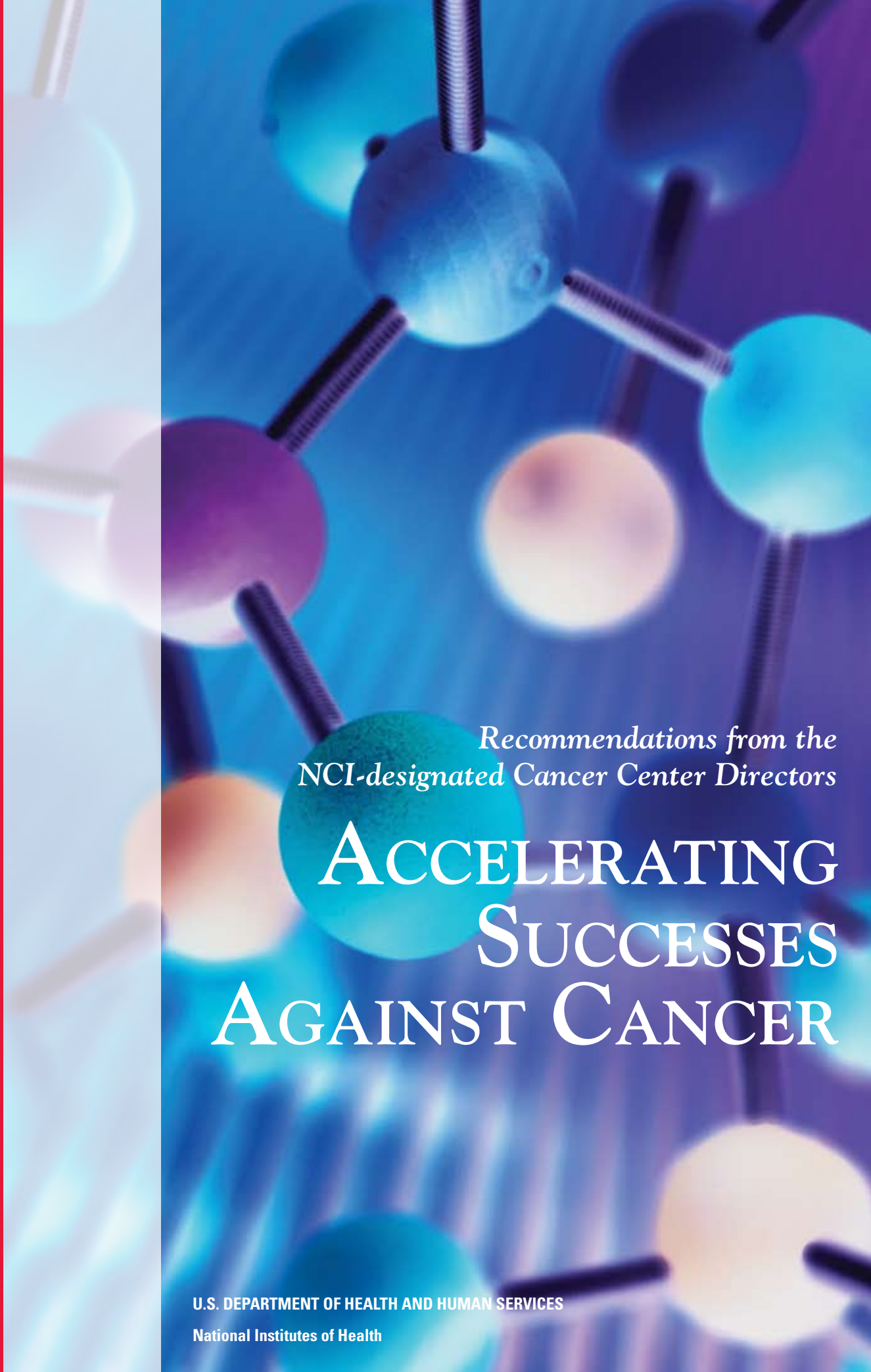
National Cancer Institute



Recommendations from the NCI-designated Cancer Center Directors

Accelerating Successes Against Cancer

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

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Statement of Purpose

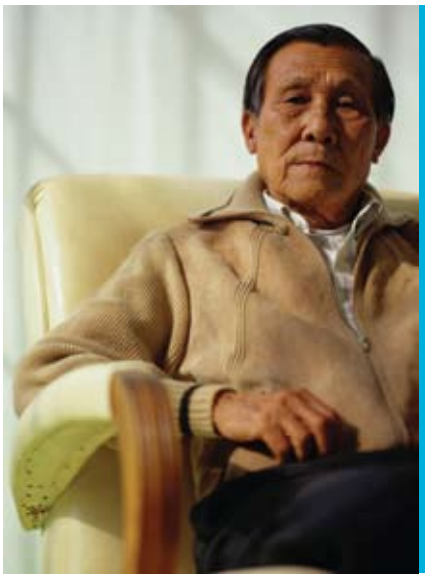
Never has there been such opportunity and promise for improving outcomes for patients with cancer. The human genome project and other recent accomplishments in molecular biology and technology development have made it possible to revolutionize the way physicians and researchers can address the challenge of preventing and curing cancer.

In 1971, with the passage of the National Cancer Act, the National Cancer Institute (NCI) initiated creation of centers of excellence and charged them with gathering together the expertise to greatly expand research on understanding the causes of cancer and improving its treatment. Initially the centers of excellence consisted of three NCI-designated Cancer Centers. Today there are 61 Centers, spread widely across the United States.

As a result of the government's increased investment in research over a period of more than three decades, we now know that cancer is caused by mutations or abnormal functioning of critical genes which control the replication and behavior of the cells in our bodies. This statement could not have been made in 1971.

The National Institutes of Health (NIH) Director Dr. Elias Zerhouni's new NIH Roadmap Initiative contains three key concepts: 1) exploring new pathways to discovery focusing on molecular networks associated with disease, imaging technologies, and nanomedicine; 2) creating interdisciplinary research teams of the future;

and 3) re-engineering the clinical research enterprise and incorporating community-based physicians, in order to place more patients in innovative clinical trials. The Nation's Cancer Centers and academic cancer research programs are leading the way in all three of these areas, and have been doing so for decades. By their very nature, research programs in NCI-designated Cancer Centers bring together basic, clinical, and population scientists to focus on cancer. Since their inception, the Cancer Centers have been peer-reviewed and scored by NCI based upon