



Division of Extramural Activities

A New Agenda for Cancer Control Research Report of the Cancer Control Review Group

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EXECUTIVE SUMMARY

Cancer will likely be the leading cause of death early in the next century. This year 560,000 Americans will die of cancer-related causes and 1,382,400 new cancer cases are expected. Despite these sobering numbers, there have been recent breakthroughs in knowledge about what causes cancer and what can be done. Cancer control research aims to generate new basic knowledge about how to change individual, collective, and provider behavior, and to ensure that this newfound knowledge is translated into practice rapidly, effectively, and efficiently. Many of the large numbers of people who die from cancer could be spared if what is known today about how to prevent, detect, and treat cancer were adopted and disseminated to every level of our social structure. Thus, cancer control research is an integral component of the National Cancer Institute (NCI) mission, and is mandated under Section 412 [285a-1] of the Public Health Service Act.

Four important trends have emerged as the year 2000 dawns-changing demographics (an aging population), and the remarkable revolutions in electronic communications, health care management, and molecular biology. In addition, a new public health agenda concerning tobacco control provides new opportunities for health care systems, community organizations, families, and individuals to employ innovative techniques in smoking prevention and cessation. Collectively, these trends open up vast new areas for research, the success of which will hinge on collaborative, multidisciplinary partnerships. As such, this is a unique and timely window of opportunity for a review of cancer control research at NCI.

The Cancer Control Program Review Group was convened in 1996 by the NCI Director and the Chair of the NCI Board of Scientific Advisors. The Review Group met monthly from December 1996 until July 1997 to review the scope of the NCI cancer control research program and to make recommendations regarding the pursuit of research opportunities most likely to accelerate reductions in the nation's cancer burden. In its deliberations the Review Group considered the scope of NCI's current cancer control research program and assessed the potential impact of a restructured and reorganized research investment in this field.

Data show that lifestyle and environmental influences are responsible for a majority of the cancer burden. Thus, the Review Group recommends that NCI pursue a vigorous effort to exploit existing and emerging opportunities in behavioral

prevention and cancer control. Given what is now known about the natural course of cancer, NCI must make a long-term commitment to develop a more balanced partnership between the biomedical and behavioral/public health paradigms to continue to reverse the upward trend in cancer mortality observed over the past century. Moreover, research should aim to reduce the burden and improve the quality of life of those who will get cancer despite our best efforts. To achieve this the Review Group recommends several organizational changes in NCI's approach to cancer control and highlights areas of research opportunity that require focused attention in the immediate future.

Moreover, the Review Group endorses recently announced plans to establish an NCI Division of Cancer Control and Population Science, a Division of Cancer Prevention, and a new position of Deputy Director for Extramural Research. These organizational changes were considered by the Review Group in the development of its final recommendations. The Review Group, however, did not evaluate the Division of Epidemiology and Genetics, which is situated as an extramural program in the new Division of Cancer Control and Population Science. In general, the Review Group believes that these organizational changes will strengthen NCI and its cancer control research activities, and based on this reorganization, makes the following major recommendations. (More specific and detailed recommendations regarding cancer control research opportunities are contained in the full report.)

- To build an even stronger cancer control research program, the new Division of Cancer Control and Population Science should create or enhance four major research initiatives in: basic behavioral science, primary prevention, screening, and rehabilitation and survivorship. The Division should support these initiatives with other cross-cutting units in surveillance, biometry, epidemiology, health services and outcomes research, underserved and high-risk populations, communication and informatics, and training.
- To enhance the extraordinary research opportunity provided by the Cancer Information System (CIS), the new Division of Cancer Control and Population Science should establish a formal system of two-way communication and collaboration between the Division and CIS to further capitalize on CIS as a resource for the Division's research programs in tailored communication. This system should be implemented once the task force reviewing CIS has reported to the Board of Scientific Advisors and a decision has been made about the organizational location of CIS.
- To facilitate the development of behavioral prevention and control research relevant to community-based activities: 1) explore within the Community Clinical Oncology the development of new organizational constructs, including a cancer control cooperative group; and 2) revise existing guidelines and incentives for behavioral prevention and control trials within existing cooperative groups.

Because of historic and lingering concerns about the proper integration of prevention and control research, the NCI Director should ensure through mechanisms of formal

review and accountability that the newly appointed Deputy Director be responsible for ensuring the appropriate balance and coordination of cancer prevention and control activities among the two new divisions, across NCI-both extramurally and intramurally-and when feasible, with other institutes of NIH and relevant federal agencies. The Deputy Director should also ensure that there is stability in funding and consistent peer review for the research areas housed in the Division of Cancer Control and Population Science, as these areas of research have only recently been supported within the NCI R01 review structure and have yet to build a critical mass of research and researchers.

If NCI and the Division of Cancer Control and Population Science implement these recommendations it will create a focused endeavor to unite multidisciplinary scientists working in cancer control. The vision of cancer control research is to achieve virtually cancer-free generations of Americans, and the lowest possible burden of cancer among adults. This complex research effort must work seamlessly to optimize programs of monitoring and surveillance, prevention, and screening, as well as ensure compassionate care for those who have cancer and may die because the vision is yet unfulfilled. A stronger and more vibrant cancer control research program will bring sufficient numbers of outstanding researchers to this multidisciplinary partnership to create a critical mass of scientists will fulfill a key component of NCI's central mission, the control of cancer and a more rapid reduction in the absolute disease burden of cancer.

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Introduction

Events of the 20th century have demonstrated that the cancer burden can dramatically change with changing lifestyles and environmental influences. In 1900, cancer ranked eighth as a cause of death with a rate of 64 cases per 100,000 persons. By 1950, cancer was the second leading age-adjusted cause of death with a rate of 158 cases per 100,000 persons: the rate rose to 172 cases per 100,000 deaths in 1993, almost triple the 1900 rate. A major cause of the increase in cancer-related deaths in this century was the rise in lung cancer from tobacco use. Conversely, some cancer rates were reversed due to positive changes in society. For example, stomach cancer and cervical cancer declined from 1950 to 1993, due largely to changes in food preparation and storage and improvements in medical screening and early treatment. In the 1990s, for the first time since cancer statistics have been kept, there has been a modest (1 to 3 percent) but encouraging overall age-adjusted decrease in cancer deaths. The decrease in rate can be attributed largely to changes in behavior and environment, for example, successful reductions in smoking and better early detection of cancer. These observations provide compelling evidence in support of broad and aggressive behavioral and public health action in the control of cancer.

In 1997 there will be over 1.3 million new cancers diagnosed and 560,000 cancer deaths.

One in four Americans die of cancer—far more than the combined deaths from airplane crashes, traffic accidents, alcohol, violence, suicide, and HIV-AIDS. The burden of cancer is disproportionately borne by the poor and the undereducated, as well as by populations at higher risk due to lifestyle, environmental exposure, or genetic susceptibility to cancer. Furthermore, the aging baby boomers will dramatically change the patterns of cancer in the next century as cancer risks increase with age. Moreover, given that most cancers develop after a long period of exposure, the primary prevention of exposure among children and youth is paramount.

Current cancer rates are disheartening facts in the face of the colossal effort this country has made to eradicate cancer over the past 25 years. It is reasonable, even imperative, to examine the direction of the nation's cancer research in order to reinforce the modest gains made and to seek a more dramatic rate of reversal of the rise in cancer death rates experienced this century.

Cancer control seeks to apply in the community and at the bedside what is known about interrupting the progression of carcinogenesis. The best way to control cancer is to prevent it in the first place. Many estimates of cancer incidence support the recognition that, in an ideal world, over 50 to 75 percent of cancers could be prevented if what is already known about its etiology and early course was acted on and fully adopted. Tobacco use accounts for 30 to 40 percent of cancer mortality; diet for another 20 to 40 percent; and alcohol, occupational exposure, and pollution for the remaining 5 to 17 percent. More explicitly, the estimated 193,000 deaths caused by tobacco and alcohol in 1997 could be prevented completely. If these deaths could be prevented, overnight we would witness a 30 percent reduction in total cancer deaths in our nation. Another 30 percent of the expected total of 560,000 cancer deaths in 1997 are related to nutrition and could be prevented with proper diet and exercise habits. Many of the 900,000 cases of skin cancer expected to be diagnosed in 1997 could have been prevented by protection from ultraviolet sun rays. If cancer control research helped prevent only half of the avoidable cancers, there would be one million fewer deaths every five years.

