

PHOTOCOPY
PRESERVATION

CANCER PANEL

PRESIDENT'S CANCER PANEL

THE ISSUES

THE STATES:

QUALITY OF LIFE

NATIONAL CANCER PROGRAM
NATIONAL CANCER INSTITUTE

President's Cancer Panel

January 1, 1997–December 31, 1998

**Cancer Care Issues in the United States:
Quality of Care, Quality of Life**

***National Cancer Program
National Cancer Institute***

Table of Contents

	Page
Executive Summary.....	i
Introduction	1
I. Concerns About Cancer Care in the United States.....	2
II. Quality of Cancer Care and Quality of Life.....	7
III. Conclusions	20
IV. Recommendations	23
 Appendices	
A. Meeting Summary: <i>Concerns of Special Populations in the National Cancer Program—Cancer and the Aging Population</i> , July 31, 1997, Ann Arbor, Michigan.	
B. Meeting Summary: <i>Concerns of Special Populations in the National Cancer Program—The Real Impact of the Reduction in Cancer Mortality</i> , September 29, 1997, Bethesda, Maryland.	
C. Meeting Summary: <i>Concerns of Special Populations in the National Cancer Program—The Responsiveness of the Health Care System to the Needs of Special Populations</i> , November 21, 1997, Tampa, Florida.	
D. Meeting Summary: <i>Quality of Cancer Care/Quality of Life—Defining “Quality” for Cancer Care</i> , April 23, 1998, Los Angeles, California.	
E. Meeting Summary: <i>Quality of Cancer Care/Quality of Life—Quality of Life and Survivorship</i> , June 2, 1998, New Haven, Connecticut.	
F. Meeting Summary: <i>Quality of Cancer Care/Quality of Life—Decision Making Based on Quality of Care Guidelines and Their Impact</i> , October 6, 1998, Buffalo, New York.	

Cancer Care Issues in the United States:

Quality of Care, Quality of Life

Executive Summary

For the more than 1.2 million people diagnosed with cancer each year and the 8.2 million living with this disease, high quality cancer care is not a luxury—it is a matter of life and death. At this time, however, there is no professional consensus and considerable public confusion as to what constitutes quality care for the more than 100 types of cancer. Cancer statistics reflect marked disparities in treatments provided, in access to cancer prevention and treatment services, and most essentially, in patient outcomes. Most people in America are not receiving what might be considered the highest quality care.

Efforts to define, implement, measure, and assess quality in cancer care have been stymied by insufficient data, scientific evidence of widely varying rigor, and competing professional, payer, and patient interests. In addition, such efforts have largely failed to consider key aspects of quality, such as the cultural appropriateness of care, quality of life concerns, the effects of socioeconomic status, and the economic consequences of cancer. Most of the literature on quality of care in cancer has not kept pace with current treatment. These problems are complicated by the fact that standards of care for cancer are—as they should be—highly dynamic, reflecting the extraordinary rate of scientific discovery that is transforming concepts of care across the continuum from cancer prevention to end of life care.

We will not be able to improve upon this situation unless appropriate data on all aspects of quality are gathered. Optimally, this evidence will come from findings from randomized controlled trials. It also must be acknowledged that it will derive from less rigorous forms of evidence such as published expert consensus, observational studies, anecdotal reports, and local “best practices.” All of the available evidence must be evaluated based on scientific methodologies acceptable to all stakeholders—those who provide, receive, and pay for care.

Clinical practice guidelines chart paths to achieving standards of care and as such reflect expectations of quality. To a great extent, however, the current health care environment falls short in meeting expectations of comprehensive, quality cancer care. Increasingly, guidelines themselves, and adherence to them, are being equated with quality, even though they do not take into account all components of quality. Moreover, while many guidelines exist for the treatment of diagnosed cancers, guidelines are lacking in major areas of cancer care, such as prevention, cancer control, rehabilitation, follow-up care, survivorship, and palliative care. Clinical practice guidelines that may flow from definitions of quality care based on evidence available at a given point in time must be updated as clinical advances are demonstrated. Rigid guidelines that pose a barrier to clinical innovation, to effective care, or to reimbursement for such care will endanger patients and impede the progress of the National Cancer Program.

A central focus is critically needed to improve coordination and consistency in the definition of quality cancer care and its implementation in all segments of the population, including the uninsured and other vulnerable populations. As comprehensive definitions of quality and related clinical guidelines are agreed upon, they must be disseminated to

cancer care professionals, payers, employers, and the public. Mechanisms must be established to foster the consistent integration of clinical advances into routine cancer care.

Discussions of quality of care must include consideration of quality of life and how it is affected by a given type of care. Quality of life, which requires increased study, may be judged differently depending on whose life—an individual, a cultural group, or other defined group—is being considered, and who is making the assessment. The patient's perceptions and preferences concerning quality of life must be given greater emphasis in cancer care decision making.

To continue improving the quality of cancer care and quality of life, we must maintain a vital research program, since research findings are the mainspring of advances in preventive, diagnostic, therapeutic, supportive, and palliative interventions. Unless it is completely curative or provides effective control, standard care is never good enough. Research is, and has always been, the source of improvements in cancer care. There is a particular need to address quality issues specific to vulnerable populations, to improve access to clinical trials, to better understand cultural differences that affect the quality of care and quality of life, and to accelerate research on both disease- and patient-oriented outcomes of cancer care.

Steps are needed now to address the many rapidly emerging issues related to defining and providing quality cancer care and improving quality of life. These steps must be taken to ensure that all of the people in this Nation have access to the care best able to prevent and treat cancer, and to safeguard the evolution of care through research—the process by which we achieve continuing advances against the suffering and death caused by cancer.

Pursuant to its charge to identify and recommend remedies to barriers to the optimal development and implementation of the National Cancer Program, the President's Cancer Panel recommends specifically that:

- Considerations of cancer care quality, related both to the disease and to quality of life, must place priority on the welfare of the patient over short-term cost. Cost, while relevant, should not be the arbiter of quality care.
- Definitions of quality should embrace both individual and public health concerns.
- Quality definitions and clinical practice guidelines that may be derived from them must not be allowed to inhibit innovation in cancer care. Guidelines must be updated frequently as clinical advances are demonstrated and must not become barriers to access or reimbursement.
- Concepts of quality should be informed by scientific evidence. In the absence of data from one or more large, well-designed randomized controlled trials, other forms of evidence should be evaluated according to commonly accepted methodologies determined by consensus. Quality evaluations should also take into account quality of life and the economic survival of the patient and family, including employment and insurance ramifications.
- Data are needed in all areas integral to quality of care, including socioeconomic status, cultural values, quality of life perceptions, the impact of cancer on family members, and patient-focused outcomes. These data are needed at the local and regional levels, and for diverse population groups and subgroups of major population segments to support the

development, implementation, and evaluation of tailored interventions to improve the quality of cancer care.

- All of the stakeholders in the definition and provision of quality cancer care—health care payers of all types; research sponsors including government, voluntary agencies, and the pharmaceutical and biotechnology industries; employers; employees and other health care consumers—must bear their fair share of the cost of quality evaluations, guideline development, and the data collection and analysis needed to support these efforts.
- A full spectrum of participants should be responsible for organizing and coordinating the development, dissemination, and updating of cancer care guidelines across the continuum of care, and for the data collection activities that support these efforts. Without a central focus, present issues—the lack of standards for some aspects of cancer care, inconsistent or duplicative guidelines, lack of relevant data to define quality and evaluate guidelines, uneven reimbursement for care, and insufficient communication to health professionals and the public—will not be resolved.
- Health professionals require training to improve their ability to: understand evidence and apply definitions of quality; help patients understand care options; facilitate appropriate patient participation in cancer screening and clinical trials; provide appropriately for psychosocial, rehabilitation, lifelong follow-up, and end of life care; address the cancer care needs of the growing elderly population; and understand, explain, and protect the privacy of genetic information.
- Mechanisms are needed to help patients, their families, and all segments of the public to evaluate cancer care options and recommendations effectively.
- Continued funding across the research spectrum is needed to continue the flow of discovery that leads to improvements in care across the cancer continuum. Efforts should focus particularly on cancer prevention, cancer control, rehabilitation, palliation, and end of life care, and on outcomes research. Behavioral and other research to improve quality of care in vulnerable populations may require targeted funding.
- Greater emphasis and research support should be directed to studies of short- and long-term survivorship issues, including but not limited to long-term effects of treatment, family issues, socioeconomic status, and employability. Contemporary definitions of survival reflecting both treatment advances and quality of life factors are needed.
- Studies are needed to assess whether cancer care quality is being impeded by payer restrictions on appointment durations; off-label use of medications for which growing clinical evidence indicates efficacy; and access to appropriate treatments, oncology specialists, and clinical trials. Identified barriers to appropriate care should be corrected. Coverage of patient care costs for participants in approved clinical trials should be provided routinely.
- Participation in quality clinical trials should be part of the standard of care for cancer. Clinical guidelines should provide recommendations as to when a patient should enter a clinical trial, but should not be permitted to become a barrier to access to such care. Guidelines also must not be used to exclude patient choice of effective treatment alternatives and payers should not erect barriers to such care.

Cancer Care Issues in the United States:

Quality of Care, Quality of Life

Introduction

As the health care financing and delivery system in the United States continues to evolve, concerns persist about the extent to which all segments of our population have access to necessary and appropriate cancer-related care, and about the quality of the care provided in managed care and other health care settings. These concerns, shared by consumers and health professionals alike, are reflected in a growing consumer advocacy movement, in the efforts of cancer caregivers and researchers to provide and measure quality in cancer care in an era of rapid scientific discovery and constrained resources, and more broadly, in proposed patient rights legislation.

The President's Cancer Panel is charged to identify barriers to the optimal development and implementation of the National Cancer Program (NCP); to raise questions and research issues through the solicitation of testimony from leaders in cancer-related medicine, academic research, industry, the advocacy community, and the public at large; and to report annually to the President its recommendations for removing identified impediments and addressing identified needs.

Concern about the quality of health care, including cancer care, is not new. For example, public dissatisfaction with the continuity and comprehensiveness of care under fee-for-service (FFS) systems was, in addition to national health care cost concerns, a major impetus for the growth of health maintenance organizations (HMOs) in the 1970s. HMOs' provision of preventive services, well-child care, and other services responded to some of these quality of care issues. In both FFS and managed care settings, concerns about high hysterectomy and cesarean birth rates have led to changes in the frequency with which these procedures are performed.

While questions about the quality of care have been raised for decades, the overall interest of the scientific community in measuring quality of care and its effect on quality of life has been low. A notable exception is the Institute of Medicine's explorations of these issues since the early 1970s. Recent changes in the health care system, especially the shift to various forms of managed care and increasingly "managed" fee-for-service health financing and delivery approaches, have forced individual and institutional providers of cancer care to confront the issues of health care quality and quality of life in the context of continuing pressure to contain health care costs.

The Panel, as well as numerous public and private institutions, consumers, and advocates, have called repeatedly for improved access to quality cancer care across the diverse communities of America, including greater access to cancer prevention and treatment clinical trials. Detailed recommendations in this regard are contained in the Panel's 1996 report¹. In 1997, the need to define quality in cancer care, the need for current and consistent cancer care standards, and the importance of quality care to cancer survivors' quality of life were recurrent themes in testimony provided to the Panel. It became clear that the time was ripe to assess the current capacity of the National Cancer Program to

¹ President's Cancer Panel. *Fighting the War on Cancer in an Evolving Health Care System*, July 1997.

define and evaluate the quality of cancer care and address cancer-related quality of life issues.

Reliable methods of defining and measuring the quality of cancer care in this country are crucial, for cancer is not one, but a family of more than 100 diseases, for which the scope and breadth of care may differ markedly. The vast majority of cancer care is delivered not in our premier cancer centers, but in varied settings by a wide range of health and health-related professionals to a highly diverse and geographically dispersed population.

Quality is an issue across the full continuum of cancer care—from prevention through the end of life. Moreover, the Panel recognizes that quality is being defined not solely through scientific research and medical practice, but by the perceptions of those receiving the care. This report attempts to reflect this complex current reality².

Section I below highlights concerns about cancer care expressed in testimony presented in three meetings during 1997. These concerns gave rise to the Panel's detailed exploration of quality of care and quality of life issues in three meetings convened in 1998. Findings from the 1998 meetings are summarized in Section II. The Panel recognizes that invited testimony does not carry the weight of empirical study. However, this testimony, provided to the Panel by a cross-section of leaders in cancer research, medicine, and the consumer community, reflects recurrent and emerging research, cancer care, and consumer issues and should not be dismissed as anecdotal.

The final sections of this document provide the Panel's conclusions (Section III) and recommendations (Section IV) for improving the quality of cancer care provided to the people of this Nation. Summaries of the 1997 and 1998 meetings are included as appendices A through F.

I. Concerns About Cancer Care in the United States

The cancer care needs of special populations formed the principal focus of the Panel's meetings in 1997; however, these meetings illuminated quality of care and quality of life issues relevant to all populations. Testimony from 54 speakers at three meetings detailed quality issues as they are reflected in cancer statistics, issues specific to our growing aging population, and current health care system concerns that affect the quality of cancer care and patients' quality of life.

Quality of Care Issues Reflected in Cancer Statistics

At its September 1997 meeting, the Panel reviewed current cancer rates and trends for the most prevalent cancers in various population subgroups. For the first time since cancer statistics have been collected, mortality from all cancers declined, albeit only 2.6 percent, for the period 1991 to 1995. These declines accrued principally to those under age 65, and to men more than to women. In 1999, it is expected that more than 1.2 million new cases of cancer will be diagnosed, and cancer will claim more than a half million lives. Thus, although the downturn in cancer mortality statistics, reflecting population lifestyle changes (e.g., fewer lung cancer deaths among white men due to decreasing smoking rates), earlier

²The Panel also recommends as a reference a complementary effort on this important subject undertaken by the National Cancer Policy Board (NCPB), which offers conclusions and recommendations based principally on a review of the existing literature. See *Ensuring Quality Cancer Care*, Hewitt, M. and Simone, J., eds., National Academy Press, 1999.

detection, and better treatment is highly encouraging, these benefits did not accrue equally to all parts of the population. The continuing, heavy burden of cancer in the United States leaves no room for complacency.

As many of the speakers emphasized, social disparities are linked to differences in health care access that often result in disparities in health outcomes. Cancer statistics provide an essential tool for understanding what these disparate outcomes reflect about relative quality of care and for setting research and health care priorities. The statistics show clearly that vulnerable populations—the poor, elderly, less educated, medically underserved, the uninsured, and some minorities, however defined—bear a disproportionate share of the cancer burden, though there are important variations both across populations and specific cancers. Speakers pointed out that race is frequently a proxy measure of socioeconomic status (SES), which in turn is often a proxy measure of both health care access and the quality of available care. Income and education, important indicators of SES, are also correlated with variations in cancer risk and disease variables, e.g., people with lower income and/or education have a greater risk of dying from cancer. Though extremely difficult to measure, wealth—including assets, savings, and access to family support—may be a better measure of SES than current income. This distinction is important relative to cancer care, since an individual with assets could choose to use them to pay out-of-pocket for care, an option that would be unavailable to another person having equal income but lacking assets.

Speakers also pointed out that patterns of disease and related mortality typical of the home countries of rapidly growing immigrant populations are starting to be observed in the United States. Most of the study of cancer patterns has focused on tracking rising cancer rates in acculturating immigrant populations with historically low rates of certain cancers (e.g., increased breast cancer rates of Japanese and Chinese women with increasing length of residence in the U.S.). The impact of these and other cancer patterns (e.g., high cervical cancer rates among Vietnamese and Hispanic women; high nasopharyngeal cancer rates among some Asian populations) on U.S. cancer statistics and trends must be understood and addressed in the provision of cancer care at all levels, since these patterns are influenced by differences in culture and lifestyle as well as geography. Language barriers and cultural differences in perceptions about the importance of personal health, disease risk, and the meaning of disease all influence the perception and provision of “quality” cancer care.

Continuing high rates for certain cancers, most notably the tobacco-related neoplasms and those linked to obesity (e.g., endometrial and postmenopausal breast cancers), highlight the need for more effective cancer prevention and control interventions, and their wider application in all populations. Improvements have been made, however, particularly in effecting certain population lifestyle changes (e.g., smoking cessation) and in the technologic quality of and access to cancer screening and detection services. These improvements are reflected in the recent declines in cancer incidence and mortality rates, and the diagnosis of certain cancers at earlier, more treatable stages.

At the same time, speakers noted that data (particularly on subpopulations and at the local level) on the use of state-of-the-art treatment and on outcomes are sparse; these data would provide important measures of the quality of cancer care and better monitoring of the cancer burden in these populations. It was recognized that population mobility complicates efforts to monitor cancer in specific populations and the quality of care they receive. It was

also underscored that improving care in Native American and other racial/ethnic communities requires consistent, continued effort and community involvement to overcome mistrust. Unfortunately, most health care outreach efforts, regardless of target population, have been initiated as pilot efforts by research funding bodies. Because outreach services have not generally been reimbursable, they have not been integrated into the continuum of care and sustained.

Quality of Care Concerns of the Aging

Also in 1997, the Panel met to review current statistics on cancer in the elderly; explore specific epidemiologic, genetic, and biologic issues of cancer and aging; and consider the preventive, screening, therapeutic, and supportive care needs of the older population with cancer and at risk for the disease. Our population is aging—by the year 2030, persons over age 65 will comprise 20 percent of the U.S. population, compared with 12.8 percent in 1995. The functional spectrum of the older population is wide, ranging from those who are robust, well-educated, financially secure, and socially engaged, to individuals who are dependent, educationally and financially disadvantaged, and in need of significant care and support.

Currently, the median age at cancer diagnosis is 70 years and approximately 60 percent of all cancers occur in those aged 65 years and older. People over age 65 have a risk of developing cancer 10 times that of younger individuals. The need for cancer prevention and control strategies, cancer treatment, and palliative care for the elderly is already great, and can be expected to increase. Yet speakers indicated that the older population receives less cancer screening, less staging of disease, and less aggressive therapies—or no therapy—simply because they are older.

Older patients generally want and can benefit from cancer screening, but many do not understand current guidelines, and as some speakers noted, because they may have fatalistic views about cancer, fail to appreciate the benefit of finding a cancer at its early stages. The importance of physician recommendation for screening, and the unexploited power of the physician relationship with regard to screening, was underscored repeatedly. To date, we have not strongly targeted cancer screening outreach and education efforts to the elderly. Moreover, screening recommendations may not include older people because they have not been included in studies to determine screening efficacy (e.g., mammography for women older than age 70); these data are needed.