the strength of their intra- and interprogrammatic interactions. This model has contributed significantly to the successes that have been achieved in understanding the molecular basis of cancer and in developing targeted therapies and new imaging modalities. The nationwide program of clinical trials investigating new cancer treatments on many thousands of patients is a model of clinical investigation.



While our knowledge of cancer will never be complete, we have reached the point where medical researchers can at last envision ways to greatly improve our ability to reduce death and suffering from cancer. The age-adjusted rate of cancer mortality has been falling for a decade. Recently, it was reported that in 2003, for the first time, the absolute number of cancer deaths in the United States was reduced from the previous year. This is despite the fact that as a whole the U.S. population is living longer and cancer is a disease whose risk increases with aging. We can substantially reduce deaths from cancer just by broadening the application of knowledge we have today. By expanding our knowledge through further research, even greater gains are well within our reach.

The Cancer Centers Directors working group, described below, was not in a position to pursue an independent economic analysis of the benefits of improving cancer care. However it is worth making a few points from the available literature. The cost of caring for patients with cancer reached $40 billion in 1996. Medicare bears over one-third of these costs. This figure has increased during the past decade to $72 billion. This does not include the cost of screening and the value of time lost from work during treatment, as well as the cost of premature death with loss of productivity. As an example, the cost of treating an early stage breast cancer patient over her lifetime is over $70,000. There were 213,000 new cases of this disease alone in 2006.

The total impact of cancer on health is high. It was recently reported that for Americans under the age of 85, cancer is the leading cause of death. The American Cancer Society reported that last year there were 1,399,790 new cases of cancer and 564,830 deaths. Economists at the University of Chicago estimate that a 1% reduction in cancer deaths would be worth over $400 billion.