New opportunities in screening and early diagnosis deserve focused attention. The stage at diagnosis is the best predictor of survival from cancer. For many of the major cancers, five-year relative survival rates are over 90 percent for local disease, and below 25 percent for disease which has metastasized to distant sites. For almost all cancers, overall survival rates depend critically on the proportion of cases diagnosed in local stage. Effective health policy with respect to cancer screening requires an understanding of the behavior of individuals and the factors which affect their choices about screening and treatment. Currently, the potential of screening is not being realized. Even for strategies proven to be effective we have not achieved the full measure of success.

Although treatment for metastatic cancer is seldom curative, most cancer is curable when it is diagnosed and treated before it has spread beyond its site of origin. The more that is known about the fundamental properties of a tumor cell, the more likely

it is that an effective treatment can be identified. Although aggressive cancer treatments can offer the promise of possible cure, they also cause many functional problems which disrupt normal life, sometimes well into the post-treatment period. Quality of life is better in cancer survivors whose disease is diagnosed early and who receive treatment specific to their tumor. Rehabilitation and survivorship research reveals improved ways of enhancing access to treatment, adherence to therapy, coping, adjustment, and social support.

Treatment and rehabilitation efforts benefit from cancer control research. For example, most cancer patients are faced with diagnostic and treatment decisions which must be made in settings where the outcomes are uncertain. The scientific underpinnings of decision making, health status assessment, treatment preferences, and health policy have matured to the point where they can make a major impact on improving the quality of life of people living with cancer.

For a subset of the population who will eventually get cancer, cancer control research can contribute to improving screening and early detection of second cancers or reoccurrences by finding ways to reach and motivate those at high risk. Moreover, there is great variation in cancer rates across ethnic and racial groups, socioeconomic levels, and by gender and age-variations derived from environmental and genetic interactions. Changing behavior in early childhood and adolescence could dramatically alter the burden of cancer among the next generation of Americans. This recognition demands that cancer control science be fully involved in research and applications in this area.

Research in cancer control must keep pace not only with new knowledge but with changing demographic trends. We must have the capacity to track cancer and the factors that increase risk. We must find ways to raise the rate of early detection, lower the barriers to access to treatment, and understand more fully the information and organizational needs of schools, work sites, communities, and health care practices-primary locations for cancer control. All of these activities must be continuously synthesized, evaluated, and fed back to those who set cancer research priorities for the nation. Thus the programs in surveillance, epidemiology and applied research are crucial to the development of a more timely and useful "report card" to inform decision making about where the research gaps and opportunities lie for cancer control.

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Definition of Cancer Control

Historically, cancer control was not viewed as science, perceived as lacking scientific credibility and with no firm research base. As the field evolved, cancer control has been recognized as operating within a sound scientific framework-as a research science rather than only a demonstration, information, and education program. Much of this is due to the concerted effort made by NCI to promote cancer control research, particularly through programs such as tobacco control. The legislation mandating NCI

cancer control programs provided early guidance on public expectations of research in this area.

For the last 15 years the NCI's Division of Cancer Prevention and Control (DCPC) has defined cancer control as "the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad systematic application of the research results." The NCI Budget Proposal for Fiscal Years 1997/98 (NCI, *The Nation's Investment in Research*, May 1996) defines cancer control research as that which "bridges the gap between laboratory, clinical and population-based research, and health care by focusing on how to bring our discoveries to the practice of cancer prevention, detection, treatment and rehabilitation."

The Review Group identified a tension between its view of the scope of cancer control research, the description that appears in the NCI Budget Proposal for Fiscal Years 1997/98, and the view that cancer control research should focus on behavioral sciences to the exclusion of biomedical research. The Review Group reflected on this tension in light of the different but parallel research paradigms followed by biomedical and behavioral-public health science, and developed its own definition.

The Review Group defines cancer control research as the conduct of basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that, independently or in combination with biomedical approaches, reduce cancer risk, incidence, morbidity, and mortality.

Thus cancer control research crosscuts both biomedical and behavioral/public health paradigms and also seeks to improve interventions across the human lifespan and over the entire carcinogenesis process.

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Charge to the Review Group

In December 1996 the Director of NCI and the Chair of the NCI Board of Scientific Advisors convened a Review Group on Cancer Control. The Review Group was charged to evaluate the full scope of cancer control research activities supported by NCI. Generally, the Review Group was asked to evaluate the current and past activities of the cancer control program and to identify research areas in which there has been insufficient effort, particularly in the behavioral sciences. More specifically, the Review Group was asked to consider the following:

- How should cancer control and behavioral prevention research best be defined at this time?
- What is the present status of research in the field? Which elements of it hold greatest promise for future progress?
- What should be the leading priorities of research in this field in the next decade?

- How can the newest advances in cancer research, both clinical and fundamental, in behavioral analysis, and those emerging technologies with greatest promise in disease and population analysis best be linked to NCI-sponsored cancer control and behavioral prevention research?
- Is cancer control appropriately organized within NCI? What is the appropriate level and configuration of infrastructure, resources, and organization needed to take the greatest advantage of future opportunities?
- What is the relationship between cancer control and behavioral prevention and other elements of the extramural program? Are they optimal? How can the connectivity with other relevant NCI extramural programs be maximized?
- What is the appropriate mix of basic, clinical, public health, and policy research in the cancer control program?
- What are the most effective and appropriate relationships of the program to the activities of other governmental agencies with allied interests?

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Vision of the Review Group

This is a unique and timely window of opportunity for a review of cancer control research. Four important trends have emerged as the year 2000 dawns-changing demographics (an aging population), and the remarkable revolutions in electronic communications, health care management, and molecular biology. These trends open up vast new areas for research, the success of which will hinge on collaborative, multidisciplinary research involving numerous partnerships. A stronger and more vibrant cancer control research program must be created to bring sufficient numbers of outstanding researchers to these partnerships.

The Review Group's vision is to reduce avoidable exposure to risk, incidence, morbidity and mortality from cancer. To achieve this, there must be a substantial, vigorous, and long-standing commitment by NCI to cancer control research. This necessarily complex research effort must work seamlessly to optimize programs of monitoring, surveillance, prevention, and screening, as well as ensure compassionate care for those who have cancer and may die because the vision is yet unfulfilled. As such, cancer control research is central to the overall NCI mission to eradicate cancer. As knowledge and technology changes, so must the emphasis of cancer control research.

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Process of the Review Group and Organization of the Report

The Review Group met monthly between December 1996 and July 1997. It requested and received written and verbal reports from NCI staff, extramural scientists, and representatives of scientific and medical committees. Meeting dates and acknowledgments appear in Appendix B.

The report is organized around the following themes deemed essential by the Review Group to a strong cancer control research program, including: the psychobiologic basis of behavior; communication and informatics; primary prevention in youth and across the lifespan; cancer screening; rehabilitation and survivorship; opportunities for research in health care delivery systems; surveillance; biometry; underserved and high-risk populations; and training.

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Challenges and Opportunities for Cancer Control Research

The vision of cancer control research is to achieve virtually cancer-free generations of Americans, and the lowest possible burden of cancer among adults. To achieve this vision, there must be a substantial, vigorous, and long-standing commitment to cancer control research, conducted by investigators of diverse disciplines. This complex research effort must work seamlessly to optimize programs of monitoring and surveillance, prevention, and screening, as well as ensure compassionate care for those who have cancer and may die because the vision is yet unfulfilled. Cancer control research is dedicated to finding the best ways to apply current knowledge about the causes, prevention, course, diagnosis, and treatment of cancer to diverse populations. As such, it is central to NCI mission to eradicate cancer.

In its deliberations, the Review Group identified areas of research that should be emphasized in the new Division of Cancer Control and Population Science. Each is described below, accompanied by specific recommendations for NCI action in each research area.

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Create a Unit Focused on Basic Behavioral and Social Research in Cancer Control

Historically, cancer control research within NCI has emphasized intervention and applications research. Attention to and funding for basic behavioral and social research in cancer control research has been limited. Basic research in the behavioral and social sciences furthers understanding of fundamental mechanisms underlying behavioral and social functioning of direct relevance to cancer control. As in basic biomedical research, it does not always address outcomes per se, but provides essential knowledge of mechanisms and universal principles necessary for better prediction, prevention, and control of cancer.

