as well as new agents and devices, to support more expeditious coverage decisions. These activities reflect a growing recognition that cancer treatment is becoming more individualized, and that treatment planning and reimbursement should become more decentralized. CMS is teaming with NCI to, among other objectives, develop data collection and data sharing strategies to expedite coverage decisions and improve patient and provider information access, and create a process for post-approval studies on priority questions.

Health Insurance Portability and Accountability Act (HIPAA)

Obstacles to research erected by the HIPAA privacy provisions that took effect in 2003 include redundancy with existing privacy-related components of informed consent documentation that creates unnecessary burdens on clinical researchers and trial participants without improving patient protection. Further, HIPAA prohibits access to medical records that would enable researchers to: (1) identify patients who may benefit from participating in a specific clinical trial, (2) use tissue specimens remaining from a previous clinical trial for additional studies, including outcomes research, (3) examine linkages between disease trends and environmental factors, (4) obtain long-term follow-up data on patients, and (5) more easily use existing databases and tissue banks.

Dissemination, Education, and Communication Issues Affecting Translation

Since 80 percent of cancer patients and survivors receive their care in the community, disseminating prompt, accurate information in usable formats to physician and non-physician health care providers and the public about cancer prevention and treatment advances is a critical step in the translation process – the link between an intervention's development and its adoption into clinical practice. Yet research to identify the most effective strategies for disseminating advances to multiple audiences is in its infancy. Moreover, dissemination suffers from a lack of leadership and chronic underfunding, as no agency has been given the authority and budget to coordinate dissemination research and activities. To achieve the ultimate goal of dissemination – enabling individuals and organizations to adopt evidence-based approaches that will help reduce the risk and burden of cancer – specific education and communication needs of the public, health care professionals, and research community must be met.

Public education is needed in three important, though not mutually exclusive areas: (1) education about basic scientific and research concepts, (2) general education about cancer as a disease process and about available cancer prevention and care interventions, and (3) clinical trials education and awareness. Provider education is needed to increase the adoption of cancer screening, preventive interventions, and other care shown to be of benefit; to facilitate adoption of new treatments and technologies; and to improve provider openness to and awareness of clinical trials, as well as their ability to communicate with patients about trials. In the research community, targeted education is needed to improve the ability of scientists to communicate with potential clinical trial participants about the risks, processes, and potential benefits of trials. Researchers also need training to better understand regulatory requirements related to drug and device development, and the tasks and resources needed to successfully commercialize new products.

…some of the expertise needed for dissemination may exist outside our academic medical centers and cancer centers. For example, it may reside within business schools. Partnerships may be needed to stimulate discussions between people with effective interventions and those who know something about marketing and dissemination.

– Dissemination researcher and cancer center administrator

The Impact of Public Trust and Community Participation

Public trust and community participation are essential if research advances are to make the transition from the clinic to community cancer patients/survivors and those at risk for cancer. Issues of public trust permeated the testimony presented to the Panel. Trust is an expectation of certain behaviors, reliability, competence, and power sharing. The research community has fallen short in meeting the public's expectations in this area such that a longstanding distrust of medical research is firmly entrenched and is a significant obstacle to clinical trials participation and the acceptance of new treatments and other interventions. Establishing trust between researchers and minority communities is of special importance.

Involving the community (the public, physician and non-physician care providers, regulators, advocates, and local government) in assessing the need for specific studies, and in planning and conducting the research itself have proven effective in overcoming distrust and expanding the reach of prevention and treatment advances into communities. Specifically, communities must be involved early in research protocol development, and researchers must ensure that the community benefits from participation and receives research results. Further, the expertise of cancer advocates and survivors, who can help maintain a patient-centered focus on research projects, could be utilized more fully. Community involvement and support is particularly crucial to ensure the sustainability of interventions shown to be of benefit.