The elderly tend to be underrepresented in clinical cancer research, for reasons that include comorbid conditions; physician assumption of unacceptable treatment toxicity based solely on age; patient reluctance, lack of understanding, or lack of information about clinical trials; lack of physician referral to trials; lack of appropriate trials for the patient's condition; lack of social support; financial barriers; and geographic or transportation barriers. Cancer treatment for older patients is complicated by many of these factors, as well as by the nonspecific presentation of many cancers, potentially decreased physical and psychologic functioning, polypharmacy common to older patients, documented differences in drug metabolism and clearance compared with younger patients, and the potential for secondary complications. Speakers suggested that older cancer patients who do receive treatment in cancer centers tend to have fewer comorbidities (and take fewer medications) than patients treated by community physicians in local hospitals. Speakers also indicated that older patients are more likely to receive treatment in cancer centers or otherwise participate in clinical studies if their physicians are knowledgeable about how to access

information about available trials. Further, some speakers noted that the informed consent process and documentation can be confusing and frightening to older patients, and may discourage those who may be eligible from participating in clinical studies.

Older cancer patients may be referred to hospice or nursing home care rather than being entered into treatment programs, yet presenters indicated that with modification of treatment regimens, older patients can withstand and benefit from chemotherapy and other cancer treatments. In patients whose overall health status is good, such modifications may not be needed. Speakers emphasized that eligibility for various cancer treatments should be based on health status, projected life expectancy, and quality of life rather than age. For example, eligibility for a particular treatment might include the criterion of a five year life expectancy with "reasonable" quality of life; it was emphasized, however, that the patient's view of quality of life should be paramount in this determination. Older patients may also be overtreated because of family and/or physician inability to accept a terminal prognosis.

At this time, data on cancer treatment outcomes for older patients are sparse. As the number of elderly citizens who are survivors of early cancer diagnoses continues to rise, the special needs of these long-term survivors must be met. Medicare coverage for long-term follow-up care, including screening and treatment for second cancers, is a crucial element of quality care in this population.

Testimony presented to the Panel underscored the importance of quality of life for the elderly with cancer, who must measure the risks of treatment against the benefits of survival. As noted above, and as also occurs in other populations, older cancer patients' ideas about what constitutes quality care may differ significantly from those of their physicians, and at times, those of their loved ones. Curative treatment may not be necessary or desired by some older patients, for whom effective palliation and control of the disease may be just as, if not more, desirable.

Palliative and end of life care for older patients is a critical need. In particular, pain control for the majority of older cancer patients (particularly those in nursing homes) remains seriously inadequate. It was stressed that symptom management should extend from initial care with curative intent through the terminal phase of disease.

To better address the many issues of caring for older cancer patients, some medical centers and cancer centers are creating specialized geriatric oncology programs with a multidisciplinary team approach. These programs often have the dual focus of improving disease eradication or control and exploring research questions concerning age-related differences in cancer prevention, etiology, and treatment. Other innovative programs were highlighted, including a supportive care program that combines the goals of the medical model of care (emphasizing disease eradication and prolongation of life) and the hospice model (focusing on symptom relief and quality of life). There is a clear need for training to develop a critical mass of investigators and caregivers to work in these programs.

Health Care Delivery System Issues

At its November 1997 meeting on the responsiveness of the health care delivery system to the needs of special populations, the Panel revisited quality issues as they relate to care provided under evolving health care payer arrangements, in public and private health programs, and in community-based cancer research settings such as the Community Clinical Oncology Programs (CCOPs). These included pharmacy-related problems, such as

the use of non-formulary drugs, limited pharmacist and pharmacy technician manpower, and most importantly, restrictions on the off-label use of drugs in cancer care.

Representatives from CCOPs noted that community physicians tend to refer patients to clinical trials late in the course of disease and often only as a last resort. Reasons for this include physicians' lack of awareness of appropriate trials, bias against investigational therapies, lack of compensation for the increased documentation associated with trials, and fiscally based fear of losing patients.

In addition, speakers addressed more fundamental health care system issues that profoundly affect the current and future quality of cancer care. Chief among these was health care access, including access to clinical trials. Speakers also underscored the importance of adequate research funding to improving the quality of cancer care and quality of life. The research enterprise, and the survival of the academic research centers, is central to continued improvements in care across the cancer care continuum, and particularly for patients with still-intractable and metastatic cancers.

Presenters called for communications strategies and interventions to disseminate research findings to local practitioners to improve the quality of care in the community. Continued research into communications, imaging, telemedicine, other technologies, and behavioral interventions will be essential to improve the quality of cancer care and to extend state-of-the-art care to rural and other underserved populations. Speakers further called for additional research funding to support studies with sufficient statistical power to answer the questions most relevant to various population groups.

Lack of insurance coverage is another central issue affecting the quality of cancer care provided in this Nation. For example, the quality of care—in fact, the provision of any care—to uninsured patients typically treated at public hospitals is in particular jeopardy. Public sector hospitals historically have been major providers of care for the uninsured, but the loss of Medicaid dollars, along with reduced state and Federal funding, is crippling their ability to provide appropriate cancer care to this large and growing population. The private sector and managed care companies are competing for paying patients, including Medicaid and Medicare patients, but there is no competition to provide care to the uninsured. It was also noted that data collection and reporting on cancer incidence, mortality, morbidity, and survival in some underserved or special populations is inadequate to support program and service planning or to evaluate quality of care.

Speakers highlighted the needs of cancer patients at the end of life for hospice care and other services. The quality of care provided to dying patients remains woefully inadequate and is a major failure of our health care system. Dying patients frequently face abandonment by their physicians and inadequate pain and other symptom control when treatment with curative intent is no longer tenable. Further, it has been recognized that we lack adequate language about dying in our culture; in response, the American Medical Association and the Annenberg Foundation have begun taking steps to help physicians develop such language and to better understand and meet the needs of the dying patient. Studies to date on symptom management and bereavement care conducted by hospice organizations have been small and continue to be viewed as anecdotal by insurers. In 1997, however, the Institute of Medicine published *Approaching Death: Improving Care at the End of Life*³; if disseminated widely to the medical community, this document has

³ Institute of Medicine, *Approaching Death: Improving Care at the End of Life*, Field, M.J. and Cassel, C.K., eds. National Academy Press, 1997.

substantial potential to educate health professionals about the needs of dying patients and improve the care provided to them.

II. Quality of Cancer Care and Quality of Life

The quality of care issues that surfaced repeatedly in testimony during 1997 provided the impetus for three meetings in 1998 to explore in detail quality of care and quality of life issues for cancer patients/survivors, their families, and those at risk for cancer. In all, 42 speakers representing the research, clinical, health industry, and advocacy communities provided testimony on issues in defining quality cancer care, the development and use of cancer care guidelines, and the importance of quality care to quality of life.

Defining Quality in Cancer Care

Motivated both by continuing pressure to reduce health care costs and the desire to provide the most effective care, numerous health care organizations and health care practitioners are attempting to delineate when certain care is merited. These detailed descriptions of care are becoming equated with the provision and measurement of quality in cancer care. Defining quality care for the many cancers is made increasingly difficult by the explosion of new knowledge and new interventions. Because of the life-threatening nature of cancer, consumer pressure for any promising new therapy, test, or technology is extreme. For example, tests for newly identified markers, risk assessments, and imaging technologies often become available before they have undergone long-term validation studies.

Textbook definitions of quality care⁴ exist, and quality health care has been defined for certain medical conditions, but it is not clear how these relate to cancer care quality in the United States, particularly considering recognized disparities in cancer care, outcomes, and perceptions of quality. In addition, evaluations of quality have focused largely on the delivery of acute care in crisis situations. By contrast, relatively few evaluations of quality have been conducted for diseases of a chronic nature, such as cancer.

Two basic approaches to quality assessment have been taken. The first approach, employed in most quality assessments to date, relies on professional judgement based on a retrospective review of information judged to be pertinent. However, such assessments have not been systematic or necessarily data driven, even though those conducting them may believe they have reviewed the relevant standard(s) of care. The second approach, reflecting current trends, is a more explicit review involving the use of care standards to assess quality. Yet, to establish standards, quality care for a specific cancer or for care common to all cancers (e.g., supportive care for patients undergoing chemotherapy, end of life care) must be defined.

Structure, Process, and Outcomes

In the literature on quality of care, quality is usually analyzed in terms of its structure, process, and outcomes⁵; however, these dimensions have not been well studied in cancer

⁴ For example, in 1990, the Institute of Medicine defined quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." (IOM, *Medicare: A Strategy for Quality Assurance*, Lohr, K.N., ed., National Academy Press, 1990, p.21).

⁵ Donabedian, A. *Explorations in Quality Assessment and Monitoring: Volume 1: The Definition of Quality and Approaches to Its Assessment*. Health Administration Press, 1980.

care. In many instances, analyses to date have been applied to old data and/or data limited to a narrow range of disease-oriented parameters⁶.

Structure refers to characteristics of the health care system (e.g., number of beds, staffing patterns) or individuals working in it (e.g., provider qualifications and experience, specialty mix) that affect the system's ability to meet the health care needs of individuals or communities. Structure also takes into account infrastructural characteristics of the community (e.g., number and types of facilities, transportation patterns) that impact the health care system, as well as population characteristics such as economic status or ethnicity. Service accessibility is an important element in assessing structure, but speakers suggested that service volume—specific treatment of a given condition in a critical threshold number of patients by the same individual or institutional provider—is perhaps the most significant structural characteristic associated with quality care. In cancer care, the low incidence of particular types of cancer in a particular hospital or health plan challenges meaningful quality assessment at the institutional level, or by cancer site. At the same time, the importance of access cannot be underestimated. It refers not only to the geographic location of services and a person's ability to get to that location to obtain services, but to the ability of the individual to pay for those services, whether through subscription to a private insurance plan, Medicare, Medicaid, another public program, or out-of-pocket.

The *process* of care includes both the technical expertise of the provider and his or her interpersonal skills. Process assessment considers not only whether the provider makes the right choices as to diagnosis and treatment and is sufficiently aware of treatment alternatives, but also whether care is provided skillfully and effectively. Interpersonal measures of quality assess whether care is provided in a patient-focused, humane manner, whether patient preferences are incorporated, and whether sufficient information is provided to support informed decision making. The need for better tools for explaining complex treatment options in the office setting or at the bedside has long been recognized.

Process measures also take into account whether an intervention or service—including referral—is appropriate (i.e., expected benefits outweigh risks), necessary (there is a reasonable chance of patient benefit and withholding care would be harmful or unethical), and adheres to prevailing views of quality care. Appropriateness should be based on evidence, yet testimony underscored current shortcomings in this area. On one hand, proven advances may diffuse slowly and unevenly into routine medical practice (e.g., lumpectomy versus mastectomy); at the same time, certain procedures or treatments may be unproven in randomized trials (e.g., bone marrow transplant/stem cell rescue for breast cancer), yet become the standard of care (or readily available) even lacking such evidence. Fiscal biases toward or against a particular type of care may exist. For example, fiscal disincentives to refer to clinical trials may exist due to anticipated income from local administration of chemotherapy. It also may be difficult to assess the prevalence of unnecessary care (e.g., third-line chemotherapies, unneeded or marginally efficacious surgeries), since such care is seldom studied, published, or publicized, and negative outcomes are rarely reported.

An aspect of appropriateness that may be overlooked is cultural acceptability. Even if services are technically sound, geographically available, and affordable, they will not be

⁶ Schuster, M.A., Reifel, J. L., McGuigan, K. Assessment of the quality of cancer care: A review for the National Cancer Policy Board of the Institute of Medicine, 1998. (<http://www4.nas.edu/IOM/IOMHome.nsf/Pages/NCPB+Reports>)

utilized appropriately if they are culturally unacceptable. For example, it was noted that many Native American women decline to get Pap smears and mammograms because the only available providers are white male doctors. Assuming services are culturally acceptable, patient preferences may vary considerably—some may not want standard therapy, some may find the benefits of chemotherapy insufficient to endure its toxicities, and still others may prefer alternative care.

Outcomes represent the results of the health care delivery process; in cancer the classic outcomes have been mortality, including five year survival rates, and many aspects of morbidity (e.g., complication rates). With the increasing number of cancer survivors, we are now able to examine long-term treatment effects as they reflect quality of care and as they impact quality of life, but it is no longer clear what may constitute appropriate measures of survival. In recent years, due to the growing population of survivors, functional status (i.e., the ability to participate in physical, cognitive, and social activities; sense of well-being; ability to fulfill one's role in the world) and patient satisfaction with care have assumed greater importance in evaluating survival.

Five year survival rates have served as a useful disease-oriented outcome measure in research, but they are not always useful for quality assessment related to structure and some aspects of process because of the long delay associated with obtaining meaningful results. By the time results are available, the treatment environment or facility may have undergone extensive change. More timely measures are needed to inform patient decision making regarding choice of treatment and facility.

It also is important to note that five year survival rates (which typically refer to overall survival, not to disease free survival) can be misleading to patients when they are used inappropriately to support claims of cure. Five year disease free survival may reasonably be equated with cure for some cancers (e.g., testicular cancer, some lymphomas), but this cannot be said for most other cancers (e.g., breast cancer, melanoma). Simply being alive five years after diagnosis may not be enough.

Challenges in Defining Quality Cancer Care

Attempts to define quality differ in cancer from similar efforts in other diseases. For example, in cardiac care, studies of quality often focus on what drugs were given during a crisis event. By contrast, early stage cancer trials may measure only the toxicity of drugs given to patients with advanced disease. Later stage trials may be comparing the best treatment to date versus a potentially more effective, less toxic, and/or more cost-effective option. Moreover, most attempts to measure quality have focused on acute aspects of disease, whereas in cancer care, there is a need to look more comprehensively at chronic disease outcomes.

The evidence used to help define the meaning of quality in cancer care can vary greatly in terms of its scientific rigor, comprehensiveness, and representativeness of the care provided in the communities across America. Evidence may be accumulated from randomized controlled trials (RCTs), the consensus of a particular group of experts (which does not exclude the possibility of bias), observational studies, anecdotal reports, or local "best practices." There is no firm agreement among those making these assessments as to what constitutes acceptable evidence and how it should be evaluated.

In cancer as in other diseases, most care has not been and will not be studied in RCTs. Frequently, variations from "standard" practice become so routine that they evolve into the

standard of care. In addition, not all aspects of care are amenable to study in a RCT. This does not mean that current approaches are the best or that they cannot be supplanted by new scientific evidence. However, resources are limited and research is constrained by various ethical issues that preclude withholding accepted care. A continuing dilemma exists in that expert panels are asked to determine standards of care for various cancers and other conditions, yet their experience may not reflect existing scientific evidence. Moreover, little evidence from high quality controlled studies may exist to support or refute the efficacy of current practice.

Efforts to define (or evaluate) quality also are challenged by lack of documentation or poor documentation in the medical record, particularly related to counseling and discussion of treatment options. This problem is compounded by increasing fragmentation of care across delivery sites and providers, with the result that a patient may not have a single medical record containing all information on his or her care.

Much of the information related to what consumers consider quality of care may not be available to assist in decision making. In addition, what are considered important factors in cancer care decisions may vary significantly depending upon who is making the decision—the patient, the physician, the employer, or the health plan—and for what purpose. For example, some patients may care less about small differences in mortality rates among surgical or other treatment options compared with the level of debilitating side effects or disfigurement of the various options. The physician's communication skills and accessibility may also be part of the patient's perception of quality. Some physicians may equate quality with providing care consistent with current practice or complying with payer guidelines. Others may strive to ensure that patients take into account the latest results from clinical trials and that every possible alternative is explored for the patient.

The patient's employer or other purchaser of care may place more weight on the total cost of care, the associated mortality rates, and policy implications, but not other considerations the patient may value (e.g., convenience and continuity of care). The health plan may be more focused on variations in patterns of care, adherence to standards, and minimizing requests for second opinions. Health plans also want ways to contain costs, and therefore develop standard, predictable ways to measure the cost impact of patient or physician decision making; these concerns may not reflect quality from the patient's perspective.

The value of quality cancer care may differ significantly among the major stakeholders in its provision. For patients, the quality of cancer care received will dramatically affect the quality of their lives, and may mean the difference between life and death. For their families, it may mean the difference between emotional and economic devastation and a return to life's plans and promise. For most physicians and other health care professionals, providing quality cancer care brings professional fulfillment and personal satisfaction. Among health plans of all types, perceptions of quality and its value relative to its cost may differ greatly depending on factors such as the plan's financial stability, turnover in its covered population, and organizational philosophy. Some values associated with quality cancer care, such as long-term worker productivity, may be valued more highly in the aggregate as a national good than by health plans or employers that pay for care for individual patients. At a broad social level (and absent universal health care), tensions are created by the economic considerations of providing a greater good for a greater number (i.e., a population approach) versus providing state-of-the-art care to a more limited number of individuals.

Defining Quality in Cancer Prevention

Cancer prevention is one of several areas of the cancer care continuum in which we need more information to define quality and develop practice guidelines. The realm of cancer prevention includes both public health-oriented lifestyle and other behavioral interventions (a field still in its infancy) and medically oriented surgical and chemopreventive interventions.

One of the largest gaps in the cancer prevention literature is how to consistently produce and sustain lifestyle change, especially in high-risk populations, despite a large number of studies conducted in these areas. This is true for dietary issues, physical activity, smoking, and other behaviors. Although a substantial body of literature exists in each of these areas, each in the aggregate is inconclusive and not well known either to the professional community or the public. The possible exception is smoking, although the need for continued research to better understand and impact changing smoking patterns in some populations is clear. In all of these areas, however, further study is needed to learn how best to communicate research findings about which there is confidence to diverse audiences. In addition, what health professionals and researchers perceive as good quality care may not be what is valued by various populations. For example, telephone counseling is a way of providing care or information, but the limited research has found that various populations tend to be more (e.g., Hispanics) or less (e.g., Asians) comfortable with this method of intervention.

Defining quality care in cancer chemoprevention is centered in the balance between potential benefit and possible risks. Major side effects of cancer treatments are often accepted by patients and physicians because of the life-threatening nature of the disease. Acceptance of medication side effects is lower when medications are employed in non-life-threatening situations, such as estrogen replacement therapy for menopausal symptoms. Tolerance for major medication side effects must be extremely low, however, when drugs are used for prevention-related therapy in otherwise healthy populations. The research and corresponding literature on cancer-related chemopreventive interventions are still relatively sparse. But studies of the risks and benefits of estrogen replacement therapy, for example, have led to lower dosages, use of progestin to protect the endometrium, and a better (though still incomplete) understanding of the value of such therapy for various groups of women. As studies into prevention progress, the definition of acceptable quality of care in chemoprevention will continue to evolve. As in elective therapy, determination of acceptable risk in chemoprevention will need to be decided by the patient in consultation with his or her health professional.

Using Guidelines to Describe and Evaluate Quality of Care

Clinical practice guidelines chart paths to achieving the standards of care. Guidelines for cancer care are being developed and employed with increasing frequency, yet they have significant limitations. Testimony presented to the Panel highlighted a number of crucial issues in current uses of clinical practice guidelines to describe and evaluate the quality of cancer care. These include questions as to who should be involved in developing guidelines, on what level(s) of evidence guidelines should be based, and how guidelines should be applied and updated.

Guideline Development

At this time, multiple guidelines have been developed for the treatment of most cancers. Among the organizations sponsoring cancer guideline development are the American Medical Association (AMA), the Centers for Disease Control and Prevention (CDC), the Agency for Health Care Policy and Research (AHCPR), the Health Care Financing Administration (HCFA), the American Society of Clinical Oncology (ASCO), the National Comprehensive Cancer Network (NCCN), and others. Consumers generally have not participated in developing most of the guidelines now in existence, though their inclusion in guidelines development processes appears to be increasing. In addition, several organizations have developed "report cards" on health care organization performance (e.g., National Committee on Quality Assurance report cards on preventive care services provided by managed care organizations).