The need for more support in this area has been addressed by prior review groups. In 1996 a NCI Working Group on Behavioral Research in Cancer Control recommended increases in support for basic or fundamental behavioral research in addition to applied intervention studies. This recommendation echoed the conclusions of an earlier report by a working group convened by the American Cancer Society, which noted that the over-emphasis on intervention trials has created a gap in understanding of basic processes of behavior change and bio-behavioral interactions, thereby impeding the ability to develop successful cancer control interventions and social

processes influencing behavioral change.

Increased attention on and support of fundamental behavioral and social science research in cancer control is needed to develop theoretical models, identify underlying mechanisms and principles of behavior change, and conduct pre-intervention research to inform the next generation of cancer prevention and control interventions and social policies. Such research includes three essential areas: biopsychosocial research; basic behavioral research; and methods research. These research areas are central to many areas of cancer control research, such as primary prevention and screening, and are consistent with the research activities and priorities of other NIH institutes.

Biopsychosocial Research in Cancer Control focuses on the interactions of biological, psychological, and social processes in cancer etiology and progression (e.g., behavioral genetics, neuroscience of nicotine addiction, psychoneuroimmunology). In the past decade there have been notable successes in this area of research. For example, there has been considerable progress in understanding of the psychophysiological basis of chemotherapy-induced nausea and cancer pain. This work has led to successful interventions to reduce morbidity and improve the quality of life of cancer patients. Basic biopsychosocial research has also elucidated the links between psychological, neuroendocrine, and immune factors.

There remain, however, significant gaps in understanding of some aspects of the relationship between biology and behavior. For example, despite advances in comprehension of the genetic basis of human behavior, little is known about genetic influences on cancer risk behaviors. Genes involved in neurotransmitter systems, such as the dopaminergic system, have been implicated in the initiation and persistence of a variety of addictive behaviors, including nicotine dependence and alcohol abuse. Mechanisms of satiety and obesity have also been linked to specific genetic mechanisms. Basic biopsychosocial research is needed to elucidate the neuropharmacologic and behavioral factors that mediate the effects of genes on cancer risk behaviors and to explore the moderating influence of social and environmental factors (e.g., tobacco advertising and peer pressure). Such knowledge will lead to improvements in pharmacologic treatments to promote smoking cessation and dietary behavior change, and can help identify individuals who are most likely to benefit from such approaches. The failure to address these individual biological differences may be responsible, in part, for the limited success of traditional population-based behavior change interventions.

In addition, basic research is needed to understand the role of social factors as mediatory and modifying mechanisms in the behavior change process. As evidence mounts that behavioral risk factors are concentrated in "pockets of prevalence," generally defined by social class, research is needed to understand the role of the social context in health behavior change. For example, neighborhood of residence, social support and social networks, or experiences of discrimination may influence success in health behavior change. At a community level, basic research is needed to understand the factors influencing communities and organization's receptivity to

change supportive of cancer prevention.

Basic behavioral and social research in cancer control involves the study of behavioral and social processes from the individual level (e.g., risk perception, motivation, cognition, learning) to the group level (e.g., social and cultural influences, family interactions, organizational functioning). Within the realm of cancer control, this area of research focuses on fundamental cognitive, emotional, and behavioral processes such as risk perception, motivation, learning, and decision-making. An increased understanding of motivation and processes of behavior change has translated into significant improvements in cancer prevention and control practices. There remain substantial gaps, however, in knowledge of the individual and social processes that influence cancer risk perception and informed decision-making about cancer tests and treatments. Also lacking are theoretical models for describing, predicting, and changing the underlying mechanisms that drive the behaviors of health care providers and organizations. Yet we possess the necessary scientific methods to study these problems. Moreover, little research has been conducted to determine how social policies interact with other social and individual factors to influence changes in cancer prevention and control practices. There are several exciting opportunities for basic behavioral and social research in cancer. For example, the emergence of new genetic, diagnostic, and treatment technologies creates new challenges and opportunities for research related to informed consent and decision-making. The proliferation of managed health care systems also present new challenges and opportunities for both consumers and health care providers. Advances in the area of interactive tailored mass communications technologies have the potential to promote cancer prevention and control on a widespread population basis. Basic behavioral research is needed to realize the potential of these new technologies and health care delivery systems to reduce cancer morbidity and mortality at the population level.

Methods research develops innovative measurement and analysis techniques for use in behavioral research (e.g., psychometrics of self-report measures, structural equation modeling). In addition, methods research provides the foundation for developing new intervention methodologies (e.g., for use in untested settings, with populations where interventions are not effective). Progress in both basic and applied research in cancer control will require advancements in research methodology. Opportunities exist to incorporate biological markers into cancer control research as: a) validation of self-reported behavior change (e.g., cotinine testing for smoking cessation); b) motivational feedback to enhance behavior change (e.g., feedback of CYP2D6 genetic testing for smoking cessation); c) intermediate markers of the effects of behavior change interventions (e.g., cholesterol for dietary behavior change, regression of bronchial dysplasia for smoking cessation; and d) valid and reliable measures more appropriate for population-based research (e.g., for nutrition assessment, valid, brief measures are currently lacking for assessing dietary change in population-based studies). In addition, with the development of new intervention approaches, study designs and statistical analysis approaches must extend from individual analysis to multiple levels of intervention impact, such as families, schools, communities and

health care systems. Our understanding of the success of failure of these interventions will also depend on our ability to study the mechanisms of intervention impact and dissemination, using validated assessments of the processes of behavior change.

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Recommendations

- Create a unit focused on basic behavioral and social research within the new Division of Cancer Control and Population Science.

In its extended discussions of the definition and scope of cancer control the Review Group recognized the need for a scientific focus that provides the essential knowledge of behavioral and psychosocial mechanisms and universal principles necessary for better prediction, prevention, and control of cancer. This goes beyond the traditional focus of cancer control on intervention and applications research and parallels the model followed by basic and applied biomedical research. Such a unit on fundamental behavioral science is needed to develop theoretical models, identify underlying mechanisms and principles of behavioral change, conduct pre-intervention research to inform the next generation of cancer control interventions and social policies, and develop models, methods, and measures for optimal application of various electronic communications approaches to cancer communication research and cancer control research. Although these research areas sometimes overlap with the research programs of other NIH institutes, they are essential to cancer control.

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Create a Research Focus in Informatics and Communication

The revolutions in electronic communications and informatics opens up vast new possibilities for enhancing the cost-effectiveness of cancer control activities. Although past NCI research has focused on particular aspects of communication, for example, in health education, and although impressive cancer communications services are offered by agencies such as NCI, a strategic, systematic, coordinated and outstanding research emphasis in this area has been lacking.

Communication is central to effective cancer control across all phases of the carcinogenesis process, from primary prevention to survivorship. New knowledge about effective interventions, both biomedical and behavioral, are emerging at a rapid pace and appropriate information about best practices needs to be efficiently disseminated to enhance decision making. Health care providers, cancer patients, the general public, NCI, other federal agencies, health care systems, and schools are some of the target audiences for cancer communications. These communications can be targeted for greater effectiveness and, in some cases, prepared for electronic dissemination, as a means to enhancing access.

Research has shown that it is especially important to tailor communications to the profile of the target audience. A tailored message incorporates targeting but provides an individual level of customization over and above the group level of a defined population. Messages must be sensitive to sociodemographics, culture, and ethnic background. Moreover, communication must lead to action, ranging from improved strategic planning and accountability, to changes in individual and collective behavior. Audiences need access to relevant collections of facts, decision rules about how to use the factual information, and strategies and skills necessary for taking action. The reliability and effectiveness of electronic communication and informatics must be tested through rigorous research if they are to make a meaningful impact on reducing the cancer burden. In particular, the use of electronic communication as a means to inform special populations and provide access to tailored information deserves special attention at a time when there are still large segments of society with no access to computers and the Internet.

A computer information system for cancer control research is defined as one that mimics the deductive or inductive reasoning of human experts. The essential components of a computer expert system include: (a) access to a collection of facts (data base) within a particular domain; (2) decision rules pertaining to those facts; and (3) a strategy for making decisions based on the facts and rules. Many conventional educational messages about cancer, such as booklets and pamphlets, are designed to reach as wide an audience as possible. They are often lengthy and contain information not responsive to the needs of many consumers, using standard communications in a "one size fits all" approach to health education. Computer expert systems allow sophisticated tailoring of messages to individuals free of irrelevant information. New technologies permit the power of mass communications and dissemination to a large target audience with the individual attention and specific information that approximates the personal tailoring provided by a health professional.