The Importance of Access to Successful Translation

Even if research advances are translated into cancer prevention and care improvements, the burden of cancer will not be reduced unless all segments of the population have geographic and financial access to appropriate clinical trials, approved therapies and technologies, and the information that will enable individuals and their health care providers to identify and evaluate cancer-related prevention and care options. The Panel has reported extensively on issues of access to cancer care and many of these complex and pervasive issues were reiterated in the testimony received. Encouragingly, several potential models for extending the availability of clinical trials and state-of-the-art cancer care and overcoming provider and patient information access barriers were described.

We will get there with a commitment on the part of this Nation to do what is necessary...to fulfill the dream that we began in 1971 to conquer cancer...given the opportunity that's before us – if we seize it and if we accomplish it, we will end the suffering and death due to cancer and bring that about in this country by 2015.

– NCI director

Conclusions

The translation continuum described in this report – spanning the multitude of processes needed to turn a laboratory discovery into improved cancer care that is available to all who need it – is unbalanced and obstructed by bottlenecks that are keeping cancer research advances from reaching the public. The Panel's recommendations for action to remedy major barriers now limiting translation progress are enumerated in the attached matrix, along with suggested responsible stakeholders or other entities. Importantly, those suggested do not necessarily comprise the universe of stakeholders or others with an interest in these issues.

The critically needed changes described in this report cannot be achieved without cost. Specifically:

- Increased funding for translation-oriented research – particularly collaborative, team efforts – is urgently needed across the translation continuum. Targeted Federal funding for translation-oriented research is drastically out of balance relative to financial commitments to basic science. Ways must be found to increase human tissue and clinical research resources without slowing the discovery engine. Supplemental funding may offer a temporary solution but will be inadequate in the long term.

- A funding gap exists for agents or other interventions that require further development before they are ready for commercialization, but which have exhausted available public funding.

- The translational research infrastructure is inadequate to enable the work that needs to be done; resources must be committed to develop the tools and workforce required.

- Research on cancer prevention must receive higher priority and funding to expand the body of knowledge that can be translated into new interventions to reduce cancer incidence and mortality and reduce the overall cancer burden. Additional research also must be funded to improve cancer early detection interventions.

- Dissemination research must be expanded and accelerated to improve understanding and develop strategies that will increase the adoption rate of new cancer care interventions.

- Cancer centers and academic centers must be adequately funded to conduct outreach and dissemination activities. Institutional commitment is essential to sustain outreach to improve clinical trials accrual, disseminate research findings, and help ensure that advances are adopted into standard practice. Network models may offer efficiencies of scale and opportunities to extend the reach of cancer centers and academic institutions, but funding will be needed to foster and maintain regional linkages.

- Training funds are needed to strengthen and expand the translation research workforce and improve public understanding of cancer and cancer research. Specifically, funds are needed to support: (1) training and mentoring to attract investigators to translational research careers, (2) continuing training of translation-oriented investigators, (3) community provider training on clinical trials and new therapies, (4) investigator and community provider training on regulatory requirements related to drug and device approval, and (5) public education.

- Outcomes and cost-effectiveness research are needed to better understand the benefits and actual total costs of care for various types of cancer at different stages of disease; for outreach, prevention, and early detection activities; and the components of total cost. Without this information, it is difficult to assess the long-term efficacy of new interventions or align reimbursement strategies to cost.

- The funding necessary to support these essential activities across the translation continuum must be garnered, either through carefully considered reallocations of currently available funds, or by identifying and committing new resources.

In addition, the Panel believes it is imperative that the success of the numerous initiatives launched or planned to address diverse aspects of the research translation problem is assessed so that programs can be refined as needed. Therefore, the Panel further recommends:

In five years, a thorough evaluation should be conducted to assess the effectiveness of the many public and private initiatives now underway or planned to accelerate the translation of basic science discoveries into improved cancer prevention and cancer care.

Moreover, the Panel believes that:

To ensure continued progress in translating cancer research advances into new cancer care interventions, the current statutory authorities of the National Cancer Institute should be preserved in any reauthorization of the National Cancer Act.