NCI was created as a governmental agency to lead cancer research, not to deliver health care. In contrast, most of the Nation's NCI-designated Cancer Centers are imbedded in academic medical centers which have the dual missions of leading the fundamental study of disease and translating new knowledge to change the delivery of health care. The NCI's Strategic Plan published in January 2006 outlines a bold vision of strategies to investigate cancer in the laboratory, in the clinic, and in the community, and states clearly that dissemination and application of research discoveries are required for success. The Nation's Cancer Centers are

uniquely positioned to both lead in cancer research and lead in this dissemination process.

The Cancer Centers Directors' Working Group

At the November 7, 2005 meeting of the NCI Director with the directors of the NCI-designated Cancer Centers, a small working group – chaired by Dr. John Mendelsohn, President, University of Texas, MD Anderson Cancer Center – was asked to write a report providing a blueprint on how the Cancer Centers can contribute to achieving the following goals:

1. Reduce the burden of cancer through research in the areas of prevention, detection, treatment, and survivorship, and create a strategy for success.

2. Identify ways in which NCI-designated Cancer Centers can enhance collaboration with each other and with other stakeholders in the pursuit of our shared mission.

3. Suggest initiatives that will enable the Cancer Centers to extend their research beyond their local communities and to provide leadership in the wide dissemination of best practices in cancer care and prevention.

4. Create a realistic vision of the potential for future successes and identify the roadblocks that must be dealt with.

The working group was subdivided into six subcommittees concentrating on the outlined goal areas: prevention, detection, treatment, survivorship, collaboration, and dissemination. The subcommittee reports were presented and discussed at the NCI Cancer Center Directors Retreat in May 2006 and the final report of recommendations was reviewed by all of the Cancer Center directors.

We Have Made Progress

Progress has been made during the 35 years since passage of the National Cancer Act in 1971. During the 10 years between 1990 and 2002, the age-adjusted death rate from cancer declined 1% per year. This translates into over 315,000 lives saved or prolonged beyond that period of time. In 2004, the total deaths from cancer, which had been leveling off for a number of years, fell to levels slightly below the previous year's figures.

The American Cancer Society recently published a midpoint analysis of progress towards its goal of reducing cancer deaths by 50% over the 25 year period between 1990 and 2015. If trends over the first 12 years continue, the projection is for a 23% reduction in cancer deaths by 2015. However, for breast cancer, colon cancer, and lung cancer in males, the trends predict a 50% reduction.

It is worthwhile considering why these significant levels of reduction are being achieved and what more can be expected. For breast cancer, the improvement is attributed to a combination of early detection due to mammography and manual palpation and improved therapy. Significantly, only 58% of women had mammograms in 1970 while by 2002 the number reached 76%. That leaves room for helping the 24% of women who currently do not receive the benefits of early detection.

For colon cancer, the 50% trend for reduced deaths is attributed almost entirely to colon endoscopy with polypectomy. Polypectomy reduced the incidence of cancer by 80% in two large studies. Only about 50% of Americans over the age of 50 undergo colon examination, so there is high potential for further improvement in death rates.

For male lung cancer, the 50% trend for reduced death is attributed primarily to reduced tobacco use. There is likely to be a downward trend in lung cancer death rates for women, because lung cancer incidence rates have begun to fall for women in recent years, paralleling the earlier fall for men. These gains have resulted from an enlightened behavior on the part of the public, supported by educational campaigns, clean indoor air laws, cigarette taxes, improved access to counseling and pharmacologic aids, and increased commitment of time and effort by the medical profession. Obviously, a great deal more can be accomplished. It must be emphasized that nearly one-third of all cancer deaths in the United States (over 180,000 people last year) are directly attributed to tobacco, with lung cancer leading the list.

It is apparent that most of the substantial reduction in cancer deaths over the past 12 years has resulted from prevention and increased use of effective diagnostic studies. This report will present measures to further enhance prevention and early detection of cancer, as well as new

approaches to the treatment of cancer, and management of survivors. While it is impossible to precisely quantify the anticipated impact on death rates, it is reasonable to predict that if research efforts and use of evidence-based clinical practices are increased in the areas we outline, we will reduce the burden of cancer far more rapidly and come closer to achieving the American Cancer Society's goal for 2015.