A few studies have tested the efficacy of electronic communications to tailor messages. The revolution in electronic communications and informatics opens up expansive new possibilities for enhancing the cost-effectiveness of cancer control activities. Recent research has shown that personalized tailoring of cancer-relevant communications to individual needs can enhance desirable behavior change. Although research has focused on particular aspects of communication, for example, in health education, and although impressive cancer communications services are offered by agencies such as NCI, a strategic, systematic, coordinated and outstanding research emphasis in this area has only recently begun to take hold.

Within the NCI Office of Cancer Communications (OCC) is the Cancer Information Service (CIS), established in 1975 to disseminate and interpret accurate and timely information regarding the causes, prevention, detection and treatment of cancer to cancer patients, health professionals, scientists and the general public. CIS conducts significant outreach, with a network of 19 regional offices responding to over 500,000 calls per year. Some OCC programs are interactive and tailored, however, many are largely passive and reactive, in that they wait for motivated individuals to contact

them. Research on these programs has been mostly descriptive. Recent funding of a program project grant of collaborative CIS and extramural researchers, however, can serve as a prototype and is an excellent illustration of the possible advantages of a research driven CIS program.

Computer expert systems can be proactive, reaching out and penetrating chosen target audiences and allowing for sophisticated tailoring of messages to individuals. These technologies retain the power of mass communications but with the capacity to provide personalized, specific information, as well as cost-effective dissemination. But they must be studied for their potential use in cancer control efforts. Research in health education has described essential elements of delivering a desirable message to a given target audience, via a particular medium and mode of delivery. However, the generalization of these research findings to electronic communication is unknown. Only a few studies have evaluated the ability of electronic communications to tailor messages to cancer-specific topics. Several recent randomized controlled trials have focused on smoking and diet interventions, comparing computer expert systems to standard cessation, with promising short-term results regarding the former. A few studies have examined tailored messages for older smokers, but, in general, studies have been limited to samples of convenience (e.g., audiences with higher education and income, motivated volunteers) which further limit generalizability. Many parameters of tailoring have not been tested, including basic questions about the level or degree of tailoring necessary to achieve specific outcomes, and the importance of differences in modes and methods of delivery (e.g., mail, telephone, or interactive multimedia). Few studies have attempted to perform outcomes analysis or conduct internal validity checks to ensure that the intervention was delivered as intended. Data on cost of development, cost of implementation, and cost-effectiveness of outcomes are also lacking.

Aside from personal interactive communications, computer information and decision-making systems specific to cancer control can play a significant role in many other areas, including: (a) tracking in real time aggregate community or state-wide data; (b) encouraging lifestyle change in school health education curricula; (c) assisting in medical management systems by, for example, monitoring best preventive practices; (d) as part of an integrated electronic medical record, providing primary care physicians with reminders about when preventive health tests are due and patient history information relevant to interventions.

Computers can assist in many aspects of the cancer treatment decision making process, for example, where complex tradeoffs between surgical and medical treatments and quality of life depend on specific information that neither patients nor physicians may have readily available. Interactive multimedia-based systems can first assess the patients knowledge base and then provide individually tailored health information to assist in informed decision making. Computers can also be used for cancer control research in worksites, hospitals, health delivery systems, communities, and schools.

Recommendations

The Review Group makes the following specific recommendations to capitalize on opportunities in the area of electronic communications and informatics.

- Develop and fund research on the application of communication and informatics for cancer control among diverse constituencies and across the entire range of interventions, from prevention to survivorship.
- Collaborate with CIS in areas such as: (a) evaluating mass media campaigns in terms of penetrance into a population; (b) use of CIS to conduct "natural experiments," such as the impact of tobacco legislation on motivation and successful cessation; (c) collaboration with appropriate organizations to reach underserved populations; and (d) linking the resources of CIS with NCI-designated cancer centers, Community Clinical Oncology Programs, and others involved in detection, treatment, rehabilitation and survivorship to take advantage of recruitment, intervention, and follow up of patients in clinical trials, or survivors.

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Establish Programs that Recognize the Role of Behavioral Prevention Throughout the Lifespan

Research on primary prevention of cancer is necessary to: (1) reduce risk-related behaviors (e.g., smoking, low consumption of fruits and vegetables, unprotected exposure to sunlight, physical inactivity); and (2) reduce exposure to potential exposures that increase cancer risk (e.g., to environmental tobacco smoke, occupational carcinogens). Primary prevention research spans the full range of phases of investigation, from methods development and testing, to randomized controlled efficacy and effectiveness trials, to research on effective dissemination methods and policies. This research is designed to bridge the gap from laboratory and clinical research to population-based research, and thus provides a means for effective application of epidemiologic findings about cancer risk to cancer control within communities.

NCI has taken aggressive steps to implement cancer prevention and control measures to reduce cancer risk. For example, among its objectives are the reduction of average consumption of fat to 30 percent or less of calories, the increase in average consumption of fiber to 20 to 30 grams per day, an increase in servings of fruits and vegetables to 5 or more per day, and the reduction in the percentage of adults who smoke to 15 percent or less. The knowledge base regarding behavioral risk factors for cancer is sufficient, if put into practice, to markedly reduce cancer morbidity and mortality. What is needed is research that translates epidemiologic findings into effective interventions targeting behavioral risk factor change and reduced exposures

to carcinogens.

The goals of primary prevention research are the identification of effective methods for changing individual behaviors associated with cancer risk and effective methods to reduce exposure to potential exposures that increase cancer risk, and to discover the essential components for effective dissemination of effective behavior change within populations. The Review Group recommends that the new Division focus on two areas of primary

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Tobacco Control

Tobacco control is the most effective way of reducing deaths from cancer. The proposed settlements between the states and the tobacco companies offer a vital new opportunity for reducing tobacco use. Additional recent social and policy changes—ranging from increasing restrictions on smoking in public places, to increased taxation, to restrictions on youth access to tobacco—have further contributed to reductions in smoking and decreases in its social acceptability. Novel developments in pharmacologic treatments, such as nicotine replacement therapy, offer new approaches to successful smoking cessation. Taken together, these dramatic changes represent a critical window of opportunity for research aimed at reducing tobacco use.

Among youth, tobacco use continues to rise. Although effective interventions have been developed, their efforts tend to diminish over time as a result of competing messages and lack of booster programs. Few effective interventions are available for youth most at risk, such as those from low-income, less-educated families.

Particular attention needs to be given to developing effective interventions for children at early ages, when influence from adults is likely to be most effective. Attention must also be paid to children's social contexts influencing tobacco use, including parents, schools, and communities.

The reorganization of NCI provides an opportunity for interdisciplinary research among psychologists and economists in the development of behavioral theories to explain the use of tobacco by youth. Such theories, which account for incentives, regulatory constraints, and substitutability among consumption goods in the production of utility, could provide the rationale for behavioral interventions and empirically testable hypotheses.

Growing evidence supports the benefits of system-wide changes for tobacco control. For example, the American Stop Smoking Intervention Study (ASSIST) is implementing comprehensive tobacco control programs, including tobacco policy initiatives, in 17 states. Preliminary indications demonstrate the potential success of ASSIST. After 3 years of intervention, consumption of cigarettes was 7 percent lower in ASSIST states than non-ASSIST states, and ASSIST states raised the average price of cigarettes by 12 cents relative to non-ASSIST states. Recent changes in attitudes,

policy initiatives, and other social changes, present an important opportunity for the next phase of tobacco control research.

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Other Areas of Primary Prevention Research

Numerous investigator-initiated studies have tested the effectiveness of population-based cancer prevention and control interventions in an array of settings, including entire communities, and through health care providers, worksites, schools, churches, and the media. This research focuses on an array of behavioral risk factors, including diet, physical activity, and sun exposure, as well as environmental exposures. The progress and results of these trials underline several important accomplishments. For example, taken as a group, the "5-a-Day for Better Health" interventions, which focused on identifying effective methods to increase fruit and vegetable consumption, suggest that interventions targeted through specific channels, such as worksites or schools, can effectively increase fruit and vegetable consumption. This program also supports the feasibility of a public-private partnership and provides a useful model for other translational research initiatives.