All stakeholders in the cancer research, medical, public health, advocacy, legislative, and regulatory communities must make it their priority to ensure that biomedical advances are developed more rapidly into cancer care interventions and that this care is provided affordably and equitably to all – to prevent, control, and cure cancers to the maximum extent of our knowledge and skill. This is the commitment that was made to the American people, who finance with their tax dollars and their health insurance premiums the cancer research and health care delivery systems that together comprise the translation continuum. It is the promise on which we must deliver, and we must do no less.

Recommendations and Suggested Responsible Stakeholders or Other Entities

Recommendations	Responsible Stakeholder(s) or Other Entities*
Overarching Recommendations	
In five years, a thorough evaluation should be conducted to assess the effectiveness of the many public and private initiatives now underway or planned to accelerate the translation of basic science discoveries into improved cancer prevention and cancer care.	• Institute of Medicine (IOM)
To ensure continued progress in translating cancer research advances into new cancer care interventions, the current statutory authorities of the National Cancer Institute should be preserved in any reauthorization of the National Cancer Act.	• Congress
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 research activities.	• Association of American Medical Colleges (AAMC), Council of Deans • Association of Academic Health Centers (AAHC) • American Association for Cancer Research (AACR) • American Society of Clinical Oncology (ASCO) • Association of American Cancer Institutes (AACI) • Association of Community Cancer Centers (ACCC) • Association of Oncology Social Workers (AOSW) • National Comprehensive Cancer Network (NCCN) • Oncology Nursing Society (ONS) • American Society of Clinical Pathology (ASCP) • American Society for Therapeutic Radiology and Oncology (ASTRO) • International Biometric Society (IBS) • National Coalition for Cancer Survivorship (NCCS) • Biomedical Engineering Society (BES) • International Committee of Medical Journal Editors (ICJE)
2. Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical research and human tissue research. Funding mechanisms should promote collaborative science and include greater support through the R01 mechanism.	• National Cancer Institute (NCI)/National Institutes of Health (NIH) • National Science Foundation (NSF) • Centers for Disease Control and Prevention (CDC) • Department of Defense (DoD) • Department of Veterans Affairs (VA) • Pharmaceutical Research and Manufacturers Association (PhARMA) • Biotechnology Industry Organization (BIO) • Lance Armstrong Foundation (LAF) • American Cancer Society (ACS) • Howard Hughes Medical Institute (HHMI) • Agency for Healthcare Research and Quality (AHRQ)

*Please note that this list is not exhaustive and does not preclude participation by other interested parties.

Recommendations	Responsible Stakeholder(s) or Other Entities
3. The National Institutes of Health and other research sponsors should facilitate collaboration in large research projects by requiring team approaches to the extent appropriate to the science and designating a percentage of project funding for such efforts.	• NIH • DoD • CDC • VA • AHRQ • HHMI • LAF • ACS
4. To stimulate team science, the National Institutes of Health and other research sponsors should rapidly devise implementation plans for permitting co-principal investigators who share grant funding and attribution for these efforts, consistent with the January 2005 directive from the Director of the Office of Science and Technology Policy.	• NIH • VA • DoD • CDC • NSF • AHRQ
Infrastructure Required for Research Translation	
5. To attract and retain young investigators to careers in translational and clinical research: (a) Protected research time and mentoring must be provided earlier and potentially for a longer period of time than is now the norm. Government training funds may be needed to enable academic institutions to provide this supportive environment. (b) 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. (c) Academic institutions should make special efforts to recruit and retain young scientists from underrepresented population groups.	• NIH • DoD • NSF • VA • National Postdoctoral Association (NPA) • AAMC
6. The Rapid Access to Intervention Development program should be expanded and revitalized to accelerate the development of innovative interventions and technologies for cancer.	• NCI
7. Specialized Programs of Research Excellence (SPOREs) have proven effective in stimulating collaborative and translational research. The program should be expanded, with the focus of selected SPOREs shifted to emphasize clinical over basic research.	• NCI
8. The Centers for Medicare and Medicaid Services should explore the possibility of collecting cancer stage data, at least at the time of diagnosis, to better inform treatment decisionmaking, ensure appropriate payments, enrich the body of information about provider practice patterns, and support treatment research.	• Centers for Medicare and Medicaid Services (CMS)