Existing guidelines have been established based on varying levels of evidence; as noted above, the existence of evidence from large or multi-institutional randomized controlled trials (RCTs) is relatively rare. In some cases, a guideline has been developed on the basis of a single small RCT. In many cases, guidelines have been established based on the consensus of a selected group of experts (not necessarily consensus of the field in question), with or without evidence from RCTs, observational studies, anecdotal reports, or compilations of local "best practices." Multiple existing guidelines for a single condition may have been developed using one or more of these levels of evidence, complicating efforts to compare their relative merit. It also must be recognized that cancer care provided at a given point in time may reflect the state of knowledge or practice, or the influence of a particular individual or group (e.g., the Halsted radical mastectomy for the treatment of breast cancer prior to demonstration of the equivalent efficacy of more conservative procedures).

Current Uses of Guidelines

Guideline development has been uneven across the spectrum of cancer care, as has the use of existing guidelines. Research, community programs, and analyses of current practice are ongoing; however, few guidelines exist for preventive care, screening, or diagnosis. Guidelines in these areas exist for some cancers, but even these are inconsistent and their use is undermined by insurance reimbursement issues. Controversies about screening guidelines (e.g., mammography screening for younger women, prostate specific antigen prostate cancer screening) have been confusing to the public and have affected reimbursement policies. The majority of guidelines developed to date address appropriate treatment of clinically diagnosed cancers. Some supportive and palliative care guidelines exist (e.g., pain, rehabilitation from head and neck cancer treatment), but they too do not address all of the relevant issues. Those guidelines that do exist have not been systematically disseminated to, or reinforced in, the medical community and therefore are inconsistently applied⁷.

Similarly, long-term follow-up care guidelines are lacking, except perhaps for the follow-up of survivors of some pediatric cancers. It was noted that implementation of these guidelines is difficult, especially in light of health care system changes and resultant limited reimbursement for long-term follow-up care. Loss of these patients to follow-up

⁷ Smith, T.J., Hillner, B.E. Ensuring quality cancer care: Clinical practice guidelines, critical pathways, and care maps, 1998. (<http://www4.nas.edu/IOM/IOMHome.nsf/Pages/NCPB+Reports>)

has been a major impediment to efforts to assess the long-term effects of cancer treatments administered in childhood. Though speakers suggested that follow-up care for adult cancer survivors should be patterned on follow-up guidelines for childhood cancer survivors, the Panel believes such guidelines should be developed based on studies in adult populations. The likely difficulty in implementing such guidelines in the current health care environment was acknowledged.

Ambivalence about guidelines appears to exist—national guidelines are viewed as necessary to help ensure that all patients receive appropriate care; at the same time, the need for flexibility to tailor guidelines to local population characteristics was expressed. This dilemma notwithstanding, speakers emphasized the potential of guidelines to restore authority in determining appropriate practice and return medical decision making to oncologists, other cancer care professionals, and patients.

In some cases, however, guidelines have been developed to help secure insurance reimbursement as much as to define the most effective care. Local cancer care providers, or regional consortia of providers, who have developed guidelines in response to payer pressures to define reimbursable care may be understandably wedded to those guidelines if they have gained payer acceptance. Such practice guidelines may only reflect local or regional practice, and may or may not be in agreement with other existing standards for care of the same medical condition. Speakers emphasized that rather than fostering competition between providers (as sometimes occurs), guidelines must be used in service of the patient—to provide the most effective care, to avoid providing treatment unlikely to benefit the patient, and to recognize when the patient cannot be treated in the community and requires care in a specialized environment such as a cancer center.

Testimony suggests that cancer care guidelines are most likely to be applied in directing the care of well-insured populations in geographic areas with ample numbers of cancer care providers and well-equipped facilities. Those with insurance inadequate to cover the costs of the most sophisticated cancer care and underserved populations treated in public, rural, or other small hospitals are less likely to receive what is considered the most appropriate care. The uninsured may receive no care at all.

Challenges in Using Guidelines

Once guidelines have been developed, they must be disseminated to the appropriate cancer caregivers and a communication and education mechanism must be established to address providers' questions and encourage guideline implementation. It was suggested that feedback and performance accountability at the level of the individual provider is the most effective incentive for guideline implementation.

Speakers noted that to help providers and health plans become aware of existing guidelines, an electronic clearinghouse (www.guideline.gov) has been developed by AHCPR to facilitate distribution of guidelines to those with on-line access. Though an important step in disseminating guidelines, the clearinghouse is only one channel for communicating the existence and value of guidelines. Other mechanisms for diffusing guidelines to the cancer care community and encouraging their implementation are needed.

Many segments of the consumer population are becoming more sophisticated medical information seekers and more demanding concerning the quality of the health care they receive. At this point, however, few if any tools are available to help the public access appropriate care and understand cancer care guidelines. Such tools are badly needed, and

must be developed for people across the spectra of culture and education. Both patients and providers must be instructed in their use. It was suggested that the need to fill this void is all the more pressing given the declining science literacy of the general public, particularly relative to the rapidly advancing molecular, genetic, biologic, and technologic science that is redefining cancer care.

Testimony provided to the Panel underscored repeatedly that efforts to evaluate the impact of cancer care are hobbled by the severe lack of data on the outcomes of care. Outcomes data are crucial to evaluating the quality of care rendered by cancer care practitioners and institutions. Measures of cancer care quality have to date focused principally on easily counted numbers of persons screened, or percent of those screened receiving follow-up care. Disease-oriented outcome data (e.g., cancer incidence, survival, mortality) are essential but may take many years to obtain, and do not paint a complete picture of quality or take into account cofactors such as comorbidities. Measurements of morbidity and other patient-focused outcomes (including quality of life) are only beginning to be done. Likewise, behavioral medicine related to preventive and supportive care is in its infancy, with little data available on the efficacy of interventions. Information on socioeconomic status (SES), education, and other variables that influence access to quality cancer care and perceptions of quality are only starting to be collected on a systematic basis.

To enable physicians, policy makers, and patients to use guidelines effectively, both quantitative and descriptive data on disease- and patient-oriented cancer care outcomes and relevant SES indicators must be collected systematically. As new treatments and technologies are developed, these outcome data will be essential in helping patients make informed decisions about care options. Issues exist, however, as to how such data should be collected and presented in a standardized format, who should be responsible for the costs of outcome data collection and analysis, and how access to personal data will be protected.

Outcomes research and outcomes data also are needed so that cancer care, as recommended by guidelines, can be assessed in terms of its dollar, societal, and personal costs. Determining societal costs may include not just issues of lost or salvaged productivity, but assessments of the fairest and most effective allocation of resources. These relate to value judgements made at the societal and personal levels. Assessments of personal cost may include long-term treatment effects, years of life or productivity lost, quality of life, and financial ramifications for the survivor and his/her family.

Updating Guidelines

Updating guidelines regularly or as advances in the science dictate is essential to prevent guidelines from becoming a barrier to optimal care. This is a huge challenge, since like guideline development, updating requires the extensive involvement of many individuals over months or years. The same issues concerning who should be responsible for developing guidelines, and on what levels of evidence this should be done, also apply to updating efforts. Moreover, the same problems that now hinder widespread and consistent implementation of existing guidelines are likely to be faced in efforts to disseminate and implement each updated guideline.

By appearing to define as the standard of care therapies known to be suboptimal, outdated guidelines block reimbursement, and therefore access, to the most effective cancer care. Such "fossilization" created by guidelines is well illustrated by the need for "off-label" use

of drugs, a continuing issue in cancer care. Clinicians frequently make important new observations that may lead to studies of new uses of existing drugs or new drug combinations. Such innovation has been a major factor in the vastly improved survival rates for childhood cancer survivors. Reimbursement for such drug use, however, is often denied because the new use is not among the indications contained in the original Food and Drug Administration (FDA) approval and is not stipulated in guidelines used by the payer to define what care is reimbursable. Thus, while guidelines have the potential to protect patients from useless or possibly harmful care, they also have the potential to pose a further impediment to the most effective use of drugs or devices in cancer patients, and to the implementation of life-saving advances.

Impact of Quality of Life on Quality of Care

Approximately 8.2 million people are now living with cancer. Cancer survivors are rightfully demanding, if not cure, more durable control of their disease with fewer side effects and better quality of life. Simply being alive five years after diagnosis is no longer considered good enough by survivors of most cancers.

Definitions of quality of life vary. For example, quality of life has been defined as the difference or gap between the hopes and expectations of the individual and that individual's personal experience at a particular point in time. Health-related quality of life refers to the individual's perceptions of emotional and physical health, including perceived effects on physical and social functioning.

Effects of Cancer and Its Treatment on Survivors' Quality of Life

Three stages of survival—acute, extended, and permanent—have been defined⁸ and are widely recognized. “Acute” survival begins at diagnosis and continues through the end of treatment. In this stage of survival, patients generally experience depression and anxiety, energy reduction, decline in physical functioning, and distress related to disease symptoms; these effects typically relate to treatment and are independent of cancer site. Issues specific to cancer site include, for example, body image in women who undergo mastectomy, arm problems related to breast cancer surgery, abrupt menopause, and among prostate cancer patients, sexual, urinary, and bowel function issues.

“Extended” survival for some cancers may begin at the conclusion of treatment and continue until the risk of recurrence has decreased. General issues related to this stage of survival include energy reduction, sexual dysfunction, altered physical functioning (especially at older ages), body image changes, relationship issues, and work-related problems. Fertility distress (particularly related to radiation treatment) is common among testicular cancer and Hodgkin's disease survivors. For breast cancer survivors, issues include arm problems, limited mobility, and weight gain. Families may also experience communication problems if, for example, members resist discussing the survivor's continued or new emotional or other cancer-related issues. Further, communication problems that existed prior to the cancer diagnosis may be exacerbated by the cancer experience.

Among the general issues prevalent during the “permanent” stage of survival are energy loss, second cancers, work-related problems, and relationship issues. Disease-specific

⁸ Mullan, F. Seasons of survival: Reflections of a physician with cancer. *NEJM* 313:270-273, 1985.

issues include heart disease and infection risk among people treated for Hodgkin's disease, and physical disabilities among childhood cancer survivors.

Cancer survivors have recognized that the cognitive impact of cancer treatment, spanning the survival continuum, is an important issue requiring further study. Radiation effects can include early effects like cerebral edema, early delayed reactions such as demyelination, and late effects, the most dramatic of which is radiation necrosis. Systemic chemotherapies are associated with cognitive deficits such as loss of memory and concentration. Some of these deficits may be subtle, but may substantially affect survivors' ability to work in certain environments within their profession. Such changes may have a major impact on quality of life. In addition, new research on biological response modifiers shows a dose-related relationship between treatment and cognitive problems such as disorientation, impaired memory, and psychomotor slowing. For most patients, these problems resolve when therapy is discontinued, but new evidence suggests that for a subpopulation of patients, these deficits persist well after therapy is completed. Speakers emphasized the need for more longitudinal studies, particularly to distinguish cognitive effects related to radiation versus chemotherapy in patients treated with both modalities, and to separate age-related cognitive and memory losses from those related to cancer treatment. These studies, and research to better understand the predictors of treatment-related cognitive deficits, will lead to treatment regimens that reduce the risk of cognitive problems. As new therapies emerge, it also will be essential to incorporate adequate follow-up to identify the long-term effects of treatment and their impact on patients' quality of life. Cognitive rehabilitation and pharmacologic interventions are needed to address deficits that do occur.

Work is thought to be universally important to quality of life and self-esteem, and the ability to return to work and other daily activities after having cancer is an important part of the adaptation and recovery process. But speakers noted that return to work may not be a useful measure of recovery from cancer, since some studies have shown that survivors whose energy level has not fully returned expend their energy on work activities at the expense of other life activities. More research is needed on issues related to return to work (e.g., use of leave time, work ability perceptions of supervisors and coworkers), work-related problems (e.g., discrimination, self-imposed limits), measurement issues (e.g., activity patterns, work problems, differentiating between individual, work type, and work site effects), policy effects (e.g., implementation of the Americans With Disabilities Act), and relationships between work and quality of life.

Cancer survivors frequently experience sexual problems as an aftermath of their diagnosis and treatment. Sexual problems are particularly prevalent among patients with prostate and breast cancers. Approximately half of women with breast or gynecologic cancers have persistent sexual problems. Following prostate cancer treatment, up to 70 percent of men have significant sexual problems. Most of the sexual problems that cancer survivors experience are severe. They tend to affect all phases of sexuality including desire, arousability, and the ability to feel pleasure. These problems—which may have both physiologic and psychological components—tend to persist following cancer treatment after other aspects of quality of life have improved. Speakers recommended that patients be provided better information about the potential sexual side effects of cancer treatment options, and that questions about sexuality and fertility be included routinely in patient assessments initially and at follow-up intervals. Sexual health information should be included in quality of life assessments. It also was recommended that cancer treatment

teams include a sex expert who can advise patients and make appropriate referrals for problems, that insurance coverage be provided for cancer-related sexual and infertility problems, and that sexual health after cancer be actively promoted.

Impact of Family Issues on Patients' Quality of Life

Cancer survivors' quality of life also is affected dramatically by the stresses cancer places on the family unit. Cancer treatment now involves less hospitalization, more home care, and more outpatient procedures than in years past; this reality places more responsibility on the family to provide care over long periods of time. In addition, recent decades have seen vast changes (e.g., greater mobility resulting in fragmentation and loss of the extended family) in the home supports that are realistically available to many patients. These changes in the fabric of society require that the family-based care model be examined more closely. It was emphasized that quality care includes providing patients and families adequate information about likely treatment side effects on quality of life so that informed decisions can be made. Education and communication are important parts of comprehensive cancer care and are crucial to quality of life throughout a person's survivorship.

Quality of life also is affected by the extent to which the family's financial and emotional resources are drained in caring for the cancer patient, and by the life stage and responsibilities of key family members (e.g., the effect of cancer on the parenting role with young children, the ability of an older adult to care for a spouse with cancer, the impact of cancer caregiving on a middle-aged adult's career).

Family members are asked to provide financial and emotional support; assume the patient's responsibilities as he or she loses the ability to handle these; provide direct nursing care; become a surrogate specialist or dietician; and put their own life goals and activities on hold for an extended time period. Unchecked, stress on families reduces their availability to patients and can cause family members to develop physical symptoms and disabling psychological distress, suffer social isolation, and even become alienated from the patient. Also common are economic costs such as loss of work, increased medical expenses, and reduced productivity and effectiveness in both work and family functioning.

Among the key challenges to families are learning to deal with chronic stress and build family resilience; resisting the expectation that the patient will return to his or her prediagnosis psychological (e.g., self-concept, values, priorities) or physical state; maintaining communication under conditions of uncertainty; and reassigning family roles and responsibilities. Speakers emphasized the importance of increased research in this area and of focusing on the family unit in planning interventions to improve quality of life for both the patient and family.

Special Issues of Long-Term Survivors

Survivors of pediatric and adolescent cancers, and long-term survivors of adult cancers face special issues in addition to those described above. By the year 2000, one in 900 people between the ages of 16 and 44 years will be a survivor of a childhood cancer. Child and adolescent cancer survivors have an average life expectancy of 60 years compared with 15 years for the average adult cancer survivor. The long-term effects of cancer treatments and their impact on quality of life are of significant concern in this population. Of greatest concern are effects on growth and development (linear growth, intellectual

function, psychosocial adjustment, and sexual maturation), reproduction (particularly related to fertility and the health of offspring), cardiac damage from anthracycline treatment, and second cancers.

Though significant needs remain, research on this population of survivors has led to treatment modifications, follow-up guidelines, and interventions to improve both function and quality of life. Such interventions include educational techniques for children who have received cranial irradiation; replacement of growth, thyroid, and gonadal hormones; reproductive counseling for young men and women about to undergo therapies affecting fertility; and health behavior education. By comparison, relatively little research has been conducted on the needs and issues of long-term survivors of adult cancers.

Cancer survivors of all ages are the population group at highest risk of developing cancer—even higher than tobacco users. Once patients have been treated for one cancer, they are at risk for recurrence of their primary cancer, developing other primary cancers, experiencing late effects of therapy, and organ system failures. Therefore, quality of life issues and quality cancer care must be examined as a continuum of cancer survivorship beginning at the point of diagnosis and extending for the duration of the patient's life. In addition to better understanding how cancer treatment predisposes to second cancers, there also is a need to better understand how genetic susceptibilities interact with cancer treatments to influence second cancer risk. These issues, speakers stressed, highlight the critical need for ongoing surveillance, counseling, and preventive services for this population.

Ensuring Quality of Life at the End of Life

End of life care is a survivorship issue and a quality of care issue; 50 to 60 percent of patients diagnosed with cancer will eventually die from their disease. How cancer patients perceive their death dramatically affects their morbidity. A "bad death," characterized by poor symptom control, physician abandonment, or inadequate closure, creates survivors' fear of death. Speakers indicated that difficulty in addressing death with patients is an acknowledged problem in the physician community, based in a persistent physician and public view of death as a failure of medicine. Similarly, there is denial of end of life care needs and of death in the health system; it was noted that there is no Diagnosis Related Group (DRG) for dying. This barrier to institutional care at the end of life, when needed or desired, also limits the support oncologists can provide.

End of life care also is an important caregiver issue. Recent studies have demonstrated that enormous burdens are placed on caregivers who have inadequate knowledge, resources, and training to care for family members at home. Caregiver burden is often associated with caregiver depression, which in turn has a significant and major negative effect on the dying process for the cancer patient. The degree of caregiver burden is directly related to inadequate symptom control, lack of appropriate economic resources, and lack of social supports.

Each year, an estimated 450,000 patients die in hospice care nationwide. Approximately 80 percent of these deaths are cancer-related and 90 percent of these patients die at home. Many hospices require that there be a responsible caregiver at home as a condition of enrollment. Yet hospice, which is capitation-based, may only provide four hours of home health care each day. This level of support is often inadequate, particularly for elderly

patients who often subsequently require hospitalization for end of life care, even though they prefer to die at home.

Only \$2 billion per year is spent on hospice care in the United States. Hospice care reimbursement is changing with health care financing changes; capitation rates are being reduced, as is the length of time that patients may remain in hospice care. Moreover, many health care programs do not pay adequately for hospice care for patients under age 65. In addition, a number of states do not cover hospice care for Medicaid patients, forcing the poor to die in hospitals because of a lack of community-based resources to provide care at home. Most patients who die without hospice care experience poor pain control because their health care providers have limited knowledge of opiate pharmacology, poor pain assessment skills, or a reluctance to prescribe narcotics. Communication with patients about pain tends to be inadequate, and many providers fear governmental oversight and restrictions related to prescribing controlled substances. Further, for many patients with advanced cancer, the cost of pain medications and other drug therapies used in palliative care is not reimbursed, and these out-of-pocket expenses can total \$400 to \$600 per month, expending all of the patient's Social Security income. There are cases of patients foregoing the use of necessary pain medication because the costs were prohibitive.