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Primary Prevention in Youth

Research on dietary habits starting in childhood is needed to better understand primary prevention of cancer. There is little published evidence that tracking encompasses major life transitions (i.e., that behaviors learned in early childhood set the pattern for a life-long lifestyle). Preliminary research highlights the influence of environment, general parenting and socialization behaviors, target behaviors, and persuasion in designing primary interventions in children, but more research is needed to assess family influence, psychosocial predictors of children's health related behaviors, diet and physical activity interventions in schools, and the effect of comprehensive school health programs.

Skin cancer prevention research studies in childhood populations have been conducted at the preschool, primary, and secondary school levels to test the effectiveness of different interventions in changing sun protection behaviors, knowledge, and attitudes among children. In addition to school interventions, community and worksite interventions have been designed to promote sun protection awareness and behaviors among parents of newborn and young children. Interventions have included sun safety curricula and media campaigns. While interventions have been successful to date in showing increases in knowledge and modification of attitudes, few have demonstrated change in sun protection behaviors. Future research needs to focus on year-round institutionalization, promotion of change in policy or physical environment, social environment, the health care setting, and care givers.

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Primary Prevention in Adults

As the American population ages, opportunities for primary prevention remain important. Insufficient research has been conducted into changing lifestyle behaviors in the older years (50 plus) although it is known that smoking cessation has beneficial effects at any age. The benefits of dietary modification in later years have been demonstrated in colon cancer prevention studies and are under study in women's health projects. The research strategies for initiating and maintaining diet modification needs to be extended beyond the "5-a-Day" initiative, across population groups (including high risk and special populations), and encompassing multiple social structures (family, worksites, community points of exposure such as restaurants, stores, and marketing campaigns). Physical activity levels are modifiable throughout the lifespan and physiological/disease preventing benefits have been demonstrated. Behavioral intervention research largely has been focused in cardiovascular disease in healthy or at risk populations.

Clinical research on primary prevention in both adults and youth will also contribute to our ability to reduce cancer morbidity and mortality. For example, it is well known that there is individual genetic variation in the metabolism and detoxification of carcinogens in tobacco and diet. Such knowledge can lead to the targeting of prevention interventions to those individuals who are most susceptible.

Primary prevention research must encompass the full range of research phases. Methods and criteria for moving to large-scale, population-based trials must be defined (see Appendix A). Population-level interventions must be judged according to their public health significance, not their clinical relevance. Relatively small changes at the individual level contribute to large benefits at the population level.

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Recommendations

Building on the successes to date, there are numerous opportunities to make important advances in primary prevention, including the following:

- Create a Tobacco Control Program as a separate and distinct entity in the new Division of Cancer Control and Population Science.
- Appoint a Tobacco Control Chief to assist in developing a research-based tobacco control plan for the nation, including seeking the orderly transition of proven interventions, such as ASSIST, into public health policy and broad community dissemination.
- Support the development and testing of interventions tailored to the specific needs of populations with high prevalence of behavioral risk factors, including those with lower income and lower education, and some ethnic groups.
- Evaluate the impact of policy and other system changes on risk related behaviors and reduced exposures to carcinogens (e.g., tobacco policy and regulation). Research is needed to identify effective policy and systems

changes that may influence both behavioral risk factors as well as potential environmental and occupational exposures to carcinogens.

- Increase the focus on interventions with children and youth, in order to establish preventive behaviors for the next generation.

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Increase Integration of the Support for Cancer Screening Research

A high priority area for cancer control research with promising returns on investment is screening. Screening has always been important because the stage at diagnosis is the best predictor of survival from cancer. For many of the major cancers, overall survival rates depend critically on the proportion of cases diagnosed in local stage. This is because 5-year relative survival rates are over 90 percent for local disease and below 25 percent for disease which has metastasized. In addition, quality of life is better in cancer survivors whose disease is diagnosed early and who receive treatment specific to their tumor.

With recent technological advances in molecular biology, screening includes the identification of markers for inherited disease susceptibility, and markers for gene alterations suggesting the development of disease, as well as markers of existing disease. These have important implications for cancer control research because they allow the targeting of interventions based on genetic status. The more that is understood about the fundamental properties of a tumor cell, the more likely it is that an effective intervention can be identified.

By definition, screening is performed in asymptomatic individuals, including cancer survivors who are at particularly high risk of new primary tumors. Research on cancer screening requires interdisciplinary collaboration among laboratory scientists, clinicians, epidemiologists, biostatisticians, and behavioral scientists. There are both adverse and beneficial effects of screening, including psychological as well physical and monetary effects. For example, the ability to identify cancer very early in the disease process may lead to unnecessary treatment unless methods are also found to predict outcome in the absence of treatment and in response to specific treatments. On the other hand, identification of individuals at elevated risk due to genetic or environmental conditions will soon make selective screening potentially cost-effective, and diagnostic tests will be developed which will provide information about the fundamental properties of a tumor cell so that treatment can be targeted.

There have been some notable screening success stories. Significant progress has been made in the areas of cytology for cervical cancer and imaging techniques for breast cancer. Most women have become users of mammography during the last five years, and screening has high visibility with the public. Techniques for early detection of other major cancers such as prostate and colon cancer have been identified and are being evaluated, and exciting recent discoveries have been made with respect to screening for cancer susceptibility. Genetic markers for predisposition to several

important cancers, including breast and colon cancer have been identified and are becoming available to the public. Genetic markers associated with risk-related environmental exposures have also been identified.

Research on screening is challenging because it takes place at the intersection of behavioral and biomedical science and targets the transition between health and disease. A research infrastructure already exists which includes the SEER cancer registry, the Cooperative Trials, including the Community Clinical Oncology Program (CCOP) network of collaborating clinicians, and ongoing trials such as the Women's Health Initiative and the Prostate, Lung, Colon, and Ovary Screening Trial, as well as proposed initiatives, such as the Cancer Genetics Network. In addition, methods have been developed to provide tailored communications to patients and their physicians to promote effective use of sophisticated screening technologies. These are valuable but insufficient to support screening research in the coming decades.

The best ways to apply screening tests in practice are also largely unknown. Efficient strategies will be needed for using tumor protein markers and markers of gene alterations to identify the presence of disease as early as possible in the disease process. Methods will be needed to measure their performance characteristics, their value to treatment and prognosis, and their value to society when they are used in various ways in different populations. Changing systems of medical care delivery are introducing new opportunities to use HMOs and other payer systems to conduct population-based research on screening and early detection. Networks of primary care and other physicians are potentially a powerful tool for dissemination of screening technologies as well as research on new screening approaches. Randomized controlled trials (RCTs) to evaluate them are necessarily large, long, and expensive. Mechanisms are needed to decide when a RCT is justified. A strong biometry group in the new Division of Cancer Control and Population Science will ensure the development and application of such methods.

Of concern as well is that the diffusion patterns of detection and diagnostic techniques may not be optimal, resulting in overuse of some technologies and under-use of others, particularly by subgroups of the population. The development of methods to evaluate the applicability of the tests in practice may lag behind the scientific and technical discoveries themselves, leading to inappropriate application and controversy regarding use. Overall, the potential of existing screening technology is not being realized. Methods are needed for identifying barriers to use of effective screening modalities, reaching underserved populations, ensuring adherence to recommended screening regimens including maintenance of repeat screening, and promoting physician-patient communication and informed patient decision-making. Advances in behavioral theory and informatics have made it possible to tailor messages to special population groups, including underusers of effective screening technologies. A strong behavioral science group in the Division of Cancer Control and Population Science is critical to the realization of the opportunities now available through advances in informatics and molecular diagnostics.

Investment in new and better cancer screening techniques should be a high priority for cancer control research and throughout NCI, with at least as much emphasis on protein markers of tumor cells as on diagnostic imaging in order to realize the full down-staging potential of molecular diagnostics. An important function of the new Deputy Director is to ensure that appropriate interdisciplinary collaborations take place and that the goal of cancer control is integrated in the process of scientific discovery throughout NCI.

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Recommendations

- Ensure that the new Deputy Director coordinates research on cancer screening throughout NCI.
- Base screening research in the new Division of Cancer Control and Population Science and assure access to clinical cooperative groups as well as to a critical mass of investigators with expertise in biometry, outcomes research, and basic and applied behavioral science.