Recommendations	Responsible Stakeholder(s) or Other Entities
9. The proposed Human Cancer Genome Project should be supported to accelerate progress in genetic knowledge that will enable the development of new cancer prevention and treatment advances. Funding for this large effort should come from a special supplement rather than from participating agencies' budgets.	• Congress • NIH • NCI • National Human Genome Research Institute (NHGRI) • DoD
Regulatory Issues Affecting Translation	
10. The current partnerships between the National Cancer Institute (NCI) and the Food and Drug Administration to expedite cancer drug reviews and between NCI and the Centers for Medicare and Medicaid Services to generate clinical data on new interventions to support Medicare coverage decisions should be continued and strengthened.	• NCI • FDA • CMS
11. To encourage private sector investment in cancer therapies, all new cancer chemoprevention and chemotherapy drugs and biologics should be designated orphan drugs under the Orphan Drug Act of 1983.	• Congress
12. A task force of private, nonprofit, academic, and government stakeholders affected by current barriers to research translation due to intellectual property and patent issues should be convened to develop and reach consensus on: (1) standard language for patent exemptions for research purposes, (2) standard clauses for contracts governing collaborative research, and (3) other agreements as needed to resolve intellectual property and data-sharing issues.	• NIH • DoD • VA • FDA • CMS • AACI • AACR • PhARMA • BIO • AAMC • HHMI • ACCC • ASCP • ASTRO
13. The Institute of Medicine should be commissioned to evaluate the impact of the Health Insurance Portability and Accountability Act provisions and provide guidance to legislators on amendments needed to remove unnecessary obstacles to cancer research and make this law better serve the interests of cancer patients and survivors. *(This is a restatement of prior Panel recommendations.)*	• Congress • IOM
Dissemination, Education, and Communication Issues Affecting Translation	
14. A lead agency for cancer-related dissemination research and activities should be designated and provided with the budget and authority to carry out this crucial function.	• Office of Science and Technology Policy, White House

Recommendations	Responsible Stakeholder(s) or Other Entities
15. The National Cancer Institute should increase significantly 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.	• NCI/NIH • Congress • NCI-designated Comprehensive Cancer Centers • Coalition of National Cancer Cooperative Groups (CNCCG) • NCCN
16. The translation process should be expedited through bi-directional education between regulators and cancer researchers to ensure that regulators better understand rapid advances in biomedical science and technologies, and that researchers better understand and are able to navigate and meet regulatory requirements.	• NCI • FDA • NSF • Private sector pharmaceutical and biotechnology companies
The Impact of Public Trust and Community Participation	
17. Clinical and prevention research funders should require community participation early in protocol design and in research implementation.	• NCI/NIH • CDC • CNCCG • AHRQ
18. Research results must be shared with the individuals and communities that participate in clinical trials and other studies.	• NIH • CDC • DoD • VA • CNCCG
19. Clinical and prevention research grantees should be required to include as part of the grant application a plan for disseminating and sustaining new interventions into the community.	• NCI/NIH • CDC
20. Existing community-based participatory research models should be evaluated to determine the potential for adopting them in other geographic areas and populations.	• IOM • AHRQ
The Importance of Access to Successful Translation	
The President's Cancer Panel has made recommendations to improve access to cancer care. These recommendations may be found in the following reports: • *Living Beyond Cancer: Finding a New Balance*, May 2004 • *Facing Cancer in Indian Country: The Yakama Nation and Pacific Northwest Tribes*, December 2003 • *Voices of a Broken System: Real People, Real Problems*, March 2002	(See recommendations in these documents)