Speakers emphasized the need for a compassionate and humane system of care for cancer patients at the end of life, including improved financing of hospice care, expanding the availability of palliative care approaches from hospice programs to cancer centers (including offering palliative care as an option in all clinical trials), establishing a focal point for end of life research at the NCI, improving health care professional education about palliative care, and fostering more honest health professional and public dialogue about dying. A number of respected organizations, including the American Society of Clinical Oncology, the Institute of Medicine, and the World Health Organization, have developed reports and accompanying recommendations to address the deeply ingrained obstacles to compassionate end of life care for people with cancer. However, implementation of these recommendations and their integration into the standard of care is slow.

Assessing and Measuring Quality of Life

Although quality of life assessment—including some psychosocial aspects of quality of life—is now included in most clinical trials, this aspect of cancer care quality evaluation is relatively new. Quality of life data on patients not treated on trials, and data on most survivors who have completed treatment remain sparse.

Speakers noted that quality of life is a multidimensional concept that should be measured based on individual perceptions rather than proxy measures such as the Karnofsky scale. Measuring quality of life has been difficult until relatively recently, when health services researchers and social scientists began systematically to collect this information from patients, and validated, easily administered quality of life instruments became more readily available. Speakers also stressed the importance of cancer-specific quality of life measures, since certain cancers and their treatment options have varying impact on patients' quality of life. In addition, self-administration of written quality of life instruments is extremely important to obtain accurate and candid information. This point was demonstrated clearly in a comparative study of postsurgical quality of life assessments made by prostate cancer

survivors and their physicians in which the physicians consistently underrated level of impairment compared with the patients' assessment.

Some issues related to quality of life (e.g., depression, anxiety, quality of relationships) may not be cancer-related. This may be more true as a person gets further from treatment (i.e., a cancer history does not necessarily define all aspects of an individual, especially a long-term survivor). It is important to be able to differentiate aspects of quality of life that relate to quality of care from those that do not. For example, personality traits that could be predicted to have a significantly negative impact on an individual's interpersonal relationships would likely do so even absent a history of cancer and cancer treatment. Similarly, speakers emphasized the need for comparative data to place research results into perspective; one such comparative study suggested that psychological outcomes attributed to breast cancer surgery may in fact be normal consequences of any type of surgery.

Many opportunities exist to expand the base of knowledge on the impact of cancer care on quality of life. These include incorporating thorough quality of life assessments routinely into clinical studies and follow-up protocols; appending quality of life assessments onto ongoing prevention, treatment, and supportive care trials; and continued research to improve quality of life instrumentation. This is an area that could benefit substantially from increased research support.

III. Conclusions

The American consumer expects to receive high quality health care, but quality in cancer care, a complex composite of several factors, has not been well defined. At a minimum, every person needs access to effective cancer prevention and screening services, and each person waging a personal war against cancer needs timely access to the diagnostic, treatment, and supportive services best able to fight his or her disease. Cancer care should also respond to cultural differences and quality of life concerns during and after treatment. Unfortunately, quality of care and quality of life are also influenced substantially by the economic circumstances of the patient and his or her family.

Our ability to detect and treat many cancers remains inadequate, and most people are not receiving what might be considered the highest quality cancer care. Perspectives on quality care, which may differ from typical standards of care, are highly dynamic due to the rapid pace of discovery and constraints imposed by the health care system. Furthermore, there is no consensus as to how to define, implement, measure, or evaluate quality in cancer care.

Yet clearly, the quality of cancer care provided to the American public—however described—varies considerably. Disparities are evident in the treatments provided, in access to treatment, and in patient outcomes. They are reflected in cancer statistics. Disparities in care exist among people of different ages, cultures, socioeconomic strata, and geographic regions of the country, in part due to the structure of our evolving health care system.

Part of the difficulty in providing quality care consistently to the entire population has been the difficulty in deciding what constitutes quality service across the continuum of cancer care. Though there is philosophical agreement that quality should be defined by "evidence," the quality of evidence itself varies. Evidence exists at many levels, including randomized controlled clinical trials, published expert consensus based on various combinations of randomized and observational studies and anecdotal reports, accepted

experience of the medical community, and informal compilations of local “best practices.” The soundness and reliability within and between these various forms of evidence can differ quite considerably. Thus, merely having “evidence” is not enough to ensure quality.

To date, relatively little effort has been made to collect and assemble systematically the data needed to make these extremely complex quality assessments, and the literature on quality of care assessment is insufficient. With the ever-accelerating pace of discovery in molecular and genetic medicine and advances in traditional therapies (e.g., chemotherapy, radiation, and surgery), cancer treatments and recommendations concerning all aspects of cancer care are changing rapidly. Many of the attempts to evaluate cancer care quality have been based on retrospective studies of treatments that had already been supplanted, and may not have examined the most relevant parameters of care. In many cases, the data considered most relevant do not exist.

Moreover, attempts to define quality have suffered from a lack of professional consensus on what quality means, what parameters should be measured, what data should be gathered as evidence, how assessments should be conducted, and who is qualified to judge quality of care. In addition, consumer perceptions of quality may differ markedly from professional judgements, in some cases placing relatively higher priority on cultural acceptability and psychosocial or other outcomes of care as cancer mortality has decreased.

“Value” has also become a measure of quality in the cost-driven health care system. An economic definition of value relates to delivering the greatest health care benefit at a reasonable cost, yet even such a definition is open to interpretation. At a broader social level and absent universal health care, tensions are created by the economic considerations of providing a greater good for a greater number (i.e., a population approach) versus providing state-of-the-art care to a more limited number of individuals. It must also be acknowledged that distribution of resources is an issue even in existing universal health care systems—in such settings, not everyone has access to all care. It is unclear who should make these decisions and how issues of value should be taken into account in relation to standards of care and clinical practice guidelines currently being developed or evaluated.

Although pressure toward the provision of evidence-based medicine is growing, the reality is that most cancer care is not and will not be based on the highest level of evidence—the randomized controlled trial. The limitations of professional consensus and other forms of evidence relative to controlled trial proof must, therefore, be recognized and accommodated. Given the long duration of most controlled trials and the current lack of suitable surrogate endpoints for many conditions, there is a need for commonly accepted methodologies for evaluating other levels of evidence. Such methodologies should be established by consensus of a full spectrum of stakeholders.

Clinical practice guidelines chart paths to achieving standards of care, and as such reflect expectations of quality. Though guidelines for the provision of medical care are not new, recent years have brought an explosion in attempts to define and measure quality of care, including cancer care. These assessments of cancer care, embodied in clinical care guidelines, have been established largely for measurement purposes. Yet guidelines are not absolutes; they are tools for assessing certain components of care, but do not take into account all of the components of quality, such as consumer satisfaction, patient quality of life, and economic ramifications of care. In the evolving health care system, many of the

guideline development efforts to date have been driven substantially by providers' attempts to define care that is medically appropriate—and therefore reimbursable—and payers' desire to influence the behavior of physicians and institutional health care providers and thereby contain costs.

At this time, existing guidelines do not evenly span the continuum of cancer care. Cancer care begins with prevention and continues through treatment to either survivorship or end of life care, yet few guidelines exist for prevention, screening, diagnosis, follow-up care for survivors, or palliative and end of life care. The multiple guidelines now in existence focus heavily on the treatment of diagnosed cancers and are confusing to health care professionals and consumers alike. To a significant extent, however, neither practitioners nor the public are aware of current cancer care guidelines, the evidence on which they are based, and how guidelines for a given disease can or should be evaluated and used to inform care choices. All guidelines are not equal, and no matter how precise any guideline may be, it is only one component to be used in a comprehensive assessment of quality of care.

Further, existing guidelines are being applied principally to insured populations. People who are not full participants in the health care system—the uninsured and underinsured—are receiving inadequate cancer care, or none at all. Even a substantial proportion of the insured are receiving inadequate cancer care; this occurs because of health providers' lack of knowledge of available care options, lack of communication tools to support informed decision making, fiscal disincentives to providing certain types of care, and cost constraints imposed by both employers and payers.

Organizations appear to be moving toward performance measurement and the collection of practice outcome data that provide feedback to individuals and institutions on the quality of care delivered. It is believed that these data will indicate how guidelines are being used, provide useful benchmarks to measure their impact, and potentially reduce the costs of cancer care. However, the outcomes selected for measurement must be meaningful; for example, simply counting the number of mammograms provided at a given facility is no measure of quality if treatment is not available for detected abnormalities or if women do not return for subsequent screenings. How to select appropriate outcomes, how to collect meaningful data in a standardized manner across institutions, how to obtain the cooperation of providers and institutions, how to fund the cost of data collection and analysis, and how to assure that data are not misused are among the challenges remaining to be faced.

It also is crucial that assessments of evidence leading to guidelines do not quash the creativity and innovation that have led to advances in cancer care. Our remarkable progress in caring for children with cancer provides ample testament to the importance of support for innovative treatment approaches. Rigid guidelines that promote a cookbook approach to care so as to ensure insurance reimbursement or for other purposes are quite likely to stifle such advances. A balance must be struck between supporting clinical innovation that advances the standards of cancer care and protecting patients from unsubstantiated and potentially harmful interventions.

Any discussion of quality of care must include discussion of quality of life and how it is affected by a given type of care. Although quality of life is a component of quality of care, it requires separate study. Quality of life may be judged differently depending on whose

life—an individual, a cultural group, or other defined group—is being considered, and who is making the assessment. It must also be recognized that a person's quality of life before cancer treatment affects his or her quality of life after treatment.

In addition, to continue improving the quality of care and quality of life we must maintain a vital research program, since research findings are the mainspring of advances in preventive, diagnostic, therapeutic, supportive, and palliative interventions. Unless it is completely curative or provides effective control, standard care is never good enough. Research is, and has always been, the source of improvements in cancer care.

There is a continued need for research to address quality issues specific to vulnerable populations, as well as to the population as a whole. It is a moral imperative that we provide access to high quality prevention, detection, and treatment to vulnerable populations; doing so simply means providing them with interventions known to be effective, and learning more about how to modify treatment strategies for populations such as the elderly. Similarly, improved access to effective care, including clinical trials when a trial represents the most promising treatment option, must be achieved for those in health plans of all types, and for the uninsured. Cultural differences that affect both the provision of quality care and quality of life must be addressed.

It is the Panel's conclusion that at this time, we have more questions than answers as to the meaning and implementation of quality cancer care in America. We must address these crucial issues concerning how quality in cancer care should be defined, how and by whom clinical practice guidelines that chart paths to achieving the standards of care should be developed and updated, and how they should be used to achieve the best balance between effective cancer care for all populations, reasonable cost, and quality of life. Consistency, organization, and coordination in the development and use of clinical practice guidelines are seriously lacking at this point in the evolution of this important aspect of the health care system. At the same time, the Panel maintains that the application of rigid guidelines would impede the progress of the National Cancer Program. The Panel believes that improvements are needed in information collection and sharing, improved tools for decision making, and appropriate training and education for health professionals and consumers of care. Most importantly, an unwavering focus on the well-being of the patient will be key to advancing the standard of care for all populations.

IV. Recommendations

The Panel believes that important steps are needed now to address the rapidly emerging issues related to defining and providing quality cancer care and improving quality of life. These steps are needed to ensure that all of the American people have access to the care best able to prevent and treat cancer, and to safeguard the research processes by which we achieve continuing advances against the suffering and death caused by cancer. Specifically, the Panel recommends:

- The welfare of the patient—related both to his or her disease and to quality of life—must inform the quality of cancer care. Evaluations of quality must place priority on the patient over short-term cost. Cost, while relevant, should not be the arbiter of quality care.
- Definitions of quality should take into account both the concerns of the individual and public health as a whole.

- Quality definitions and clinical practice guidelines that may be derived from them should not be so rigid as to inhibit innovation in cancer care. Guidelines must be updated frequently to maintain their consistency with advances in knowledge, technology, and practice and to avoid barriers to reimbursement.
- Evidence is one of several components in quality of care evaluation. The randomized controlled trial (RCT) is the gold standard of evidence for evaluating clinical care. In the absence of data from one or more large, well-designed RCTs, other forms of evidence should be evaluated according to commonly accepted methodologies determined by consensus. Quality evaluations should also take into account quality of life, economic survival of the patient and family, and related issues including employment and insurance ramifications.
- Data are needed in areas that are integral components of quality of care, e.g., socioeconomic status, cultural values, quality of life perceptions, the impact of cancer on family members, and patient-focused outcomes. These data are needed at the local and regional levels, and for diverse population groups and subgroups of major population segments, to support the development, implementation, and evaluation of tailored interventions to improve the quality of cancer care.
- All of the stakeholders in the definition and provision of quality cancer care—health care payers of all types; research sponsors including government, voluntary agencies, and the pharmaceutical and biotechnology industries; employers; employees and other health care consumers—must bear their fair share of the cost of quality evaluations, guideline development, and the data collection and analysis needed to support these efforts.
- A full spectrum of participants should be responsible for organizing and coordinating the development, dissemination, and updating of cancer care guidelines across the continuum of care, and for the data collection activities that support these efforts. Without a central focus, present issues concerning the lack of standards for certain aspects of cancer care, inconsistent or duplicative guidelines, lack of relevant data to define quality and evaluate guidelines, uneven reimbursement for care, and insufficient communication to health professionals and the public will not be resolved.
- Training is needed to improve the ability of physicians and other health professionals to:
 - Understand evidence and how to implement definitions of quality care
 - Facilitate patient understanding of current standards of care and care options
 - Make appropriate recommendations concerning cancer prevention and screening
 - Understand clinical trials and facilitate patients' understanding of and access to clinical trials
 - Recognize and provide for appropriate rehabilitation services for cancer survivors, including psychosocial services and lifelong surveillance for delayed treatment effects and second tumors
 - Acknowledge that death and end of life issues are a part of the cancer experience for some patients, and provide more comprehensive and compassionate care to dying patients and their families

- Better understand, explain, and protect the privacy of genetic risk information
- Better address the cancer care needs of the growing elderly population; collaborative efforts between geriatrics and oncology should be fostered.
- Mechanisms must be developed to educate patients, their families, and the public at all educational levels and from differing cultures to effectively evaluate care options and recommendations.
- Continued funding across the research spectrum is needed to continue the flow of discovery that leads to improvements in care across the cancer continuum. Research efforts should focus particularly on improving interventions in the areas of cancer prevention, cancer control, rehabilitation, palliation, and end of life care, and on outcomes research. In addition, targeted funding may be needed for behavioral and other research to improve quality of care in vulnerable populations, including those with low income and/or educational levels, differing cultures, the elderly, and rural populations.
- To improve our understanding of and ability to address the short- and long-term issues associated with surviving cancer, greater emphasis and research support should be directed to studies of survivorship issues, including but not limited to long-term effects of treatment, family issues, socioeconomic status, and employability. Contemporary definitions of survival that reflect both treatment advances and quality of life factors should be developed.
- Current concerns should be investigated to assess whether cancer care quality is being impeded by payer restrictions on appointment durations; off-label use of medications for which growing clinical evidence indicates efficacy; and access to appropriate treatments, oncology specialists, and clinical trials. Identified barriers to appropriate care should be corrected, and coverage of patient care costs for participants in approved clinical trials should be provided routinely.
- Participation in quality clinical trials should become part of the standard of care for cancer. To ensure access to promising investigational treatments, guidelines should provide recommendations for when a patient should enter a clinical trial, but guidelines should not be permitted to become a barrier to access to such care. In addition, guidelines must not be used to exclude patient choice of effective treatment alternatives and payers should not erect barriers to such care.

CONCERNS OF SPECIAL POPULATIONS IN THE NATIONAL CANCER PROGRAM

JULY 31, 1997
ANN ARBOR, MI

PRESIDENT'S CANCER PANEL

NATIONAL CANCER PROGRAM

CHAIRMAN
HAROLD P. FREEMAN, M.D.
HARLEM HOSPITAL CENTER

MEMBER
FRANCES M. VISCO, J.D.
NATIONAL BREAST
CANCER COALITION

NATIONAL CANCER INSTITUTE

MEMBER
PAUL CALABRESI, M.D.
BROWN-TUFTS CANCER CENTER
RHODE ISLAND HOSPITAL
NEW ENGLAND MEDICAL CENTER

EXECUTIVE SECRETARY
MAUREEN O. WILSON, Ph.D.
ASSISTANT DIRECTOR
NATIONAL CANCER INSTITUTE

Concerns of Special Populations in the National Cancer Program

Cancer and the Aging Population

July 31, 1997, Ann Arbor, Michigan

Opening Remarks	Dr. Harold Freeman
Welcome	Drs. Max S. Wicha and Jeffrey B. Halter
National Cancer Institute Report	Dr. Alan Rabson
National Institute on Aging Report	Dr. Dan L. Longo
History and Identification of Older Americans as a Special Population	
Moderator—Dr. B.J. Kennedy	
Cancer in Older Americans—Statistics	Ms. Lynn A. Gloeckler-Ries
Epidemiology and Aging	Dr. Rosemary Yancik
Health Research Questions for Older Americans	Dr. William Hazzard
Needs of Older Americans	Ms. Edna Kane-Williams
Research Findings and Issues Among the Aging	
Moderator—Dr. William Ershler	
Molecular Biologic Questions—Cell Culture Models	Dr. Judith Campisi
Molecular Biologic Questions—Animal Models	Dr. Richard A. Miller
Pharmacology and Aging	Dr. Robert Vestal
Clinical Findings and Issues Among the Aging	
Moderator—Dr. Harvey Cohen	
Prevention/Detection	Dr. Patricia A. Ganz
Health and Behavior	Dr. Sarah Fox
Treatment	Dr. Lodovico Balducci
Management	Dr. Paul Carbone
Access and Outreach	Dr. Lawrence Baker
Health Advocacy	
Moderator—Dr. Elizabeth Clark	
Survivorship	Dr. Barbara Given
Supportive Care Models	Dr. Kenneth J. Pienta
Education	Dr. Harmon Eyre
Closing Remarks	Drs. Paul Calabresi and Harold Freeman

Speakers List

Concerns of Special Populations in the National Cancer Program

Cancer and the Aging Population

July 31, 1997, Ann Arbor, Michigan

Lawrence Baker, D.O.

Director for Clinical Research
University of Michigan Comprehensive Cancer Center

Lodovico Balducci, M.D.

Program Leader
H. Lee Moffitt Cancer Center and Research Institute

Judith Campisi, Ph.D.

Department Head, Cancer Biology Department
Lawrence Berkeley National Laboratory
University of California

Paul Carbone, M.D.

Professor of Medicine, Emeritus
University of Wisconsin, Medical School

Elizabeth Clark, Ph.D.

President
Coalition for Cancer Survivorship

Harvey J. Cohen, M.D.

Director, Center for Aging
Chief, Division of Geriatrics
Duke University Medical Center

William B. Ershler, M.D.

Director, Glennan Center for Geriatrics
Eastern Virginia Medical School

Harmon Eyre, M.D.

Executive Vice President for Research and
Cancer Control
American Cancer Society

Sarah Fox, Ed.D.