Conclusion

We conclude that the Nation's 35-year-old cancer plan can be re-energized to increase the pace of discovery and dissemination of improvements in cancer care. This document is presented as a blueprint for accelerating successes against cancer, both by expanding knowledge of cancer and by applying these discoveries expeditiously to improving the care of cancer patients. Our report of recommendations builds on and expands the NCI Strategic Plan.

NCI-designated Cancer Centers are in the privileged position of being able to contribute to both research and patient care goals, and we make a renewed commitment to do so in partnership with the NCI. We invite collaborators from the many sectors of our society with an interest in reducing the burden of cancer to join in this endeavor with renewed commitment of their efforts and resources.

We wish to emphasize that this must be a joint effort, involving academia, medical care providers, professional organizations, governmental agencies and the U.S. Congress, pharmaceutical and biotechnology companies, and – most importantly – patient advocacy groups and the public. These stakeholders will need to synchronize their goals and actions. From the beginning of planning the National Cancer Act, and continuing up to the present, patient advocacy groups have played a critical role in bringing together the public, the government, and the biomedical research community, and reminding us all to focus on the patient.

References

Murphy K, et al. Diminishing returns? The costs and benefits of improving health. *Perspect Bio Med* 2003; 46(3 Suppl): S129-37.

NIH Cost of Illness Report to the U.S. Congress, (FY 2000).

Warren JL, et al. Costs of treatment for elderly women with early-stage breast cancer in fee-for-service settings. *J Clin Oncol* 2002; 20(1):307-316.

Byers T, et al. A midpoint assessment of the American Cancer Society Challenge Goal to Halve the U.S. Cancer Mortality Rates Between the Years 1990 and 2015. *Cancer* 2006; 107(2):396-405.

Marks JS, et al. On the Threshold of a Dream. *Cancer* 2006; 107(2):217-220, 2006.

Weinberg RA. The Biology of Cancer. Garland Science, Taylor and Francis Group, LLC, 2007.

NCI Strategic Plan 2006; ***http://strategicplan.nci.nih.gov/***.

Executive Summary

The following is a summary of the major recommendations in each of the six areas targeted for review by the working group of the Cancer Center directors.

Prevention

In addressing the challenge of reducing the burden of cancer, prevention is the most desirable goal. Population studies have identified lifestyle changes that can reduce the risk of cancer, the most prominent of which is avoidance of tobacco use and exposure. We also have discovered that molecular and biological changes in blood and tissue specimens from patients can serve as markers, identifying individuals who bear higher risk for developing certain cancers, including those who show the very earliest biological

changes in the development of cancer. These individuals may benefit from active interventions in their lifestyle and behavior and, in the future, from treatment with agents that can retard or prevent the development of cancer.

We endorse the recommendations of the National Cancer Policy Board on cancer prevention and early detection, which are summarized in this report.

Strategies that Can Immediately Begin to Reduce the Risk of Cancer

- Implement known methods and investigate improved methods for preventing initiation and enabling discontinuation of tobacco use. If successful, this measure alone can reduce the incidence of cancer by more than 30%, after an estimated lag time of about two decades.
- Implement other evidence-based changes in lifestyle that will reduce the incidence of cancer, including a healthy diet, avoidance of obesity, and increased physical activity.
- Implement scientifically established medical strategies, including administration of tamoxifen or raloxifene to prevent breast cancer in high-risk postmenopausal women and HPV vaccination to prevent cervical cancer in young females.
- Utilize rapidly developing knowledge of inherited and environmentally induced mutations to begin to establish risk profiles for high-risk populations, to set the stage for rational chemoprevention and other strategies.

Cancer Centers can partner with governmental agencies and health care providers to extend these measures to the entire U.S. population through improved delivery and targeted education. Vaccination against certain cancers should eventually become as standard in medical practice as vaccination against serious viral infections.