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Create a Research Focus on Rehabilitation and Survivorship

More than 1.2 million Americans are diagnosed with cancer each year, and approximately 7.4 million are currently living with the disease. Most of them have completed their primary therapy and are either in remission or are cured of their disease. Yet these survivors face a vast spectrum of physical and psychosocial sequelae, many of which are iatrogenic. Second cancers are now the sixth-leading cause of cancer deaths. Adverse treatment effects upon major organ systems, cognitive function, and quality of life have been documented and are likely to increase as treatments become more aggressive. Debilitating fatigue, for example, is a persisting complaint of the majority of cancer patients long after treatment has been completed. The emerging set of life-limiting and life-threatening problems of cancer survivors is in need of research aimed toward prevention where possible, and intervention/rehabilitation when not preventable. The large and increasing number of cancer survivors, and their increased organization and advocacy over the past 10 years provides an opportunity to push forward. The combination of known and unknown burdens experienced by these survivors is considerable, and not matched by current NCI resource allocation relative to other aspects of the nation's cancer burden. Palliative medicine must be viewed as the completion of comprehensive cancer care, not the converse.

Although there has been little program emphasis aimed at helping the millions of people surviving cancer, during the early 1990s the NCI Division of Cancer Prevention and Control issued several important Requests for Applications that focused on the needs of cancer survivors, such as pain management, quality of life assessment, and psychosocial research in younger women with breast cancer. While

this provide one mechanism for addressing the needs of survivors, it and the other modest efforts carried out by NCI have fallen far short of addressing these needs.

As a result, the Review Group recommends that a clear mandate be given to the new Division of Cancer Control and population Science to conduct research on the identification, prevention, understanding, and treatment of the problems experienced by individuals surviving cancer. This research will require that a significantly larger proportion of available cancer control funding be devoted to cancer survivors. In spite of the Review Group's endorsement of the pre-eminence of early detection and screening, and with the full realization that all quality of life problems experienced after cancer are not due to the cancer, the Review Group recommends specific program emphasis in rehabilitation and survivorship. In fact, the growing number of cancer survivors may require a continually growing investment in this area of research.

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Recommendations

The Review Group endorses the placement of the Office of Cancer Survivorship in the newly created Division of Cancer Control and Population Science and recommends that, as part of its mission, it:

- Conduct research on how to best quantify, prevent, and treat physical and psychological symptoms that result from cancer and its treatment, including fatigue and pain.

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Establish Links to Various Health Care Delivery Systems

There has been a major upheaval in its health care delivery system in the last decade with the rapid growth of managed care organizations (MCOs). Health maintenance organizations (HMOs) and other MCOs now cover a major proportion of all insured persons in this country and thereby present obvious challenges and opportunities for the conduct of cancer control research. By the year 2000 as many as 100 million people will be insured by some system of managed care. Understanding these systems of health care delivery and how to work with and within them is a new opportunity for cancer control researchers and a new and exciting element of the research agenda. In particular, the advantages of having a large, defined, and accessible member base lends itself to an epidemiologic perspective and the conduct of clinical trials in treatment and prevention. There are many similarities among the purview of managed care organizations that are oriented to their population base and the traditional roles of public health departments. Likewise, new challenges are presented in the realm of health care policy as interventions of proven efficacy in reducing the cancer burden require research on implementation within these large health care systems.

Changing health care delivery systems explicitly recognize the importance of defined populations, information systems, and the evaluation of quality of care and performance—a recognition which can have important implications for cancer control research. In addition, there is the emergence of a culture of "accountability" and an emphasis on "value added" in the provision of all forms of health services. General national concerns about the cost and quality of medical care and the crucible of the managed care environment provide a specific challenge to cancer control. Research on access to care, cost-effectiveness, medical care outcomes, diffusion and dissemination, and health care policy are all highly relevant in the new health care environment and efforts are needed to align the delivery system with a rigorous cancer control research program.

Current NCI programs have supported research in this area in several ways. Behavioral research has made an impact in these settings in developing interventions to control pain and nausea in persons with cancer, in developing family social support systems, and in promoting lifestyle changes in the context of treatment and follow-up. Successful cancer control research in HMOs, supported by NCI's Division of Cancer Prevention and Control, include those that use the defined HMO population for its epidemiologically advantageous characteristics, as well as those that evaluate health care delivery and primary prevention interventions. Likewise, studies of the costs of cancer care in HMOs and other activities of the NCI Applied Research Branch have provided useful data and have demonstrated the value of collaborations between NCI and HMO investigators. However, NCI has not clearly embraced health services research related to cancer as part of its mission.

Clinical trials successfully carried out in community settings by the CCOP program are now finding application in managed care settings and represent a major resource for cancer prevention and control studies. Recognizing that managed care organizations and community coalitions have access to defined populations, including survivors and primary care physicians within the community, the Review Group believes that NCI should experiment with a variety of organizational arrangements in the development and implementation of community-based behavioral prevention and control trials. These arrangements should utilize the existing CCOP mechanism and include direct affiliation with various types of managed care and community-based organizations willing and able to develop research activities appropriate to populations at risk.

Technological advances in informatics are highly integrated into most large managed care settings. This presents a real opportunity to define and pursue research issues in dissemination through building state-of-the-art capacity in medical informatics related to cancer control. Support is needed for research on innovative uses of technology that provide cost-effective methods to assist in the delivery of preventive services in general and cancer prevention services in particular.

As interventions to lower cancer incidence and mortality have been identified and tested over the past decade, interest in their relative cost-effectiveness has grown.

Managed care organizations are particularly good environments in which to study the cost-effectiveness of cancer control interventions because of their defined populations and data systems describing physician and patient behavior and the costs and outcomes of prevention, screening, and treatment interventions. If properly linked to new activities of the SEER program, methods could be developed to measure years of life saved (YLS), costs, and quality of life (QOL), and to estimate quality-adjusted years of life and costs over the lifetime of an individual.

The development, implementation, and evaluation of the quality of care as measured by health processes and outcomes is a new area of research that is still being defined. Such measures are complex and require understanding of the different perspectives involved, including those of patients, individual providers, medical groups, treatments, health plans, institutions, and systems. True outcomes measure biologic or health consequences of health care, but measures of the process of health care and structural aspects of systems are also used. Research is required to define the best outcomes for cancer prevention, early detection services, and treatment outcome, and to seek standardization of these measures in an effort to facilitate comparison.

While most of the examples of successful cancer control research have been from the older, established research units in group- and staff-model HMOs, more recent collaborations between academic medical centers and network model managed care organizations demonstrate the potential for cancer control research in the for profit sector. Implementing the results of cancer control research into health system operations, however, remains a challenge of planning and dissemination, itself a topic of critical research.

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Recommendations

Features of cancer control studies that are important to pursue in the new health care environment include:

- Support research on large-scale interventions within health care systems to introduce or improve the delivery of cancer prevention and control services, not only for those who seek medical care, but to the broader insured population for which they are responsible.
- Strengthen the in-house research capability of NCI in applied cancer control research. This requires including health services and health policy research as part of the perspective of cancer control. Additional professional expertise in the area of health services and health policy research are needed.
- To facilitate the development of behavioral prevention and control research relevant to community-based activities: 1) explore within the Community Clinical Oncology the development of new organizational constructs, including a cancer control cooperative group; and 2) revise existing guidelines and incentives for behavioral prevention and control trials within existing

Expand Cancer Surveillance and Produce a "Cancer Report Card"

The National Cancer Act of 1971 mandated surveillance of cancer incidence, diagnosis, treatment, and survival within the United States. The Surveillance, Epidemiology, and End Results (SEER) program was created in 1973 as the major tool of surveillance, and has been appropriately located within the current Division of Disease Control and Prevention. The SEER program collects incidence, diagnostic, treatment, survival, and demographic data from patient medical records for about 14 percent of the U.S. population. Data collected are of high quality and have been used nationally for reports on cancer patterns in many populations over time, and through data linkages to costs and patterns of cancer care. The SEER program has also built an infrastructure in the 11 geographic areas where the data are collected to maximize its utilization for local reports and information, and for patient identification to facilitate data collection for epidemiologic, cancer control, and genetic studies.

Though the SEER program collects and produces reports on most of the data mandated by the National Cancer Act of 1971, today additional measures of the total cancer burden are needed to measure progress in reducing this cancer burden and to allow NCI to properly plan and evaluate its research agenda. The opportunity exists to use an existing infrastructure (SEER) to collect more complete data to create an expanded "cancer report card" for the nation. To capitalize on this opportunity, the Review Group noted areas of surveillance where data are needed and resources are required to appropriately analyze and disperse the data and to produce the report card.