Associate Professor
University of California, Los Angeles
Senior Behavioral Scientist
The RAND Corporation

Patricia A. Ganz, M.D.

Professor
UCLA School of Medicine and Public Health
Director
Jonsson Comprehensive Cancer Center
Division of Prevention and Control Research

Barbara Given, R.N., Ph.D., FAAN

Professor, College of Nursing
Michigan State University

Jeffrey B. Halter, M.D.

Director, Geriatrics Center
University of Michigan Hospital

William Hazzard, M.D.

Professor and Chairman
Bowman Gray School of Medicine

Edna Kane-Williams

Manager, Health and Long Term Care Issues
American Association of Retired Persons

B.J. Kennedy, M.D.

Regents' Professor of Medicine, Emeritus
Masonic Professor of Oncology, Emeritus
University of Minnesota Medical School

Dan L. Longo, M.D.

Scientific Director
National Institute on Aging

Richard A. Miller, Ph.D.

Associate Director, Geriatrics Center
University of Michigan

Kenneth J. Pienta, M.D.

University of Michigan

Alan Rabson

Deputy Director
National Cancer Institute
National Institutes of Health

Lynn A. Gloeckler Ries, M.S.

Health Statistician
National Cancer Institute
National Institutes of Health

Robert Vestal, M.D.

Associate Chief of Staff for Research and Development
Veterans Affairs Medical Center

Max S. Wicha, M.D.

Director
Comprehensive Cancer Center
University of Michigan
President
Association of American Cancer Institutes

Rosemary Yancik, Ph.D.

Chief, Cancer Section
Geriatrics Program
National Institute on Aging, NIH

CONCERNS OF SPECIAL POPULATIONS IN THE NATIONAL CANCER PROGRAM

Cancer and the Aging Population

July 31, 1997, Ann Arbor, Michigan

OVERVIEW

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. The purpose of this meeting, the second in a series of four meetings focusing on the concerns of special populations in the National Cancer Program, was to consider the particular issues and concerns of older Americans. Twenty-three speakers representing varied disciplines presented testimony to the Panel on current activities of the National Cancer Institute and the National Institute on Aging related to cancer and aging, reviewed current statistics on cancer in older Americans, outlined epidemiologic issues related to cancer and aging, and considered health research questions for older Americans. Cell culture and animal models for studying molecular biologic questions of aging were described, as were pharmacologic issues in aging. Prevention, detection, behavioral, treatment, management, access, and outreach issues specific to aging populations were discussed. In addition, issues of survivorship, supportive care, and education of the public and health professions on issues of aging and cancer were reviewed. Speakers offered specific recommendations for better addressing the issues of the older person with cancer or at risk for cancer for consideration by the Panel.

OPENING REMARKS—Dr. Harold Freeman, Chair

In opening the meeting, Dr. Freeman stated that:

- This is the second of four meetings to pursue the concerns of special populations in the National Cancer Program. The Panel held its first meeting on this subject in April 1997 on the meaning of race in science and related considerations for cancer research. The two upcoming meetings will examine the real impact of the reduction in cancer mortality, and will review the responsiveness of the health care system to special populations.
- Addressing cancer issues related to the aging population has become increasingly critical as the numbers of young-old (those aged 65-74 years), older-old (aged 75-84 years), and oldest-old (85 years and older) continue to grow.
- The population aged 65 and older increased eleven-fold (to 33.5 million or one in eight Americans) from 1900 to 1995. During the same period, the under 65 population grew only three-fold. Further, since 1900, the percentage of Americans over age 65 has tripled from 4.1 percent in 1900 to 12.8 percent in 1995. In 1995, persons reaching age 65 had an average life expectancy of an additional 17.4 years. The growth in the older population is expected to continue, with the most rapid increase between 2010 and 2030, when the "baby-boom" generation reaches age 65. By 2030, there will be an estimated 70 million older persons, more than twice the number in 1900, comprising about 20 percent of the U.S. population. It also is projected that in the coming decades the older population will be much more racially and ethnically diverse than it is today.
- Overall, 58 percent of all cancer incidence is in the older segment of the population. Older persons have a risk of developing cancer 10 times that of individuals younger than age 65.

- These data suggest an urgent need to address the special concerns of the aging population within the National Cancer Program. The need for prevention and control strategies and cancer treatment and care for the elderly is already great, and is likely to increase.
- Among the potential age-related factors that may be involved in the etiology of cancer in this population are decreased cancer surveillance, longer duration of exposure to carcinogens, increased cell susceptibility to carcinogens, decreased DNA repair function, amplified oncogene activation, and defects in tumor suppressor genes. Detecting cancer in the elderly is often complicated by nonspecific presentation of a malignancy, and treatment often must take into account comorbidities, decreased physical and psychologic functioning, differences in drug metabolism, and the potential for secondary complications.
- Other relevant concerns for the aging population are issues in understanding medical procedures and options, diminished social support, limited financial resources, and quality of life. The Panel believes quality of life is a particularly important consideration for aging Americans, who must measure the risk of treatment against the benefits of survival (or perhaps, the benefits of treatment against the risk of survival).

WELCOME—Dr. Max S. Wicha, Director, Comprehensive Cancer Center, University of Michigan

Dr. Wicha welcomed the Panel, speakers, and other attendees, adding that:

- The establishment of centers for geriatric medicine and cancer at the University of Michigan, now co-located at a newly opened facility, reflects a recognition of aging and cancer (and their relationship to each other) as priority areas in medicine for the next decade.
- Further, housing together both research laboratories and patient care facilities is expected to facilitate understanding of the impact of changes in aging cells on cancer development and the special clinical problems of the elderly.

WELCOME—Dr. Jeffrey B. Halter, Director, Geriatrics Center, University of Michigan Hospital

Dr. Halter posed several questions that he hoped would be addressed at least in part during the meeting:

- Why do so many older people develop cancer?
- What is the current level of funding nationally for the study of cancer and aging?
- Why is there such a large gap between what is known about cancer prevention, screening, and detection, and what is applied in general practice in the care of older people?
- Why are so many older patients with cancer referred rapidly to hospice instead of being entered into treatment programs?
- Why are there few treatment programs designed for older patients with cancer? What are the limiting factors for designing such regimens?
- Why is so little known about treatment outcomes in older adults?

Dr. Halter expressed his optimism that through activities of the President's Cancer Panel, some of these issues will be brought forward and more fully addressed.

DIRECTOR'S REMARKS—Dr. Alan Rabson, Deputy Director, National Cancer Institute

Representing Dr. Richard Klausner, Director, NCI, Dr. Rabson indicated that Dr. Klausner was unable to attend because of activities related to the NCI's Congressionally mandated study of radioactivity exposures following nuclear tests conducted in the 1950s and 1960s. The study, employing computer modeling based on the scant available data, identified 24 counties in the United States most heavily exposed to radioactive fallout. A briefing and press conference on the study are scheduled.

PRESENTATION HIGHLIGHTS: National Institute on Aging Report

Dr. Dan L. Longo

Key Points

- Age is the single greatest risk factor for cancer; old people are disproportionately affected by cancer in terms of its incidence, and to an even greater extent, in cancer deaths. The median age of cancer patients in the United States is 70 years.
- It is unclear why cancer occurs more frequently in the elderly. Key issues may include exposure to carcinogens, greater cellular susceptibility to cancer over time, greater opportunities for mutagenesis and transforming events in older cells, decreased DNA repair capability with age, a favorable microenvironment, and failures of immune surveillance.
- Several areas of biology are of interest both in cancer and aging. Growth regulation by a cell or organ in response to environmental stimuli is influenced by proto-oncogene expression, oncogene expression, and tumor suppressor gene mutation. The processes that affect cell replication are important both in cancer and in aging, however, there are anti-carcinogenic elements of the aging process that require further exploration. One such process involves the preservation of telomeres through inappropriate expression of telomerase, allowing cells to escape normal cell death.
- Free radical damage is an important partial contributor to the aging process and is also thought to play a role in carcinogenesis.
- Immune system decline with age may allow cancer cells to develop without immune surveillance. It is also possible that decreased immunity is responsible for what appears to be slower tumor growth in older people, however, certain immune system products can enhance tumor growth.
- Considerable common ground exists between medical oncology and geriatrics: both provide care for predominantly older people, involve multi-disciplinary approaches, and involve end of life care, including hospice. It is important, however, to acknowledge the fundamental cultural and training differences between the two disciplines. For example, geriatricians may tend to be risk and toxicity averse compared with oncologists as a group, who may tend to be more aggressive, except in treating older patients.
- Two joint NIA/NCI program announcements have been issued. One is intended to foster research on the issues of aging, women, and breast cancer; breast cancer incidence clearly is influenced enormously by age. The second announcement focuses on aging, race, and ethnicity in prostate cancer; prostate cancer mortality is quite high in older men, and is twice as high in African American men as in white men. Applications submitted under these program announcements will be reviewed through the usual peer-review process. The importance of these areas may justify fostering research with more targeted funding.

- In response to environmental stimuli, an individual cell may grow, differentiate, stop dividing reversibly, stop dividing irreversibly (senescence), or undergo transformation and become immortalized. Understanding the process by which these manifestations are regulated is extremely important. There is a great deal of debate as to whether or not the aging of individual cells equates to aging of the organism. It is known that different organs age at different rates, but these different rates may not be related to the replicative capacity of the cells in the organ. Cellular proteins change in conformation and function, which may be related to aging, but not to replication. A better understanding is needed of the relationship between senescence in cells in vitro and aging in vivo in organs and in people.
- Older cancer patients experience differences in drug metabolic activation and clearance compared to younger patients; these differences impact the treatment regimens given older patients and the toxicities they experience. Prognostic indicators also are likely to be different in older people, and cancers may present differently in the elderly.
- Comorbidity, including previous illness, disability, and degenerative conditions, have been used as a justification for not treating older people with cancer aggressively. We need to know which conditions actually influence anticancer drug toxicity, and which do not. The NCI Cooperative Groups could be an excellent vehicle for addressing treatment questions in older people, such as pharmacology evaluations or comparing the usefulness of the geriatric method of patient assessment to that of the Karnofsky index used in oncology as a measure of a patient's physiologic reserve to tolerate treatment.
- Evidence exists that even when older people are treated with surgery alone, their incidence of second and third cancers is higher than would be expected. This suggests that intrinsic aspects of aging create susceptibility, and there may be undiscovered multiple tumor syndromes that affect older people most frequently. Epidemiologic evidence also suggests that cancer incidence may be decreased in the oldest old (i.e., those aged 85 years and older). The NIA intramural program is conducting pilot trials to determine whether the in vitro DNA repair capability of bone marrow cells or lymphocytes from an individual patient can predict the toxicity that person will experience from chemotherapy. Pharmacology and vaccine development are also under study.

Additional Research Needs and Other Recommendations

- It is incumbent upon the NIA and the NCI to work together to develop jointly funded research programs dealing with the interrelationship of aging processes and cancer development. Because fundamental differences exist in the culture and the body of knowledge in geriatrics and oncology, joint training initiatives are also needed. The Hartford Foundation is currently conducting geriatric education retreats with various medical subspecialties. There should be geriatric oncology fellowships, which could be expected to give rise to new geriatrics requirements for medical oncology training universally and requirements for board certification.
- Funds should be set aside for research on high-priority questions in cancer and aging.
- We need to become better educated about the real issues of aging and cancer so that effective treatment programs can be developed that accommodate the decreased physiologic reserve of the elderly.
- Outcomes research focusing on the older cancer patient population is needed. Little longitudinal data exist on survivorship issues of older aged cancer survivors. Research is also needed on health care access issues of older cancer patients and their families.

PRESENTATION HIGHLIGHTS: History and Identification of Older Americans as a Special Population

OPENING REMARKS—DR. B. J. Kennedy, Moderator

Key Points

- Many definitions of aging exist; Dr. Kennedy prefers to define the aged as those who are chronologically gifted. In the past century, we have seen a remarkable increase in survival. For example, according to Minnesota cancer surveillance data, 25 percent of Minnesota women born today can expect to live to age 92, and an equal percentage of Minnesota men can expect to achieve age 86 years, assuming current conditions. However, aging typically precedes the development of cancer, therefore, an increasing elderly population with a high incidence of cancer may prove to be a factor that limits the continued extension of the average lifespan.
- The older population receives less cancer screening, less staging of disease, and less aggressive therapies (often, no therapy at all), simply because they are older. Little research has been done on people over age 65-70. The primary reasons cited have been unacceptable toxicity, comorbidity, lack of benefit from treatment, limited financial resources, lack of support, other social factors, and transportation problems.
- Some research has been done; for example, a national study of Hodgkin's disease showed that older people (at diagnosis) do less well, stage for stage, than do younger people, and suggested that Hodgkin's disease in older people differs biologically from the disease in younger individuals.

Additional Research Needed and Other Recommendations

- Older cancer patients should be offered more aggressive primary surgery, and more aggressive chemotherapy (particularly for those with tumors known to be responsive).
- Older cancer patients need to be involved in setting goals for their care, and physicians need to become more expert in caring for patients who are dying of cancer.
- Economic, social, and bioethical issues related to cancer in the older population will be a part of our future and must be addressed.

CANCER IN OLDER AMERICANS—STATISTICS—Ms. Lynn A. Gloeckler Ries

Key Points

- The Surveillance, Epidemiology, and End Results (SEER) program monitors cancer incidence and survival in approximately 14 percent of the United States population. For the period 1990-1994, the median age at cancer diagnosis was 68 years, with 60 percent of cases occurring in persons 65 years and older. The median age for cancer mortality was 71 years, with 69 percent of cancer deaths occurring in people over age 65.
- The cancer incidence rate in the over age 65 population is more than 10 times that of the under 65 population (all cancer sites). Two in every 100 Americans aged 65 and older will be diagnosed with cancer each year.
- Between 1973 and 1994, the cancer incidence and survival rate for all sites combined has gone up 15 percent among those under age 65; for those 65 years and older, it has increased more than 31 percent. For the same period, cancer mortality (all sites) has declined by almost 10 percent for those under age 65, but has increased almost 17 percent for those 65 years and older. Different racial and ethnic groups have differing cancer patterns. For all cancers combined, incidence is lowest among American Indians, and

highest among African Americans. For every ethnic and racial group, however, cancer rates increase with age. Among women, breast cancer incidence peaks around age 80 years, but colorectal cancer rates are higher than breast cancer rates in the 85 years and older group. Lung cancer in women peaks in incidence around age 70, then declines.

- Among men, prostate cancer overwhelms the age curve (1,400 cases per 100,000 men) at ages 70-74; incidence rates for colorectal and lung cancer show patterns similar to those in women.
- Although breast cancer incidence is 74 per 100,000 for those under age 65 and 443 per 100,000 for those 65 and older, survival is worst for the youngest age group. Median age at diagnosis is 64 years. Between 1973 and 1994, breast cancer mortality declined in the population under 65 years old (by 15 percent) and increased almost 12 percent among those 65 years and older.
- Colorectal cancer incidence (median age 72 years) among men and women has been declining for both the under 65 and 65 and older age groups, but the decline has been steeper for the younger age group. The same is true for mortality from this disease.
- The risk of developing lung cancer is much lower in those under age 65 (approximately 27 per 100,000) than for those 65 and older (346 per 100,000). Median age at diagnosis is 68 years (men and women). The trend in incidence between 1973 and 1994 shows a less than five percent increase in those under age 65, but a nearly 60 percent increase among those 65 years and older. Survival is worst for the oldest age groups. Between 1973 and 1994, mortality increased by almost 73 percent among those 65 and older, but increased less than nine percent for those under age 65.
- Prostate cancer is clearly a disease of older men. The median age at diagnosis is 71 years. The risk of developing prostate cancer is 43 per 100,000 for men under age 65, but 1,236 for those 65 and older. One in 100 men aged 65 and older will develop prostate cancer. Although the trend in incidence of prostate cancer in men under age 65 has increased more rapidly between 1973 and 1994 than for men 65 years and older, since 1993/1994, there has been a substantial decrease in the disease; this decrease, or at least a leveling off, is expected to continue and should be demonstrated in final data for 1995. Between 1973 and 1994, prostate cancer mortality (median age 78 years) has been virtually unchanged in the under 65 age group, but has risen over 23 percent for men 65 years and older.
- The data presented above are from the SEER Cancer Statistics Review and Racial/Ethnic Patterns of Cancer; both documents are available from the Cancer Information Service (1-800-4-CANCER), by order, and from the SEER Web page under "Publications."

EPIDEMIOLOGY AND AGING—Dr. Rosemary Yancik

Key Points

- Generally, we define "older age persons" as those 65 years and older; this is a point of reference that has been used traditionally, but does not reflect the heterogeneity of aging.
- Although 60 percent of cancers (all sites combined) occur in the 65 and older age group, many cancers (lung, rectum, stomach, bladder, pancreas, colon, prostate) occur even more frequently in this age group. At least half of certain other cancers (leukemias, ovarian cancer, non-Hodgkin's lymphoma) occur in those 65 years or older. For all cancer sites combined, 69 percent of cancer deaths occur in the 65 years and older age group. However, mortality rates for various cancers vary significantly by age and gender, with progressive increases by five-year age cohort for the major cancer sites. The exception is lung cancer,

in which mortality for the oldest age groups declines; this difference is associated with smoking patterns in the various cohorts.

- The population aged 65 years and older, estimated at 13 percent of the U.S. population for the period 1990-2000, is expected to rise to 70 million people (20 percent) in 2030, or one in five persons. In addition, the older population will be older (i.e., the older age segments of this population will comprise larger fractions of the population aged 65 and older). Moreover, the numbers of older Americans will continue to swell through 2050, resulting in a rectangularization of the population age structure that was distinctly pyramidal until 1982.
- Since cancer is primarily a disease of older age persons, these population trends mean that, absent major treatment and/or prevention breakthroughs, we will have a growing population that is highly vulnerable to cancer.
- The NIA/NCI SEER Collaborative Study on Comorbidity and Early Diagnosis of Cancer in the Elderly, a retrospective medical records review of more than 7,600 patients with any of seven tumor types (identified through six of the SEER registries), demonstrates the heterogeneity of older cancer patients with respect to comorbid conditions. The study data have shown that as age increases, greater numbers of comorbid conditions are likely to be present, though many comorbid conditions are not life threatening. The data have also demonstrated that some older individuals, even in the older age groups, may have no comorbid conditions at the time of their cancer diagnosis.

Additional Research Needs and Other Recommendations

- Research is needed to address the following questions:
- How do the pathophysiology of aging, the interaction of aging with normal physiologic processes, and comorbidities impact cancer, cancer treatment, and cancer prevention?
- Do the various forms of cancer present differently in older persons?
- How can the complications inherent in the management of older patients be anticipated? What tools can be used as prognostic indicators?
- What are the potentialities, hazards, and limitations of surgery, radiation therapy, and chemotherapy in the older cancer patient? To what adverse reactions related to cancer treatment drugs and drug interactions are older patients at increased risk?