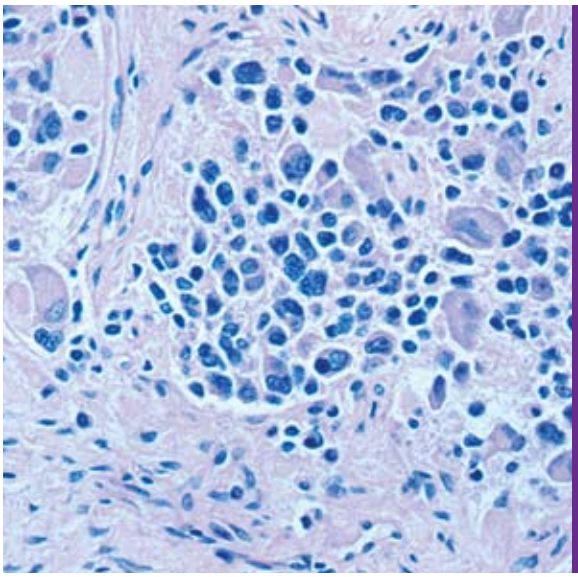
Strategies Involving Either Change in Policies or Further Research and Requiring a Decade or More Before Clinical Application

- Perform research on the application of "personalized medicine" to intraepithelial neoplasias (IENs) and precancerous conditions, by carrying out clinical trials to discover molecular targets for both early detection of high-risk lesions and targets for chemoprevention treatments.
- Increase clinical research in the behavioral sciences that will identify improved methods for changing personal lifestyles and promote informed decisions about health-related behaviors.
- Continue to pursue chemoprevention clinical trials, based on the successes with anti-estrogen agents in preventing or postponing breast cancer in high-risk groups.

While Cancer Centers can collaborate in carrying out these large-scale and long duration clinical studies, funding will be needed from governmental agencies or from companies willing to partner in these efforts.

Early Detection

Early detection of cancer can enhance the chances of achieving



cure or prolonging life for individuals diagnosed with cancer. In spite of the great interest in identifying markers in blood or cells that can identify the presence of cancers at the earliest possible time, progress in research has been slow. This is due to limitations in available technology and lack of adequate funding to support the large-scale and expensive clinical trials required to first identify and then validate these markers.

The effort and expense involved are highly worthwhile. This is because the chances for cure of most early stage cancers is typically higher than 90%, whereas cure rates for advanced stage cancers can be lower than 5% for most, but not all, solid tumors. Detection at an early stage can yield tremendous benefits in reducing death rates in cancers of the breast, colon, lung and prostate, which together account for nearly two thirds of all cancers.

Strategies that Can Immediately Increase Early Detection of Cancer

- Cancer Centers should partner with governmental agencies and health care providers to expand the use of currently validated screening methods for early detection, especially in underserved populations. These methods include colonoscopy, Pap tests, mammography, and the PSA test.
- Cancer Centers should join advocacy groups in pursuing payment for validated early detection tests by Centers for Medicare and Medicaid (CMS), insurance companies and health plans, and for extending access to uninsured Americans.
- Cancer Centers should partner with state departments of health and medical provider systems to disseminate information on the benefits of early detection of cancer and on locations where access to these measures are available.
- Cancer Centers should partner with each other to develop collaborative networks and cross-disciplinary teams that can share tissue resources and advanced technology platforms.

Strategies Involving Further Research and Requiring Up to a Decade or More Before Clinical Application

- Cancer Centers should perform large-scale, collaborative clinical trials designed to identify potential markers, using the expanding technologies of genomics, proteomics, immunohistochemistry and molecular imaging. These must be followed by clinical trials validating the capacity of these markers to accurately predict the presence of cancer. This research will require large-scale funding from the NCI or other sources.
- Fundamental research investigating specific genetic and molecular abnormalities that contribute to the malignant phenotype must continue full force because this approach will continue to contribute importantly to identification of markers that predict risk, prognosis, and appropriate therapy.
- With guidance and support from the NCI, Cancer Centers should develop and adopt a standardized and secure web-based tool for collecting and querying histories of patients and their families in a uniform way that will enable informed communication between patients and families and their health care providers, and provide data for researchers seeking to identify high-risk populations.
- Standardized and uniformly utilized electronic medical records would support initiatives in detection, treatment, and survivorship and should be a national priority. Collection, storage, and annotation of tissue specimens from each patient in a standardized way would also support these initiatives. Both initiatives will require substantial funding, collegiality, and visionary leadership.