SEER data are collected from 11 geographic areas in the U.S. and adequately represent (and even over-represent) most subgroups of the population. However, the Review Group suggests that the SEER coverage be expanded to include several populations not adequately represented: Appalachia; the rural south (with emphasis on African Americans); Native Americans; and Hispanics from Cuban, Puerto Rican and similar ancestries.

Data collected by the SEER registries have been almost exclusively collected from medical records. Additional data exist and additional data resulting from molecular genetics increasingly are becoming available in these records and are needed to characterize the cancer burden, aid in prognosis, and provide data for research. The Review Group suggests that, at a minimum and perhaps on a sampling basis, SEER should add the following information from the medical record:

- data regarding relevant biomarkers as they become available for measuring success in early detection and outcomes
- availability of tumor tissue for genetic epidemiologic studies
- co-morbidities as these influence diagnosis, treatment, quality of life and often

outcome

- cancer recurrence to study cancer aggression and treatment success, and
- type of payment and medical care which affects access to care, treatment, and follow-up.

The Review Group also suggests that efforts be made to collect data in a more timely manner by use of electronics and other efficiencies.

In addition, perhaps on a sample basis, data not available in the medical record should be collected directly from patients, such as: 1) behaviors prior to diagnosis, e.g., tobacco use, diet, exercise, environmental exposures, screening, and family history of cancer, and 2) morbidity data such as physical and emotional functioning, and other factors that may be mediators in the cancer outcome and contribute to quality of life of cancer patients and survivors.

An ongoing review group is needed for strategic planning to consider discontinuing collection of irrelevant or incomplete data items and to consider new data elements and repositories that might be added to the current databases. This group needs to be aware not only of research and patient needs but of market-driven forces, such as managed care and informatics, to collect relevant data for surveillance of current and future cancer burden and outcomes.

The Review Group also recommends that factors associated with cancer risk be collected from the general population. This can easily be done within the SEER areas utilizing the existing infrastructures, but also should be done in the SEER areas so risks can be directly related to incidence, mortality and morbidity, and accounting for time differences between exposures and disease. Data collected should include risk behaviors, health seeking patterns, patterns of health care delivery, public health programs messages and policies, and environmental exposures on the population level. These need to be collected so estimates can be made for appropriate sub-sets of the population (e.g. underserved, high-risk).

Since new data items will be collected, appropriate NCI scientific staff will be needed to analyze the information, and use it for research studies and dissemination. For example, biostatistical expertise will be needed in behavioral, genetic, and social science research methodology; demographic expertise will be needed to create denominators for the new measures of the cancer burden and to analyze and interpret the data, and applied scientists are needed to utilize the data for additional studies. Finally, with the rapid advances in informatics, specialists are needed in this area to facilitate data collection (e.g., automated patient records and record linkages), and to disseminate the information to multiple audiences (e.g., scientists, clinicians, and the public).

Recommendations

- Expand the SEER program to include: additional populations, more data from patient's medical records and patients themselves, and population data from the SEER regions to monitor individual and societal mediators of cancer.
- Use the SEER expanded data and expertise to produce a timely report card on the cancer burden for broad audiences.

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Maintain Strong Support of the Biometry and Applied Research Branches within the Division of Cancer Control and Population Science

Cancer control researchers—as well as basic, clinical, and prevention researchers—depend on reliable data, the collection of which is dependent upon appropriate expertise in study design, modeling, and data analyses. To be maximally productive in reaching the goals of the new Division of Cancer Control and Population Science, the Review Group strongly recommends that the current Biometry and Applied Research Branches be maintained within the new Division. (Similar Branches may also be desirable in the other extra-mural Divisions to provide specific expertise for their research agendas.) These Branches would provide technical skills and support for all research within the Division.

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Biometry Branch

Since its inception within the Division of Cancer Prevention and Control, the overall goal of the Biometry Branch has been to develop and apply statistical and epidemiologic methods in cancer control and prevention. In particular, the Branch has: 1) planned and conducted independent research studies on cancer epidemiology, prevention, screening, diagnosis, and control; 2) planned and conducted methodologic research in biostatistics and mathematical modeling; and 3) provided statistical consultation to the Division, NCI, and other cancer researchers.

This Branch has been very successful and has made substantial contributions to the research agenda of the Division of Cancer Prevention and Control. It has been productive in terms of statistical and scientific publications as well as contributing statistical input to many critical prevention and control projects within the Division. It also possesses many unique sources of expertise in conducting research in cancer screening, large complex prevention trials, and observational studies or surveys. Moreover, the Branch also has been very active in consulting and collaborating with extramural projects, especially those relating to randomized trials of screening and surveillance issues.

The Review Group believes that the expertise that exists within the Biometry Branch

is critical to the research agenda of the new Division of Cancer Control and Population Science. In addition to this fundamental biometry expertise, however, the new Division will need additional expertise in areas such as behavioral science methodology; psychometrics; quality of life; genetics and gene and environment interactions; modeling of impacts of societal mega-trends such as changes in population structures (e.g., an aging population), financing and health care delivery, and informatics; behavioral economics (e.g., pricing and tobacco use among children); cost effectiveness measures; diffusion of information and penetration in different markets (e.g., schools, workplace); and modeling for the report card on cancer.

Thus, the Review Group recommends that this new Division maintain the current Biometry Branch, since few if any statistical groups are so well positioned to have a major impact on its future success. The Review Group also recommends that the Biometry Branch be expanded so that the critical mass will exist to link together and strengthen all the elements of the Division: behavioral science, genetics, epidemiology, screening, survivorship, informatics, surveillance, and applied research. Furthermore, the Review Group believes that to be most effective, this Branch must continue to conduct independent methodologic research and engage in collaborative statistical interaction with extramurally funded projects. This collaboration is essential to the scientific direction and quality of cancer control programs.

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Applied Research Branch

The mission of the current Applied Research Branch is to access the individual, societal, and health service factors that mediate cancer incidence and mortality, directly and indirectly. Much of this work requires an interdisciplinary effort. Conducting the research within an NCI environment, rich in interdisciplinary expertise, is critical.

Staff of the Applied Research Branch are often called upon to provide technical expertise to the Office of the Director of NCI or NIH in response to congressional inquiries. They are also asked to answer a variety of queries about surveillance issues from extramural researchers, federal agencies, medical practitioners, commercial enterprises, and the press. The ability of staff to provide timely, accurate, and relevant information is greatly enhanced by the accumulated background and insights they come from independent analytical research and publishing in peer-reviewed literature.

The unique qualities of the Applied Research Branch include: proximity and collaboration with specialized experts; the rapid translation of basic and methodologic research to applied research methods; development of improved data and methods resources; and the facilitation of the use of those resources within and outside of NCI. These accomplishments are achieved by independent analytic research addressing the areas within their mandate. Retaining this in-house research experience is essential to

surveillance and methodologic research. This research, particularly the development of data and methods resources, in turn benefits the extramural community. Furthermore, the technical and research experience within the Applied Research Branch contributes to the management of those grants and cooperative agreements that require collaboration among extramural and NCI investigators. This Branch has been a model of collaboration with the extramural community and should be used as the prototype for other branches. The Review Group recommends that the Branch be maintained in the new Division of Cancer Control and Prevention Science.

However, the Applied Research Branch and its model of operation need to be expanded to provide input into activities of the entire Division. For example, the Branch is well positioned to study the impact of mega-trends on cancer, such as the aging population, changes in health care delivery and payment (work is already being done in this area), and the changing use of informatics. Past experience suggests that this Branch has the greatest possibility to capitalize on emerging trends to determine their impact on the cancer patient. In addition, applied research is needed related to genetic screening, dissemination of known cancer control information to the public, screening acceptance and barriers, quality of life issues, and survivorship. Models of the impact of cancer control programs on society would also be useful and this Branch might address these issues.

To become more interdisciplinary and to assume additional responsibilities, however, additional expertise from the behavioral sciences, genetics, and related disciplines will be needed in the future. In addition, the Branch must continue its close interactions with the Biometry and Surveillance programs.

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Recommendations

- Maintain and strengthen the Biometry and Applied Research Branches within the new Division of Cancer Control and Population Science.
- Add additional expertise in behavioral, social, genetic, economic and related methodologies to the Biometry and Applied Research Branches.