HEALTH RESEARCH QUESTIONS FOR OLDER AMERICANS—Dr. William Hazzard

Key Points

- Though often perceived as being the same, gerontology and geriatric medicine are distinct disciplines. Gerontology is the study of aging, a dynamic process that may be considered to begin before conception and end at, or perhaps after, death. It includes the programming and development of the entire life cycle and how it is played out in humans in the real world. In part, being old can be viewed as a process of having escaped certain other problems. Geriatrics is the science and art of caring for people who are old; it shares with gerontology the challenges of prevention, understanding the maintenance of health, vigor, and the social, psychological, and other aspects of robust life as an individual ages.
- The study of aging potentially has much to gain from collaboration and dialogue with those studying oncology and the processes involved in aberrant cellular replication, regulation, and death. As previous presenters have shown, we are seeing a growth in the older population and a decline in age-specific mortality rates at all ages across adulthood;

this is particularly the case among those aged 85 years and older. The functional spectrum of this group is likely to range from those who are robust, well-educated, financially secure, and socially engaged to individuals who are dependent, educationally and financially disadvantaged, and in need of enormous amounts of care and support. Additional Research Needs and Other Recommendations

- Our challenge today is to plan for the needs of the aging population. Scholars and scientists concerned with aging have an obligation to inform public policy debate. Some of the barriers to optimal care of the older person stem from traditional politics, practices, and economic considerations. For example, although the majority of cancers and cancer deaths occur in people over age 70 years, this is not reflected in the budget of the National Institute on Aging, which is one-third that of the NCI. This disparity also reflects a societal preoccupation with youth and, more recently, with middle age, rather than with the future when most people will be older. Continuing shifts in priorities can be expected as the population ages; this should be anticipated and acted upon.
- Geriatricians care for the cancer patients whose multiple comorbidities cause oncologists to reject them as candidates for cancer care. Collaborative education in aging and oncology can help to overcome this barrier to optimal care for older patients.
- One of the historical areas of acceptance of geriatricians is their understanding of the complexity of life and the need for multidisciplinary collaboration involving not only physicians, but non-physicians, therapists, psychologists, and public agencies. Oncologists will need to join forces with gerontologists to expand some of their approaches to patient care to best serve the very old, most of whom are women with multiple health problems.
- The hospice philosophy should be extended to people who have multiple health problems.

DISCUSSION—Drs. Yancik and Hazzard, and Ms. Ries

Key Points

- Multidisciplinary approaches have been acknowledged in both geriatrics and oncology as the best way to care for patients, however, these multidisciplinary approaches differ. The challenge is to integrate these two approaches, both logistically and educationally, to the best advantage of patients.
- An oncology-geriatrics retreat held in February 1997 included discussion, now leading to a formal proposal, for joint fellowship training of geriatricians and oncologists. Development of this proposal has also been one activity of a joint task force established by the American Society of Clinical Oncology and the American Geriatric Society; the task force is also discussing possibilities for joint research and clinical initiatives. At a later point, curriculum and clinical practice guidelines might also be developed for distribution to the geriatrics and oncology communities.
- It has been estimated that approximately 20 percent of the gender differential in life expectancy—currently about seven years—is attributable to gender differences in cancer incidence and mortality. Research is needed to better understand the complex mediating influences of lifestyle and behavior on this difference. Similarly, gender-related genetic and hormonal influences on processes such as inflammation and immune function (e.g., immune competence related to oncologic surveillance) are areas for further study. Gender-related differences become apparent to those treating the very old, the vast majority of whom are women.

- It was suggested that to some extent, medical oncologists have been key players in promoting interdisciplinary approaches to oncology. Other efforts that have supported this trend include the Geriatric Education Retreats noted previously and a companion program sponsored by the Hartford Foundation to encourage the incorporation of geriatric content in surgical subspecialty, emergency medical, and certain nonmedical specialty training. It was noted that creating a formalized focus on geriatric oncology within institutions attracts the interest and participation of health professionals from diverse disciplines. Having a geriatrics-oriented member on the treatment team helps to raise the awareness of all team members to the aging-related issues associated with care of older patients and can be particularly important when treatment options are being considered. In fact, it has been proposed that the geriatrician should now be included routinely on tumor boards.

NEEDS OF OLDER AMERICANS—Ms. Edna Kane-Williams

Background

The American Association of Retired Persons (AARP), a consumer organization dedicated to the needs of older adults, operates a number of educational programs under the auspices of its Health and Long-Term Care Issue Section. Two of these are cancer education programs, a prostate cancer education program for older men, and the Breast Care Campaign to encourage older women to perform breast self-examinations and be screened for breast cancer, being conducted in partnership with the NCI and the American Cancer Society.

Key Points

- In conjunction with the Breast Care Campaign, AARP conducted surveys of its membership and the general public, and also conducted focus groups with older women. Seventy-four percent of surveyed women over age 65 were aware of (had seen or heard something about) mammography in the preceding year. Older women in the western United States were found to be most aware of mammography; those in the South were least aware. Women aged 80 years and older were found to be less aware of mammography than were younger women in the survey. As expected, those with higher incomes and educational levels were found to be more aware of mammography than those with lower incomes and educational levels. The largest percentage of women surveyed learned about mammography from television; substantial percentages received information about mammography from doctors or newspapers.
- The focus groups revealed that among women who had had mammograms, the most important motivator had been their physician's recommendation. Conversely, lack of physician recommendation was found to be a major reason why older women failed to obtain mammograms. The survey findings also suggested that physicians other than obstetrician/gynecologists (whom older women tend to see infrequently) should be encouraged to recommend breast cancer screening to their patients; such physicians might include rheumatologists, cardiologists, and others.
- Most of the surveyed women (64 percent) were unaware that Medicare pays for a screening mammogram every two years. Seven percent believed Medicare paid for mammography only if a woman had symptoms. In addition, women surveyed expressed confusion as to the deductible and copayment requirements associated with Medicare mammography coverage, the distinctions between coverage for screening and diagnostic mammograms, and uncertainty as to how to locate a certified facility. These findings

suggest that the Health Care Financing Administration (HCFA) needs to more aggressively promote this benefit.

- Data collected on the Breast Care Campaign indicated the need for education about breast cancer screening, particularly for ethnically diverse populations, widows, those with low income, and those over age 80 years. The educational efforts should be designed to raise awareness that breast cancer risk increases with age, emphasize the importance of early detection, promote the three-pronged approach (breast self-examination, clinical breast examination, and mammography), and raise awareness of the Medicare mammography benefit. Strategies for achieving these objectives include advocacy efforts, use of media (e.g., video news releases, public service announcements, radio spots), and distribution of print materials such as brochures.

DISCUSSION—Ms. Kane-Williams

Key Points

- The data are insufficient and inconclusive concerning the benefit of screening women over age 80; breast cancer screening studies have typically excluded women over age 74 years. As a result, it is difficult to achieve consensus about screening recommendations for this age group. At the same time, it must be recognized that a randomized control trial of breast cancer screening in women over age 80 will never be conducted, since there are not enough women in this age group in the country to provide the necessary statistical power needed to generate a definitive answer to the question of screening efficacy in these women. Therefore, we need to find better ways to use existing data to develop sensible screening recommendations for women aged 80 and older.
- Physician-related reasons why older women do not receive screening mammography include incorrect but seldom tested assumptions that patients cannot afford the cost of mammography, do not want to be screened, or do not wish to be screened on a regular basis. Patient-related issues include the tendency for older patients to be less aggressive and assertive in asking questions of their physicians, or asking for screening. It was noted, however, that physicians generally respond positively to prompting.
- Although data on screening mammography in women above age 74 are not available, every study that has included women up to that age group has demonstrated that a significant difference in mortality results when screening is applied to the population. Therefore, in conjunction with publication of its revised mammography screening guidelines, an ACS consensus conference recommended that if a woman has a good quality of life with an estimated five year survival, she can be assumed to benefit from screening mammography. The guidelines for women in other age groups refer to essentially healthy individuals.
- Currently, women aged 65-70 years have the highest risk for breast cancer, yet less than half are receiving regular mammograms, the benefit of which is uncontested in this age group. A key question for the Panel is how to change this behavior. By contrast, 65-70 percent of women in their forties are being screened regularly, although some disagreement remains as to the mortality benefit of screening this population.
- Colorectal cancer incidence trends are declining, especially in the younger age groups. The decline in older age groups, however, has been slower. Colorectal cancer mortality among women has been declining for a longer period of time and to a greater extent than has the rate for men.

- The point was raised that while presenters and others have indicated that treatment for elderly cancer patients should be more aggressive, it has also been argued that health care expenditures in the last six months of life are often not justified by their benefit. The difficult issue of determining how to strike a balance between these conflicting views has complex bioethical, social, and economic components that will require ongoing discussion.

PRESENTATION HIGHLIGHTS: Research Findings and Issues Among the Aging

OPENING REMARKS—Dr. William Ershler, Moderator

Key Points

- Common ground between cancer and aging exists at a variety of levels, chiefly at the molecular level. We now have a good understanding of the antecedents of clinical cancer and the genes that are overexpressed, underexpressed, or mutated in the development of cancer. Gerontologists investigating cellular senescence have been studying these same genes, which they believe are also relevant to the biology of aging. Yet the distinction between cellular senescence and whole body aging is incompletely understood, and the relationship of cellular senescence and oncogenesis is not well understood.

MOLECULAR BIOLOGIC QUESTIONS—CELL CULTURE MODELS—Dr. Judith Campisi

Key Points

- In vertebrates, aging can be considered to take place in post-mitotic cells, mitotically competent cells, and the extracellular components (the source of elasticity and support for many body organs).
- Post-mitotic cells (principally neurons, muscle, and fat cells) never divide throughout an individual's life. Cell division is prevented by complex molecular mechanisms. Although tumors of the precursors of these cells may occur, when mature, post-mitotic cells never give rise to cancer. It is possible that these cells age by a fundamentally different mechanism than mitotically competent cells.
- Mitotically competent cells can divide *in vivo*; they are the source of tumors in people and animals. It has been recognized for about 40 years that noncancerous cells do not divide indefinitely. In a sample of normal cells, the ability to divide declines approximately exponentially until all cells have ceased dividing; at this point, the cells resemble post-mitotic cells. The number of cell doublings varies between 10 and 80 depending upon the age and species of the sample donor and the tissue type. Over time, the idea has developed that this process, referred to as cellular or replicative senescence, constitutes a tumor suppressive mechanism. Three exceptions to the replicative behavior of normal cells are believed to exist: germ cells, tumor cells, and perhaps, primitive stem cells. Tumor cells' replicative capacity does decline eventually, but essentially, they divide without any intrinsic limit. It is possible that stem cells of the hematopoietic system may not exhibit replicative senescence.
- The notion of replicative senescence, and its relationship to the aging of the organism, has only recently achieved legitimacy, particularly among cell and molecular biologists.
- Evolutionary theories of aging may be useful in understanding how the same cellular process can be involved in aging and cancer. It appears that the force of natural selection (the process that selects for genes that maintain reproductive fitness) declines with age. The processes associated with maintaining fitness while we reproduce (the sole concern of evolution) may have unselected adverse effects, but since these negative phenotypes only

manifest at post-reproductive ages, the evolutionary process will never correct them. Thus, the process of replicative senescence may act to keep us relatively cancer free for about the first 50 years of our lifespan, but may have negative repercussions in later age, particularly in tissues that have mitotically competent cells.

- Replicative immortality (i.e., escape from replicative senescence) places cells at extremely high risk for developing the malignant phenotypes that can be fatal. The replicative lifespan of a typical neonatal human cell (human fibroblast) is approximately 50 doublings, but this division potential is insufficient to accumulate mutations in all of the critical genes necessary to achieve aggressive malignant phenotypes and metastasis. Many tumor cells do not undergo replicative senescence, and it appears that there is a selection process associated with tumorigenesis to introduce mutations that allow cells to overcome normal senescence.
- It also appears that cells may achieve replicative immortality through the action of viral (and some cellular) oncogenes (i.e., normal proto-oncogenes converted to oncogenes by virtue of mutation). For example, we now know that some of the genes encoded by the human papillomavirus act primarily to get cells beyond the point at which they would naturally senesce. Another line of evidence for the relationship between cancer and replicative senescence is our current understanding that two tumor suppressor genes, p53 and retinoblastoma (RB), are critical for maintaining the senescent phenotype and signaling cells to cease replication. If either of these genes is inactivated in a normal cell, the cell will not senesce on schedule. If both genes are inactivated, the cell has a very high probability of becoming replicatively immortal and eventually becoming tumorigenic. It is estimated that 80 percent of naturally occurring human cancers have mutations in p53, RB, or both. Thus, tumorigenesis and the genes that control replicative senescence are intimately related in that they both rely on the activity of these two tumor suppressor genes. There are now at least two genetically engineered mouse strains (the p53 and p16 knockout mice) with complete knockouts of these tumor suppressor genes. Cultured embryonic cells from these mice do not senesce; in vivo, these mice develop cancer at an extremely accelerated rate.
- The idea that replicative senescence has a role in aging derives primarily from correlative molecular and cell biological data. It has been demonstrated repeatedly (though there are inconsistencies in the data) that there is a relationship between when a cell culture senesces and the age of the cell donor; in general, the older the donor, the fewer replications the cells have remaining. Interspecies comparisons demonstrate that the longer-lived the species, the greater the number of doublings a particular cell type is likely to have when measured in culture. For example, fibroblasts from the Galapagos tortoise undergo more than 100 population doublings; in humans 50-60 doublings are common; in the mouse 10-15 doublings are typical. The most optimistic interpretation of these data is that there may be an overlap between the genes that control life span and the genes that control the senescence of individual cells.
- Studies of premature aging syndromes in humans provide additional evidence for the relationship between aging and replicative senescence. In Werner's syndrome, an adult onset aging syndrome, affected individuals experience relatively normal development and puberty, but begin to age rapidly when the disease manifests itself in the person's twenties, thirties, or forties. People with Werner's syndrome do not get all of the diseases typically associated with aging, but frequently die from early cardiovascular disease. The second

most common cause of death is cancer. Cells isolated from people with this disease senesce much more rapidly than those from age-matched controls. The gene for Werner's syndrome has been cloned and is providing new insights into the relationship between aging and DNA repair transcription in cancer.

- Senescent cells produce an enzyme that causes the cells to stain differently from mitotic cells. In samples of young skin, staining reveals no senescent cells. In stained samples of skin from old donors, accumulations of senescent cells are apparent. There is reason to believe, therefore, that senescent cell not only exist, but accumulate in vivo. Many laboratories over the last several decades have shown that senescent cells express molecules that can act at a distance, some of which can pose a danger to healthy tissues. For example, senescent fibroblasts express enzymes that can destroy stromal portions of epithelial organs. This destruction may affect the basement membrane that contains the fibroblasts and supports and organizes the epithelial cells of the organ. These senescent cells also express molecules that are pro-inflammatory, prevent angiogenesis (causing tissues to be deprived of blood supply), and produce a number of growth factors with the capacity to stimulate growth. A testable hypothesis is that with age, accumulating senescent fibroblasts and senescent epithelial cells produce molecules that cause dramatic changes in the local microenvironment of the organ.
- The exponentiality with which cancer rates increase with age varies enormously by organ. In addition, it is known that multiple "hits" (exposures or other mutation-causing events) are required for an epithelial cell to be transformed to a fully malignant state. It is possible that during aging, molecular products of accumulating senescent cells are disrupting the microenvironment, which in turn may cause a given cell, mutated but previously controlled in the young organism, to begin to grow inappropriately. In this way, replicative senescence may contribute to the initiation of carcinogenesis. This hypothesis suggests that the relationship of cancer and aging is far more intimate than has been imagined previously; further, that the process of replicative senescence, which is critically important to keeping us cancer free, may actually be pro-carcinogenic within the atmosphere of the aged organism.

MOLECULAR BIOLOGIC QUESTIONS—ANIMAL MODELS—Dr. Richard A. Miller

Key Points

- There are important species differences in cancer risk. Although the lifetime risk of a lethal cancer is approximately 30 percent for mice (two to three year lifespan) and humans (75 year lifespan), the mouse has an average 10 percent per year risk of cancer, while a human has a 0.4 percent risk. Considering that the population of mouse cells susceptible to the cancer-forming process is far smaller than that of humans by weight, the cancer risk of mouse cells is 55,000 times higher than that of human cells.
- Scientists studying the biology of aging are in fact studying the biology of cancer. When we understand the biology of aging, we will solve the cancer problem because we will understand the fundamental biology of cancer and how it is linked to the genetics that exert evolutionary pressures.
- A major evolutionary challenge in developing a large, long-lived animal was to reduce cancer risk substantially enough and long enough to ensure the survival of breeding individuals. It is reasonable to believe that this was accomplished by making use of the pathways that also delay aging in a wide range of tissues. Thus, the genes that control

species differences in aging must also control species differences in cancer risk. One of the central problems for experimental aging research is to determine the location of these genes, their function, and the mechanisms by which they act.

- Studies in non-mammalian animal models are providing clues to the genetic regulation of aging and cancer. For example, the worm *C. elegans* normally has a lifespan of about 10 days; by changing a single gene, its lifespan can be doubled or tripled, even extended up to four-fold in the case of double mutations. Although the same genes regulating the worm's lifespan are not the same genes controlling human lifespan, the findings of this research suggest ways in which the genetics of aging in humans might also be linked through physiological processes. Other studies have shown that most of these long-lived *C. elegans* mutants share an unusual resistance to heat, ultraviolet light, and other stressors that typically damage cells. These studies and our current understanding of how humans alter their response to stressors suggest that longevity may be increased by raising resistance to certain kinds of cell stress.
- Mouse and rat studies have shown marked survival gains in animals placed on a calorie-restricted diet (40-60 percent of an average ad libitum diet). Not only is death delayed, but many age-associated changes (e.g., kidney disease, muscle failure, immune failure) are also retarded significantly. Further, calorie-restricted mice in these studies developed cancer at a delayed rate. It seems clear that the process timing the aging process and disease processes can be controlled by environmental manipulation.
- Studies of differences in longevity among various breeds of dogs suggest that more than half of the variation in their lifespans is associated with weight-determining genes. Similar studies are now being conducted with breeds of mice of different body sizes to assess weight-related differences in aging and cancer development rates.
- Other mouse studies suggest that lifespan may be predicted by testing the strength of immune response. Although the relationship demonstrated (that young mice with the lowest immune function die soonest) does not prove in any sense that the immune system controls the aging process, it provides hints that the genes that regulate aging may also have something to do with controlling the strength of an individual's immune response.
- Understanding the underlying principles that separate long-lived from short-lived animals can be of great help to gerontologists. For example, it is unexplained why certain sea birds that use enormously more glucose and generate far more free radicals than do animals such as rats or opossums nonetheless live 30-50 times longer than those mammals. To test specific questions about the aging process—such as the roles of DNA methyltransferase, brain plasminogen, the gene for Werner's syndrome, or glucose transporter genes—transgenic mice are being developed. To date, these animals have not been studied by oncologists, but it is likely that the strains of mice that are long-lived also have delayed cancer rates.
- To try to identify mouse genes involved in regulating aging and cancer rates, Dr. Miller and a colleague are studying approximately 600 animals (which are all genetically related though not genetically identical) that will be followed until death. Data are being collected on how long they live, what they die of, and their immune function at different ages. It is hoped that genetic differences associated with various outcomes will be discernable, although the principal interest is in genetic loci that regulate the age at death (i.e., the all-cause mortality risk). Preliminary results already indicate an allelic difference related to certain immune cell levels and cause of death from diverse causes including cancers, and

specific allelic differences related to fibrosarcomas, pituitary adenoma, and liver, breast and lung cancers. Some of the loci identified to date appear to be gender specific. Similar human studies by other researchers are beginning, but will take decades to complete.