Treatment

There has been tremendous progress in research leading to an understanding of the fundamental genetic and molecular causes of cancer and the development of new therapies that target these abnormalities. This has been accompanied by advances in surgery, radiation therapy, and systematic therapies which have already improved outcomes for cancer patients.

Because it already is uniformly acknowledged that fundamental research must continue to be pursued and funded, this report focuses primarily on the need for collaboration, coordination, standardization, and infrastructure support in clinical investigation. This will require participation by all stakeholders, including oncology specialists, providers, payers, regulatory agencies, government sponsors (e.g., NCI),

and patients. It also will require adequate funding specifically designated for these purposes. Cancer Centers are in an optimal position to lead in this effort, but the funding for clinical research must come from outside sources.

We endorse the findings of NCI's Clinical Trials Working Group (CTWG) entitled "Restructuring the National Cancer Clinical Trial Enterprise," which was adopted by the National Cancer Advisory Board in 2005. The CTWG action items are summarized below.

Strategies that Can Be Implemented Immediately to Improve Treatment Research

- Activate the recommendations of the CTWG for improving the NCI's capacity to lead in coordinating and supporting innovative clinical research.
- Place a top priority on supporting clinical investigators and funding the clinical research infrastructure needed for Cancer Centers, academic medical centers, and practicing physicians to carry out innovative and timely clinical trials.
- Increase collaborations between Cancer Centers in designing and performing clinical trials, sharing specialized core services and new technologies, and exchanging tissue specimens.
- Increase collaboration in new drug development between Cancer Centers and pharmaceutical/biotechnology companies. This will be greatly enhanced by agreement on both sides to reach compromise with regard to control of intellectual property, while protecting the interests of the inventors.

Strategies for Implementation in the Long Term

- Implement the extensive CTWG recommendations, which will lead to more efficient investigation of new treatments and more timely regulatory approval.
- Investigate new technologies and targeted therapies for the treatment of cancer, alone and in combination.
- Continue intensive research on the genetics and biology of cancer, which will provide increased understanding of the malignant process and identify promising targets for anticancer agents.
- Collaborate with the NCI, FDA, CMS and pharmaceutical/biotechnology companies in creating a unified and standardized web-based clinical trials information technology system for recording, reporting, and analyzing clinical research data.

Survivorship

Today there are over 10 million Americans who have survived cancer. A risk of recurrence continues beyond 5 years for some types of cancer. In addition, cancer survivors have a higher than average risk of a second malignancy. In fact, approximately 16% of cancers occur in survivors of the disease. Survivors also are subject to long-term sequellae caused by either their cancer or the therapy they received.

With the increasing mobility of the U.S. population and the frequency with which patients change their health care providers, there is a serious need for uniform guidelines and electronic summaries of medical records to enable appropriate follow up for cancer survivors. In addition, research is needed on ways of preventing the late side effects of cancer treatments and for dealing with them when they occur.

The result of these activities will be a decrease in deaths from second cancers due to earlier detection, and improved duration and quality of life due to control or elimination of late sequellae of the cancer or its therapy.

Strategies

- Cancer Centers should collaborate with the NCI Office of Cancer Survivorship to establish and populate a data warehouse containing clinical information, research protocols, educational materials, and descriptions of outreach activities for the public and for medical professionals.
- Cancer Centers should collaborate with the American Society of Clinical Oncology (ASCO) and other organizations in developing clinical practice guidelines for long-term follow up of cancer survivors and mobilizing adoption of these guidelines by the states and health care providers.
- Cancer Centers should take leadership in designing collaborative clinical trials that explore ways of avoiding late complications of cancer therapy or evaluate treatments which can control them.

Collaborations

The Cancer Center directors agree with the statement in the NCI Strategic Plan that: "Our success will depend on our ability to integrate our activities across a seamless continuum of discovery, development and delivery." The academic, commercial, and governmental sectors each have critical contributions to make. The effectiveness and efficiency of their interfaces need to be addressed with creativity and compromise.