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Focus Research Efforts on Underserved Populations and Those with a Disproportionate Cancer Burden

Several ethnic and racial populations have disturbingly high incidence and mortality rates, and these differences are even more pronounced for some cancer sites. Reasons for these disparate rates might include the presence of some genetic mutations, but are more likely to reflect differences in environmental exposures, risk behaviors (i.e., tobacco use and diet) and utilization of prevention, screening, treatment, and rehabilitation services. Population segments that experience high cancer rates and/or underserved populations (groups that have inadequate access to high quality cancer

related services) have been identified as "special populations" by NCI. These "special populations" include: Hispanics, American Indians, Alaska Natives, Asian and Pacific Islanders, African Americans, Native Hawaiians, blue-collar workers, rural, elderly, low-income, and low-literacy groups. These populations not only carry a higher burden of cancer but of many other diseases and of societal problems. Achieving better cancer control within these underserved and high-risk populations is an extremely important goal.

Recognizing the need to reduce the burden of cancer in these groups, in 1986 NCI established the Special Populations Studies Branch (SPSB) within the Division of Cancer Prevention and Control. The SPSB was charged with four functions: 1) to plan, develop, implement, and evaluate a program of extramural intervention research, targeted to these special populations; 2) to identify barriers to prevention and control for these groups; 3) to coordinate and maintain networks of researchers, health professionals, and community leaders to facilitate medically underserved populations involvement in research; and 4) to develop a program to recruit individuals from "special populations" to pursue careers in research and to participate in research studies. The SPSB staff size was small and its scientific and experiential background insufficient to build an appropriate program at NCI for these populations. In 1996 there were only seven research-based programs/initiatives in the portfolio of the SPSB and most relevant projects and programs were administered outside the SPSB.

In 1996, the NCI Director created within his office an Office of Special Populations, and all existing SPSB staff were moved to this new Office. The Office was created to provide broad oversight of efforts aimed toward "special populations throughout NCI, and with other Institutes." This office does not have a portfolio of research grants as its function, but rather the responsibility of coordination, communication, and general leadership.

The SPSB, therefore, until July 1997 has existed on the organizational chart of the DCPC but with no staff. With its recent reassignment to the new Division of Cancer Control and Population Science, there is an unusual opportunity to redefine the functions of the SPSB and to staff it with visionary leadership and an adequate number of highly trained staff. The need for research and training associated with "special populations" is greater than ever before as disparities continue to exist in incidence and mortality rates and morbidities and also because these populations are the most vulnerable to negative consequences from the rapidly changing health care system. "Special populations" also may be an important scientific resource because of the rapidly expanding field of cancer genetics. With advances in this field will arise research issues regarding genetic risk and its influence on behavior, and risk communication.

Fundamental research in the behavioral sciences is contributing knowledge as never before to the understanding of concepts such as risk perception, motivation, cognition, learning, compliance, and addiction. It is also contributing to the effectiveness of

interventions in "special populations," such as the use of tailored messages that are culturally appropriate and aimed at the persons position in the action process. There are now great opportunities to build on this knowledge for new research ideas and to use existing knowledge for focused interventions.

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Recommendations

The Review Group recommends the following structural and functional goals:

- Recruit a strong, visionary Chief for the Special Population Studies Branch.
- Provide the Branch with the authority and resources to :

develop a program of extramural intervention research targeted to the needs of underserved and high-risk populations

recruit social, behavioral, and population scientists capable of conducting fundamental and applied research to facilitate the research efforts of extramural investigators

expand the surveillance of risks, service utilization, barriers to cancer care, and measurement of incidence, morbidity, and mortality using SEER and other data sources in an effort to identify gaps in research and the cancer prevention and control needs of underserved and high-risk populations

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Expand Training in Cancer Control Research

Cancer control research requires a trained cadre of professionals with expertise in diverse basic and applied sciences, most notably behavioral and social sciences, and a corps of practicing physicians knowledgeable about cancer control research. Training of cancer control scientists poses special challenges. Cancer control is multidisciplinary in nature. The knowledge base, research methodologies, and available technologies are growing rapidly. Currently, several mechanisms exist for training future generations of cancer control researchers.

For over a decade the intramural Cancer Prevention Fellowship Program has provided two to three years of didactic teaching and mentored research to nearly 50 fellows. The major extramural training mechanisms for cancer control researchers are the T32 Institutional Research Training Grants, R25 Institutional Cancer Educational Grants, and K07 Individual Career Development Award in Preventive Oncology. Little has been done to evaluate the effectiveness and impact of these intramural and extramural expenditures. Importantly, the level of commitment to training in cancer control is woefully inadequate to take advantage of opportunities to reduce cancer incidence, morbidity, and mortality.

The nation's commitment to training cancer control researchers should be expanded, re-structured, and monitored for effectiveness. The next generation of cancer control researchers will need to be trained broadly. In addition to special expertise in defined area(s), they need to understand the vocabulary and utility of cancer biology, quantitative methods, and social and behavioral science in order to interact effectively with collaborators. For example, behavioral scientists in cancer control research should have opportunities for training in biomedical fields such as nutrition, pharmacology and genetic. After completion of their formal training, mechanisms are needed to support acquisition of new knowledge in relevant disciplines beyond the primary research focus of cancer control researchers.

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Recommendations

- Expand the extramural training/education programs in cancer control research and institute systematic tracking mechanisms to follow trainees over time.
- Incorporate cancer control research prevention behavioral research into training programs for clinical and basic scientists.
- Expand the T32 funding mechanism to include some training in cancer prevention and control research.
- Investigate ways to promote the minority training programs to increase the number of applications.

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Appendices

Recommended Methods and Parameters for Conducting Large-scale Cancer Control Trials

The Review Group focused on the interface between large research trials and program application in communities and as broad-based public health policies. NCI should develop methods and limits for conducting large-scale cancer control trials. The Review Group suggests that the following specific criteria be used to determine the appropriateness of funding large-scale and long-lived research trials. Criteria to be used for launching large-scale cancer prevention and control intervention trials should be comparable to criteria applied to initiating other NCI-sponsored large-scale research trials, and may include the following:

- a. Demonstration of solid epidemiologic evidence regarding the association of the behavioral risk factor(s) to cancer risk.
- b. The size, scope, and magnitude of the research is consistent with the cancer burden addressed by the study.
- c. Evidence from earlier phases of research supports the potential

efficacy/effectiveness of the intervention.

d. The study is able to answer questions that cannot be addressed in smaller scale studies. (e.g., prior research points to the importance of community-level changes such as policies, thereby negating the option of randomizing individuals to experimental conditions.)

e. The research design is consonant with the phase of research and the research questions being asked. (e.g., randomization of communities is appropriate for assessing the effectiveness of educational interventions, but may not be appropriate for research on impact of legislation.)

f. Criteria for stopping the trial have been determined, including if results are clearly beneficial and ready for broad dissemination, or if harmful outcomes are indicated.

g. Methods for tracking potential secular trends are in place.

h. The research includes diverse segments of the community, including women and minorities.

An oversight mechanism, possibly a subcommittee of the NCAB and/or BSA, can be established to develop guidelines and monitor and implement this recommendation for all large-scale trials across the NCI, not simply for cancer control research. NCI should also play a role in conducting research, in monitoring and in producing "report cards" on the implementation by others and on the dissemination of empirically established best intervention practices in collaboration with other agencies.

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Program Review Group Process

The Cancer Control Program Review Group met eight times over an eight-month period. The meeting dates were:

- December 4, 1996
- January 15-16, 1997
- February 19-20, 1997
- March 25-26, 1997
- April 27-29, 1997
- May 20-21, 1997
- June 18-20, 1997
- July 23-24, 1997

The Review Group requested and received detailed data on the history, budget, and operations of NCI's cancer control efforts; heard testimony from a variety of NCI personnel; and solicited and received comments in writing from members of the extramural scientific community. The Review Group wishes to acknowledge the following individuals for their presentations during the review process. Their contributions are greatly appreciated.

Faye C. Austin
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The Review Group formed eight subcommittees, each of which took primary responsibility for a set of issues identified by the full Review Group. Issues addressed by the subcommittees were discussed by the entire Review Group at each meeting. A writing subcommittee met in Newport, Rhode Island in July 1997 to draft the report, based on the subcommittee reports. The first full draft was then distributed to the Review Group for its review in July 1997. Throughout the process, the Chair provided periodic updates on the progress of the Review Group at meetings of the Board of Scientific Advisors and the National Cancer Advisory Board.

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