DISCUSSION—Drs. Campisi and Miller

Key Points

- Concern was expressed about extrapolating too liberally from mouse to human regarding cancer rates; the majority of cancers in mice have an endogenous etiology influenced by retroviruses, whereas the pathogenesis of human cancers is more frequently related to environmental exposures that accumulate over many years, resulting in the multiple genetic “hits” that lead to malignant transformation. Dr. Miller indicated that retroviral etiology was established for leukemias and certain mammary tumors in mice, but that the etiology of other mouse tumors was not well characterized. He agreed that resolving the retroviral problem was probably important in the evolution of long-lived animals, but suggested that diseases with and without retroviral etiology seem to be regulated in common by speciation and by caloric restriction.
- Concerning the heterogeneity of rats, Dr. Miller suggested that rats that appear to be resistant to cancer often have genes that predispose them to die earlier of kidney disease, pituitary adenoma, or other lethal late-life pathologies. In humans, and in other animals, the onset of lethal syndromes is influenced by one's genes and by environmental factors. Learning about environmental influences is important for understanding disease etiology, but distracts us from understanding the fundamental influence of how aging increases the risk of all of these cancer and non-cancer diseases as a whole.
- When cells reach the point of replicative senescence, they cease to divide, begin to produce molecules that can act at a distance, and become resistant to apoptosis (programmed cell death). Preliminary data suggest that resistance to apoptotic death involves an up-regulation or stabilization of bcl-2 gene expression. It is known that circumvention of the apoptotic program increases cancer risk, however, while senescent cells resist apoptosis, they cannot divide and so virtually never give rise to tumors.
- It was suggested that the mutagenic and carcinogenic effects of low-dose ionizing radiation are not being adequately investigated. It was pointed out that the Department of Energy supports substantial research in this area, and that the National Institutes of Health supports a study section devoted to radiation biology.
- It was clarified that while mouse cells have far less replicative capacity than do human cells, mouse cells are notorious for the rate at which they escape replicative senescence, which human cells rarely do. This accounts for the higher rates of malignant transformation in mouse cells compared with human cells. It may indicate that mice have a more unstable genome and a greater propensity for escaping one of the anti-tumor mechanisms nature has provided. For species other than humans, the association of replicative capacity and life span disappears when the influence of weight (i.e., cell divisions needed to create a large animal) is factored out. In the dog studies cited, the influence of dietary fat was not studied; data of this type are not known to be available at this time.
- Concerning relationships among animal size, longevity, and reproductive efficiency, it was noted that small species tend to reproduce rapidly, while large species reproduce relatively

slowly. Within species, however, there is an inverse relationship relative to size—selection pressures lead to larger animals that have larger litters. Smaller animals within a species have smaller litters but may live longer and perhaps reproduce more frequently.

- The Nurse's Health Study has demonstrated an association between body mass and higher cancer rates.

PHARMACOLOGY AND AGING—Dr. Robert Vestal

Key Points

- Older persons currently comprise about 12 percent of the population, yet they account for 25 percent of physician visits, 30 percent of all drug mentions in various surveys, and about 35 percent of drug expenditures. More than 90 percent of ambulatory older persons take at least one medication; the average is four medications.
- Nursing home patients are at particular risk for high drug use. One study in Philadelphia showed that patients over age 80 years took an average 9.3 drugs per patient and had nearly 10 distinct diagnoses per patient.
- Age-related physiological changes can affect drug disposition in the body. Little difference in drug absorption (the passage of the drug from the site of administration into the plasma compartment) has been observed in clinical investigations. Similarly, little difference in drug bioavailability (the fraction of the drug dose administered that reaches the systemic circulation) has been observed. Drug distribution in the body, however, is affected by age-related increases in body fat (influencing the distribution of fat soluble or liquid soluble drugs) and accompanying decreases in lean body mass and in total body water (10-15 percent, affecting the distribution of water soluble drugs). The information about changes in proteins relevant to the binding of drugs in plasma is unclear; serum albumin levels (involved in binding acidic drugs) have been shown to be unchanged or decreased, while alpha-1 acid glycoprotein (involved in binding basic drugs) has been shown to be increased or unchanged. It seems clear, however, that in individuals with poor nutrition (e.g., cancer patients), serum proteins are likely to be depressed, affecting the plasma protein binding of some drugs.
- Animal studies of drug metabolism suggest clear age-related differences in liver drug metabolism, but may not reflect equivalent changes in humans; alterations in plasma clearance in humans are more likely related to changes in hepatic mass than to intrinsic enzyme activity. For example, available data in primates and humans do not suggest that intrinsic cytochrome P-450 activity is altered significantly with aging. Autopsy and ultrasound liver volume studies show, however, that hepatic mass decreases across the lifespan by 23-30 percent; hepatic blood is estimated to decrease by about 35 percent. These liver mass changes influence the amount of enzyme available for drug metabolism and, therefore, the clearance of drugs from the body. Studies of Warfarin (an anti-coagulant metabolized in the liver) dose requirements showed an association of decreased dose requirements and reduced liver size with advancing age.
- Environmental factors, including nutrition and exposure to cigarette smoke, can affect drug metabolism. Cigarette smoke is a potent inducer of certain P-450 enzymes, including P-450-1A2 and 1A1; the latter in particular has been implicated in carcinogenesis.
- Little is known about genetic polymorphisms influencing the expression of P-450 and other conjugation enzymes, nor are there indications of significant age differences in the expression of those enzymes. In addition, little is known about stereospecific or

stereoselective drug metabolism. For example, it is known that oral clearance of the l-enantiomer of hexobarbital is depressed in the elderly, but there is no age difference in oral clearance of the d-enantiomer. Similar studies of propranolol and ibuprofen have not shown age differences. More research is needed in this area.

- Many cancer drugs are excreted by the kidney. Kidney mass decreases by 25-30 percent between the ages of 30 and 80 years, and renal blood flow decreases about one percent per year after age 50. In addition, tubular function (PAH secretion, concentrating and diluting ability) and glomerular filtration rate (resulting in reduced creatinine clearance) are decreased with age.
- Drug response can be evaluated at the systemic, organ, receptor, and intracellular levels; and can also be assessed at the level of molecular genetic regulation of receptor and enzyme expression. Studies have shown that elderly patients are more sensitive to medications such as analgesics and anesthetics, and this population is at higher risk for adverse drug events (two- to three-fold higher regardless of setting) than are younger populations. Epidemiologic data show that adverse drug events in the elderly have more to do with the total number of drugs taken by the individual and number of diagnoses than with age. Evidence indicates that approximately 50 percent of drug-induced deaths occur in individuals over age 60 years.
- Other age-related physiologic changes that may affect older cancer patients include homeostatic impairments such as decreased blood pressure regulation, decreased thermoregulation (resulting in increased susceptibility to hypothermia and hyperthermia), and impaired volume regulation (e.g., decreased thirst, impaired excretion of water load).
- Drug interaction is a significant issue in individuals taking many drugs. These problems can include drug-disease interactions (i.e., a drug makes a pre-existing condition worse), drug-food interactions (e.g., foods causing impaired drug absorption, drugs causing malnutrition, including use of herbal and botanical preparations), and drug-drug interactions that can result in impaired drug absorption and induction/inhibition of drug metabolism. Smoking may induce drug metabolism to a lesser extent in older individuals than in younger people, however, studies of enzyme inhibition with various agents have tended not to show age differences in the susceptibility to inhibited drug metabolism; thus, the elderly will be just as vulnerable to inhibited metabolism of a highly toxic anti-cancer agent as would younger individuals.
- A New Mexico study indicated that 70-80 percent of the Hispanic population and 50 percent of the non-Hispanic population studied in the Albuquerque area used botanicals.
- Factors predisposing the elderly to polypharmacy include: multiple prescribing physicians, multiple filling pharmacies, propensity of physicians to prescribe, patient expectations, use of medications for symptoms rather than diagnoses, reluctance by physicians and patients to discontinue drugs, automatic prescription refills, use of multiple over-the-counter medications, and borrowing medications from family and friends.
- Age is not an independent risk factor for non-adherence to treatment. Rates of unintentional non-adherence range from 25-50 percent; omission is the most common form (up to 90 percent of all non-adherence). Factors predisposing to non-adherence include: dosing schedule complexity, frequent changes in medication or brands, multiple medications, unpleasant side effects, containers that are difficult to open, medication cost, difficult routes of administration, inadequate patient education and understanding, and cognitive, visual or physical impairment.

- Responsible prescribing is based on common sense: obtaining a complete history of medications, habits, and diet; evaluating the need for drug therapy; knowing the pharmacology of drugs prescribed; titrating from smaller initial doses to reach therapeutic levels; simplifying therapeutic regimens; encouraging treatment adherence and use of home health services; revising treatment plans regularly and discontinuing drugs no longer needed; using new drugs with caution; and monitoring for adverse effects.
- In conducting clinical cancer research with older populations, ethical considerations related to patients' ability to understand consent forms and complex clinical trial protocols must be addressed. Other clinical issues include those related to study population selection, population sampling, study design, and pharmacokinetic-pharmacodynamic relationships.

Additional Research Needs and Other Recommendations

- The literature on aging and cancer chemotherapy is exceedingly scant; research is needed on the complex issue of aging and the disposition of cancer drugs. There are opportunities for collaborations between medical oncologists and clinical pharmacologists interested in aging to uncover insights that will enhance the care of the geriatric cancer patient.

DISCUSSION—Dr. Vestal

Key Points

- Thoughtful investigators, given appropriate resources and motivation, will be able to design study protocols to answer key questions about aging and cancer that accommodate the issues of polypharmacy among these study subjects. Recent attention to the relationship between aging and cancer, and the interest of the President's Cancer Panel, may help to make resources available to further research in this area.
- Older cancer patients are rarely enrolled on early-phase drug studies. Those who do come to cancer centers tend to have fewer comorbidities (and take fewer medications) than patients being treated by community physicians in local hospitals; this reflects a selection bias common to the cancer centers. In addition, many research protocols require adherence to strict physiological function thresholds that exclude participation by older patients. It will require concerted effort to enroll older patients representative of the population in studies that will address the questions of treating cancer in older individuals. There is a need to develop clinical trials that will not exclude older people with comorbidities.
- Interactions among the multiple medications taken by many patients can cause unclear thinking and slowed reaction times. These effects in turn affect patient adherence. In addition, many patients are apathetic and depressed; older women in particular are nonassertive and may hesitate to ask questions or relate to their physician all of the problems they are experiencing. The U.S. Pharmacopeia is in the process of setting standards for the manufacture of the 12-20 most commonly used botanicals and evaluating the existing (poor quality) data on their use.
- In the same way we have extrapolated from studies done in middle aged or young males the drug regimens appropriate for children and women, we are basing drug treatment for older patients on studies done in younger populations. Pharmacologic research as suggested by Dr. Vestal might be best conducted by the pharmaceutical companies rather than the NCI or NIA. It was noted that New Drug Applications (NDAs) being submitted to the Food and Drug Administration (FDA) now usually include information about older populations. Based on guidance issued by the FDA in the late 1980s, the pharmaceutical industry is conducting small studies with older subjects in cases in which aging-related

effects are potentially relevant. In addition, aging-related issues are being monitored more closely than previously in post-marketing surveillance.

Additional Research Needs and Other Recommendations

- Currently, physician ambivalence, indecision, and inaction regarding treatment selection and advice to older patients is founded in a lack of knowledge. Research is needed to answer questions on the issues of aging and cancer so that clear answers and advice can be provided to patients. Dr. Vestal reiterated that molecular techniques are becoming more useful as tools for individualizing drug therapy; these techniques can help identify older cancer patients who may be at particular risk for bone marrow suppression, neurotoxicity, or other adverse side effects of cancer chemotherapies.
- Each drug used in oncology needs to be studied for its toxicity in the older patient. It should not be assumed, however, that a drug will not be well-tolerated by elderly patients. For example, a study found that although creatinine clearance in older people is decreased, platinum drugs are well-tolerated. It was noted, however, that studies such as these are relatively mundane and fail to attract the attention and support of study sections. A commitment of resources through the Cooperative Group program or a special initiative may be needed to begin systematic investigation of cancer drug toxicity in the elderly.
- The informed consent process and documentation must be made more understandable and less frightening to older patients; advocacy groups may have an important role to play in helping older cancer patients understand the benefits of participating in clinical studies.
- Polypharmacy in the elderly is a fact of modern medical practice. There is a need to better educate medical students in clinical pharmacology for the elderly; in most institutions, this is rarely addressed except in the context of general medical training on hospital wards.

PRESENTATION HIGHLIGHTS: Clinical Findings and Issues Among the Aging

OPENING REMARKS—Dr. Harvey Cohen, Moderator

Key Points

- Among the distinguishing features of the older patient are: marked health status heterogeneity, physiologic changes, increased prevalence of disease and multiple comorbidities, underreporting of symptoms, atypical presentation of common diseases, increased importance of social support, greater rates of adverse drug and treatment effects, and varied goals of treatment.
- The goals of care in geriatrics need to be refined. Guiding principles include considering the issues of cure versus care which should not be mutually exclusive; recognizing the heterogeneity of health status to ensure appropriate treatment to improve or maintain function and quality of life; including prevention in routine care; and providing comfort for the terminally ill.
- Clinical priorities for providing better care to the older cancer patient include developing a better understanding of disease behavior, comorbidity, and treatment response in this population; identifying and using biomarkers (including biochemical markers and physical assessment markers) for treatment vulnerability; developing new approaches to pharmacotherapeutics; and developing improved approaches to symptom control and supportive care. Funding increases are needed to both discover and disseminate knowledge in these areas.

PREVENTION/DETECTION—Dr. Patricia A. Ganz

Background

Cancer prevention and control, which targets multiple populations, is the application of the public health sciences (e.g., epidemiology, behavioral science, biostatistics, health services, environmental health sciences) to the cancer problem. Healthy individuals need screening to detect disease at its earliest stages and minimize cancer-related morbidity. High risk individuals (e.g., older women whose breast cancer risk is rising; individuals who have had a polyp removed from the colon and are at risk for subsequent polyps and invasive colon cancer) are potential subjects for chemoprevention or dietary intervention studies that may reduce their risk of future cancers. Cancer patients are also the subject of cancer control research, particularly related to issues of access to care, health services delivery, and quality of care. We know, for example, that the elderly are often under-diagnosed with many of the common cancers and are often undertreated. The growing community of cancer survivors suffer from the sequelae of cancer treatment and from psychosocial concerns such as fear of recurrence.

The cancer control research continuum includes prevention (e.g., primary prevention interventions to reduce smoking exposure or improve nutrition), detection (e.g., screening for common cancers), diagnosis and treatment (e.g., studies of patterns of care, access to state-of-the-art and standard care, stage at diagnosis), management (research on strategies for improving survival, quality of life issues, rehabilitation and continuing care, pain and symptom control), dissemination of information through public and professional education, and outcomes research (e.g., non-mortality outcomes such as quality of life, cost of treatment, quality of adjusted life years studies).

With a P-20 developmental grant from the National Institute on Aging, the University of Southern California (UCLA) Jonsson Comprehensive Cancer Center has established a program on breast cancer prevention and control in older women.

Key Points

- Elderly cancer patients typically are in community settings and are not usually treated at cancer centers. In addition, geriatric researchers are not usually part of the cancer center. This poses fundamental difficulties for studying the cancer problem in the geriatric population. Geriatricians and others who treat the elderly are aware that cancer is a leading cause of death and morbidity in the elderly. Screening tests such as mammography have a demonstrated impact on mortality and morbidity in the elderly population, who in fact comprise a large underserved community of patients.
- To develop the breast cancer prevention and control program for older women, Dr. Ganz and co-principal investigator David Rubin developed a leadership group of geriatricians, cancer control researchers, and other breast cancer experts. They also actively recruited new members to the Cancer Center through this program funding and workshops; the work of some of these individuals had not previously involved cancer. In addition, Ganz and Rubin sought to encourage established investigators at the Cancer Center to focus on older women. Established seed grant funding was also used to support pilot studies by junior and established investigators across the prevention and control research continuum, emphasizing breast cancer in older women. Faculty development awards have been used to attract geriatricians and health services researchers to cancer research, and annual workshops have been conducted with the participation of external advisors who are leaders in the field of geriatric oncology. The workshops have provided the opportunity to focus on

the special issues of elderly women and present research to the center's geriatrics and cancer communities. Participation by the external advisors has added a noninstitutional perspective that has been of great value to the program leaders and funding recipients.

- To date, five of 16 research applications submitted have been funded. Study topics have included breast cancer screening in older Filipino women, diet and estrogen metabolism in postmenopausal women with breast cancer, multiple breast cancer markers in fine needle aspiration (FNA) specimens, breast cancer screening in elderly caregivers, and quality of life in elderly breast cancer patients. One goal of supporting these pilot efforts was to develop and legitimize research activity on this area of cancer control at the cancer center. One of the pilot projects has since achieved NCI funding.
- To develop a robust geriatric oncology program of the type initiated at UCLA, it is necessary to establish a critical mass of investigators. After three years of operation, it has become clear that a sustained funding opportunity (not just a single RFA) is needed to develop a multidisciplinary group of people who will work together on a continuing basis. The Cancer Center has provided an excellent framework for establishing and operating this initiative. In addition, the collaborations with geriatricians have now expanded to include other cancer sites (e.g., colon cancer) and has increased geriatric focus on cancer.

Additional Research Needs and Other Recommendations

- There is a need for joint training opportunities in geriatrics and oncology. Many of the areas of interest to geriatricians are common to clinical interests in cancer prevention and control. We also need to build the research infrastructure and improve the limited data base that exists in many areas. For example, strategies that have been demonstrated to motivate younger people to obtain screening tests may not be appropriate for the elderly.
- It is a moral imperative that we provide access to high-quality prevention, detection, and state-of-the-art treatment to the elderly. Doing so simply means providing them with interventions we already know to be effective, and learning more about how to modify other strategies for this population.
- Developing strategic alliances among all of the health care professionals and researchers involved in caring for the elderly is essential. The breast cancer prevention and control program for older women at UCLA provides a successful model for initiating such activities.