Chemoprevention

Chemoprevention trials involve large, lengthy, and extremely expensive studies of both high-risk and healthy populations, requiring large infrastructures to access and monitor data for many years. Collaborations between industry and clinical investigators – both academic and in the community – must be long term, with careful prioritization and planning, and thorough scientific review in order to optimize the use of scarce human and financial resources.

Strategy

- Form a collaborative chemoprevention trial consortium of Cancer Centers and academic medical centers with centralized infrastructure and data management, funded by the NCI and pharmaceutical companies.

Biomarkers and Imaging

The discovery and validation of useful biomarkers and imaging tests are under-explored at companies and Cancer Centers because of limited available funding, in spite of the critical role of markers in plans to speed up drug development and personalize cancer care. Multiple markers are likely to be required for early detection and for selection of therapies for each type of cancer. The economic case has not been made adequately for the utility of biomarkers for both patient care and drug development.

Strategies

- A consortium of companies should be encouraged to jointly invest in the discovery of new technologies in proteomics, marker identification, and imaging agents as a pre-competitive activity, much like the successful SNP Consortium.
- Research on biomarkers can be expedited by exploring many candidate markers at the same time in a comprehensive validation trial that provides long-term follow up of a number of surrogate markers and predictors, until mortality endpoints are reached.
- Regulatory agencies could provide financial and fast-track review incentives for companies to encourage early exploration and identification of markers that predict the efficacy of new therapies.
- For each of the topics covered in this report, research can be strengthened by bringing together expertise across Cancer Centers. Sharing of specialized, high-tech core facilities will also enhance the quality of research.

Treatment

Therapeutic clinical trials require a series of contractual partnerships between companies and clinical investigators which must last for a number of years. The timeline for preclinical and clinical studies leading to possible FDA approval is typically 10-15 years. Shortening this timeline will require increased collaboration in new drug development between companies and academia, collaborative efforts to validate and implement use of biomarkers and imaging technologies as endpoints in clinical trials, elimination of redundancy in the numerous reviews required for approval of trials, and the use of standardized licensing contracts that create agreed upon sharing of intellectual property.

Strategy

- Facilitate collaboration between companies and academic institutions, by developing shared licensing agreements which can be used to speed up contract negotiations.

Survivorship

Research on the factors influencing the health of cancer survivors requires expensive, long-term studies of many patients. As with prevention research, the requirement for funding of these extensive studies and for collaboration between institutions serving cancer patients must be acknowledged and dealt with effectively.

Strategies

- Collaborations led by Cancer Centers should develop and implement standardized databases for collecting and analyzing information on cancer survivors.
- Research to identify the problems experienced by large cohorts of cancer survivors and to explore treatments and interventions that predict or manage these problems should

be carried out collaboratively between Cancer Centers, and must be funded adequately from external sources.

Dissemination

Advances in diagnostic tests and treatments for cancer usually are made available to patients rapidly by Cancer Centers, academic medical centers, and major health care providers. However, reaching all patients with cancer and their health care providers is a goal obtainable only through concerted efforts in education and widespread adoption of best practices, especially by physicians for underserved populations. The Cancer Centers should insure that opportunities to participate in clinical trials of new cancer treatments are made available to greater numbers of individuals, including underserved and diverse populations.

Strategies

- The Federal government needs to designate a lead agency within the Department of Health and Human Services (HHS) to coordinate funding and dissemination of cancer control efforts to the entire U.S. population, by bringing together the fragmented efforts of NCI, CDC, CMS, and other HHS agencies.
- Cancer Centers should take the lead in disseminating cancer care guidelines throughout their states, in collaboration with state health departments and state cancer plans.
- Cancer Centers should work with state cancer registries to convert them into outcomes registries, and should use them to identify populations with disproportionate needs for cancer prevention and care.
- Demonstration of the medical and financial benefits of best cancer control practices should be accomplished by establishing demonstration projects in regions served by Cancer Centers, funded by CMS and led by the Cancer Centers.