HEALTH AND BEHAVIOR—Dr. Sarah Fox

Key Points

- For the population over age 55 years, we have few approved cancer screening tests that meet the criterion of reducing mortality. As of 1996, the only screening tests approved for this population by the U.S. Preventive Services Task Force are for breast, colorectal and cervical cancer. For breast cancer, the guidelines specify mammography alone or mammography plus annual clinical breast examination (CBE) every one to two years for women aged 50-69 years, continuing at age 70 and older if the woman has a reasonable life expectancy. Pap smears for cervical cancer are recommended every three years until age 65. Recommended colorectal screening, recently approved by the Task Force, does not specify an upper age limit; fecal occult blood testing (FOBT) is recommended annually and sigmoidoscopy frequency is not specified.
- 1992 National Health Interview Survey (NHIS) data indicated that approximately 60 percent of women aged 60-69 years receive Pap smears; screening rates for other tests

(CBE, mammography, colorectal cancer screening) are lower, as are rates for all tests among women and men aged 70 and older. NHIS data also show that between 1987 and 1992, gains in screening rates for Pap tests and CBE were slow for both the 60-69 year old age group and for those 70 years and older. Mammography screening, however, rose rapidly during this period.

- Although NHIS data indicate that about half of women are getting a mammogram, huge regional, age, and racial differences exist. At the national level, race differences in mammography use largely disappeared as of the 1990 survey and differences were almost totally driven by class, income, and education..
- Data (1995-6) from a Los Angeles study of the efficacy of churches as mammography-promoting agents found significant racial differences in mammography use. Approximately two thirds of white and black women over age 50 were being screened, but only 24 percent of Hispanic women reported recent screening. The most recent data, however, show a jump to 60 percent in screening rates for Hispanic women.
- Many factors predict screening rates; some of these are modifiable, others are non-modifiable demographic factors. We know little about gender differences in screening behavior because almost all of the studies have been done in female-only cancers. Colorectal cancer screening studies now being initiated will provide more data on gender differences in adoption or rejection of screening. Except as seen in Los Angeles, screening rates tend to drop with age. Race/ethnicity issues tend to vary regionally (for example, underscreening is common among black women in the South and among Hispanic and non-English speaking immigrant populations in Los Angeles), although screening rates of minorities overall tend to lag behind those of white women. Higher socioeconomic status (SES), particularly income and education, is a strong predictor of screening. Urban areas tend to have higher screening rates than do rural areas. Access, which includes health insurance, regular source of care, and continuity of care, is also a strong predictor of screening. Continuity of care is particularly important, since physicians are more likely to recommend screening to patients in an ongoing care relationship compared with new or intermittent patients.
- Group predictors at the community level, which represent intervention opportunities for enhancing screening rates among older populations, include physician offices and health maintenance organizations, churches, and retirement homes.
- Attitudes also represent modifiable predictors of screening. Older patients, despite their high cancer risk, feel less vulnerable. They feel more fatalistic about cancer should they develop it, however, not recognizing the distinction between early and late stage disease. Older people have more worries in general as they age, which can have a negative effect on screening, but they also find social support effective and respond quite well to physician recommendations. Physician attitudes can also make a difference in screening behavior. Doctors often underestimate life expectancy (e.g., a 65 year old woman has a life expectancy of 18 years and should be screened); they also misunderstand patient expectations, and believe these patients do not want screening or cannot afford it. This is not true for the majority of older people. On the other hand, physicians are highly supportive of guidelines (especially the American Cancer Society guidelines) and are open to education interventions that address their misunderstandings.
- Aspects of communication comprise another modifiable predictor of screening. Doctor/patient gender matching can be important, particularly for older women patients,

who may strongly prefer women physicians when potentially embarrassing tests (e.g., digital rectal exam, sigmoidoscopy) must be performed. Physician communication decreases with patient age, and physician recommendation for screening decreases for patients with comorbidities. Physician support is important to motivating screening behavior in older adults, and physicians respond well to requests for a referral. Older patients, however, are less likely to ask for referrals or information.

- Knowledge levels affect screening rates; compared with younger patients, older patients tend to be more confused about screening guidelines, and are less knowledgeable about risk factors. Hispanic and immigrant populations also have misperceptions, anxieties, and worries about cancer than need to be corrected. It is known that greater levels of knowledge lead to higher screening rates.

Additional Research Needs and Other Recommendations

- There is a need for more community-based programs to increase cancer screening rates among older populations. Such programs have distinct advantages: they are geographically based and therefore exportable, can achieve economies of scale in terms of modifying knowledge levels and attitudes, can include all income and race groups, and can establish networks that are reusable. It must be recognized, however, that launching a community intervention requires a great deal of money, particularly at the beginning stages of the project (e.g., to develop networks, an activity that may be unfunded or underfunded) and are difficult to complete within the typical four year grant period. In addition, it is challenging to assemble and maintain the interdisciplinary teams such efforts require.
- The power of the physician relationship can be better exploited to increase cancer and other disease screening rates among older individuals. Physicians can learn different communication techniques, particularly if they are simple, clear, and help alleviate patient adherence problems. Communication interventions are also adaptable to a variety of practice settings. Challenges to research in this area, however, include physician resistance to recruitment for studies and to being taped or observed, and costs associated with physician recruitment and their time. Despite these drawbacks, physician-oriented research is worthwhile, because of the economies of scale that can be achieved (i.e., a single primary care physician, convinced of the value of screening and trained to do it effectively, will influence the care of thousands of patients over his or her practice lifetime).
- The cost effectiveness of screening programs should be established prior to implementation.
- Better screening tests for prostate, ovarian, and pancreatic cancers are needed.
- Timely, targeted screening programs should be encouraged; some of the populations we need to reach with tailored messages are older persons, older minorities, the poor, and physicians and their patients.
- Greater funding is needed for community-based interventions.
- Interventions should focus on influencing modifiable characteristics, such as communication, knowledge, and attitudes.
- At the NIH level, funding should be increased for behavioral sciences, for community-based studies, and for the NIA. In addition, collaboration between Institutes (e.g., NCI/NIA; NCI/National Heart, Lung, and Blood Institute) should be encouraged.

DISCUSSION—Drs. Ganz and Fox

Key Points

- High yield (i.e., number of positive screens) in screening older people has been demonstrated; this is in part related to the prevalence of the target disease in the population. It is important to remember that the size of the target population shrinks in the older age groups, affecting calculation of the screening yield. In addition, the subset of the older population that gets screened is also related in part to the measures needed to reach them and the cost associated with getting these individuals in for testing.
- The older population should be considered targets for chemoprevention. The Breast Cancer Prevention Trial and the Prostate Cancer Prevention Trial both included older individuals. Chemoprevention in older women may deal with preventing both cancer initiation and promotion. A healthy older person who is at high risk for a condition (e.g., epithelial breast, bladder, pancreatic cancers) would still be a candidate for interventions that addressed the promotion aspects of the cancer process. We currently do not have a useful multi-organ preventive strategy.

TREATMENT—DR. Lodovico Balducci

Key Points

- In terms of physiologic robustness, population diversity generally begins to increase after age 50, peaking at around age 70; by age 90, most of the population belongs to the group defined by geriatricians as the “frail elderly.” The diversity of the older population complicates efforts to draw meaningful conclusions from clinical trials of cancer treatment in this group (those aged 65-90). It impacts the two major outcomes of treatment—life expectancy and quality of life—which are a function of an array of variables including physical function, comorbidity, cognition, emotion, social support, and resources.
- Certain studies of surgical outcome indicate that mortality increases with age; closer inspection of the data suggests that the increase is almost completely due to increasing mortality in emergency surgery. For elective surgery, the mortality difference between older and younger individuals is not statistically significant. This finding argues strongly for early detection in this population (e.g., identifying colorectal masses early and scheduling elective surgery before emergency bowel obstructions occur).
- Similarly, studies from Belgium and Italy of radiation therapy in several thousand older adults show that the incidence of grade 3 and 4 toxicity was minimal; similar smaller studies in the United States show similar results. It does not appear, therefore, that age is a contraindication to most, if not all, forms of radiotherapy.
- About 77 percent of patients aged 55 years and older with acute leukemia overexpress the MDR-1 gene (which indicates resistance to most chemotherapy agents) compared with 17 percent of patients younger than 50 years. This difference largely accounts for the poorer prognosis of older people with leukemia.
- Older patients (over age 70) are at increased risk of cardiotoxicity from the anthracyclines; chemotherapy-associated cerebellar toxicity is also increased in the elderly, as is myelosuppression and both peripheral and central marrow toxicity. It is possible that greater toxicities in older leukemia patients may be related to the loss of the normal reserve of bone marrow stem cells. Some strategies exist to minimize or avoid certain treatment toxicities (e.g., digoxin for anthracycline-associated cardiotoxicity, amifostin for cisplatin-caused kidney toxicity). Drug clearance can be affected by reduced liver volume and

kidney function in the older patient. Many chemotherapy drugs (and their active and toxic metabolites) are excreted through the kidney. Compromised kidney function, therefore, may in part explain increased chemotherapy toxicity in older patients. It is possible, however, to adjust chemotherapy dose to renal function. In addition to MDR-1-mediated drug resistance, apoptotic abnormalities are associated with multi-drug resistance. These abnormalities increase bcl-2 and p53 expression, which are associated with poor prognosis in many cancers, especially in older people. Other mechanisms of drug resistance include increased concentration of drug target enzymes and DNA repair abnormalities. It is also believed that tumors in older people may grow more slowly than in younger people; the lower growth fraction may offer a reduced target for the activity of cytotoxic and other agents.

- In acute myelogenous leukemia, Hodgkin's lymphoma, and some ovarian cancers, age is a predictor of poor outcome independent of stage of disease or chemotherapy dose. For a number of cancers, it is not clear why chemotherapy outcome is poorer in older patients.

Additional Research Needs and Other Recommendations

- Cancer patients less than 70 years of age should be treated in accordance with their performance status and organ function. Chemotherapy technique should be tailored to the individual situation and should err on the side of conservative treatment (i.e., using safer drugs when alternatives are available) unless individual circumstances require aggressive treatment. For example, unless necessary, older individuals should not be involved in high dose chemotherapy trials. At the same time, being conservative does not mean compromising therapeutic effects for fear of complications or excluding older individuals from the majority of clinical trials.
- Creatinine clearance should be used to adjust chemotherapy dosage for older patients.
- Immunopoeitic growth factors and cardio-protectors should be used routinely.

MANAGEMENT—Dr. Paul Carbone

Key Points

- Physiological age is more important than chronological age in treating older cancer patients. Physicians must consider the whole patient and base treatment on the individual's physiologic and other characteristics.
- Wisconsin data indicate that 78 percent of persons 65 years of age and older have at least one chronic condition (cancer, diabetes, hypertension, coronary heart disease, emphysema/bronchitis, arthritis). It is unclear how many of these conditions are important enough to affect primary cancer therapy. Older patients in good health should be considered differently for treatment compared with patients with multiple diseases and medications. Yet physicians are less likely to offer all older patients adjunctive treatment.
- If cancers in older individuals grow more slowly than those in younger people, preventive interventions need to be initiated early. If, as Dr. Carbone believes, tumors in older people do not grow more slowly, the preventive window of opportunity probably remains open up to age 50 or 60 years.
- Data from Holland and the United States (Wisconsin) indicate that while surgeons do not hesitate to operate on older breast cancer patients (though the surgery performed may be less than optimal), these patients are not receiving adjunctive radiotherapy or other potentially curative treatment.

- Wisconsin data also suggest that with increasing age, cancer patients are more likely to be diagnosed and treated at a small community hospital, and less likely to be referred to another hospital or cancer center for second opinions or other treatment. Similarly, data from the Eastern Cooperative Oncology Group (ECOG) show that accrual of patients aged 65 and older to clinical studies, which should average about 50 percent, is only 27 percent.
- In a 1989 study by Begg and Carbone of drug toxicity (19 drugs) among almost 5,500 elderly ECOG cancer patients with tumors at any of 18 sites, factors such as performance status, prior treatment, and weight loss were not age-related. Response and survival were not age-related, nor was specific organ toxicity (gastrointestinal, renal, cardiac, skin, infections, and neurologic toxicities). Most drugs were not associated with increased toxicity in the elderly; one exception was methotrexate, which was associated with greater hematologic toxicity, particularly in ovarian cancer patients. Methotrexate is excreted by the kidney; reduced renal clearance results in prolonged serum concentration and a greater likelihood of toxicity. Subsequent to this study, methotrexate dose has been based on the patient's renal clearance rate. In addition, the study concluded that chronologic age is not as important as physiologic age, and that chemotherapy for older patients needs to be individualized.
- Another study of hematologic toxicity of 20 chemotherapy drug in 16,000 patients found that certain drugs did have increased toxicity in patients older than 70 years. Chief among these were vinblastine (three-fold increase compared with younger patients), methotrexate, and VP-16. Drugs with smaller increases in toxicity in older patients included melphalan, adriamycin, cisplatin, dacarbazine, procarbazine, and cytoxan. The study concluded that while most drugs did not cause excess age-related toxicities, risk of toxic effects was greater for drugs that require biliary excretion and kidney clearance.
- A case control study of 645 Wisconsin breast cancer patients found that older women were less likely to see a radiotherapist or a medical oncologist. Surgery and hormone therapy were reported essentially equally in all age groups, but chemotherapy and radiotherapy were less often used in older patients. Younger patients were somewhat more likely than older patients to receive lumpectomy rather than mastectomy. This study did not identify geographic or insurance factors that might have influenced these differences in therapy. Older women were more likely to be diagnosed in the smaller hospitals lacking American College of Surgeons- approved hospital programs and were less likely to be referred.
- Analysis of the Wisconsin data on breast cancer patients by age and extent of disease at diagnosis did not find significant differences in stage of disease by age that would account for the observed differences in treatment.
- The World Health Organization defines palliative care as active and total care to maintain the best quality of life. Palliative care affirms life, and neither hastens nor postpones death. It provides relief from pain and other symptoms, provides psychological and spiritual support and helps the family cope with the patient's illness and death.
- Presently, palliative care is usually initiated only when anti-cancer treatment ceases. Since some of the goals of cancer treatment are relief of symptoms, pain, and chemotherapy side effects, it appropriate to integrate palliative measures into anti-cancer treatment. Pain control is a particular issue in the older population; pain may result from non-cancer causes (e.g., arthritis, osteoporosis), and many older patients resist taking opioid pain control medications for fear of their side effects and addiction potential.

- Barriers to effective palliative care include a lack of integration of these services in most health care systems, lack of knowledge of palliation principles and methods, limited knowledge of pain control options, cultural or religious barriers, insufficient numbers of minority health professionals, and inaccessibility of hospice care.

Additional Research Needs and Other Recommendations

- To overcome barriers to effective palliative care of older cancer patients, we need to: improve the education of students, residents, and physicians in this area; integrate palliative and hospice care into practice; revise reimbursement mechanisms for terminal care; ensure knowledge of and access to opioids; respect cultural and religious differences; and recruit minority physicians to this field.
- Management of symptoms should not be limited to terminal care. The spectrum of palliation extends from the initial care for cure until the terminal phase.
- Continuity of care from care for cure to palliation to hospice must be stressed.
- Oncology training must include adequate exposure to palliative and hospice care.
- Economical and humane care are important features of cancer care in the elderly.
- Oncologic management and geriatrics should be integrated.
- More studies are needed to learn how to treat older people more effectively and safely.
- Physicians must understand that most older cancer patients want the best possible treatment. It is essential to maintain communication with patients throughout the disease process to help maintain quality of life and hope; this is as important as curing the cancer.

ACCESS AND OUTREACH—Dr. Lawrence Baker

Background

Like the other major Cooperative Groups, the Southwest Oncology Group (SWOG) began with a number of member institutions and expanded to involve physicians throughout the community and throughout the country. These community oncology programs (focusing on high priority trials, minority recruitment, urologic cancer, and gynecologic cancers) have brought clinical trials to the communities where patients live.

Key Points

- Of nearly 700 cancer patients entered onto primarily Phase I and II clinical trials in 1996 at the University of Michigan, only 11 percent were aged 65 years or older.
- Currently, the principal participation of SWOG member institutions is in generating new ideas for trials; the community institutions enroll the vast majority of the patients.
- Of nearly 3,500 breast cancer patients treated in SWOG trials in 1995, only seven percent were older than age 65. This is explained largely by age caps on participation (typically up to age 65) and by age limitations specifically on intensive chemotherapy trials in breast cancer. For all sites combined, only 24 percent of more than 10,000 patients in SWOG trials were over age 65. Participation of older patients varied considerably by cancer site, however, ranging from seven to 50 percent for the most current year measured. Although participation in trials by older patients has increased for some cancers (leukemia, lung, and melanoma), it has decreased in others (breast, gynecologic, lymphoma, and myeloma) as the Group's interest has focused on transplantation treatment strategies.
- A study of patients presenting for inclusion in clinical trials found that more than 50 percent were not entered onto a protocol because there was no ongoing study on their

clinical problem, not because there was an age or other exclusion that prevented their participation.

- Major barriers to participation of the older patient in clinical trials include transportation (which may explain why so many older patients are treated in small community hospitals), cost (such as Medicare prohibition on reimbursing for antiemetics if given orally rather than intravenously), loss of mobility, physician prejudice against treating the older patient, and patient prejudices such as fear of cancer, cancer care, and its costs.

Additional Research Needs and Other Recommendations

- Older patients' access to clinical trials can be improved by raising awareness of issues related to aging and cancer treatment, supporting joint oncology-geriatrics training opportunities, and tailoring protocols to the needs of older patients.

DISCUSSION—Drs. Balducci, Carbone, and Baker

Key Points

- Some of the complex issues of increasing older patients' participation in trials were revisited: lack of a trial addressing the patient's particular problem, perhaps excessive focus on treatment strategies that may not be appropriate to the majority of patients (e.g., bone marrow transplant for breast cancer), physician reluctance to treat eligible older patients, and patient reluctance to enter a trial. Another barrier is the manner in which clinical trials are presented to older patients. The NIA and AARP could have a significant role in improving the informed consent process for older people and helping older patients (particularly those in good health) understand that clinical trials are the principal avenue for finding ways to remove one of the major threats to their health and welfare.
- To the extent the question has been investigated, it appears that outcomes for patients who do enter trials are not markedly better or worse than those who do not participate in clinical studies. This question has not, however, been studied specifically concerning the older population.
- The importance of carefully selecting older patients for clinical studies was reemphasized. Many can do well, even in autologous bone marrow transplant and myeloma treatment trials, but there are instances in which older patients are at risk for serious toxicities (e.g., ifosfamide treatment for sarcoma).
- To adequately tailor trials to the older patient, more data are needed on age-related functional changes that may need to be accommodated.
- Questions needing further study regarding older patients' appropriateness for bone marrow transplant include whether older patients do less well because their own bone marrow has limited reproductive potential (i.e., too many senescent cells) and whether their bone marrow has a greater potential to develop malignancies. It was suggested that in addition to physicians' reluctance to place older patients at risk for serious toxicity in transplant settings, there are clear indications that graft versus host disease (GVHD) can be very severe in some of the oldest patients enrolled in transplant studies.
- Chemotherapy does reduce mortality among cancer patients; considerable advances have been made in certain cancers (e.g., breast cancer, Hodgkin's disease). Conversely, chemotherapy has shown little efficacy for certain other malignancies, such as lung and pancreatic cancers.

PRESENTATION HIGHLIGHTS: Health Advocacy

OPENING REMARKS—Dr. Elizabeth Clark, Moderator

Key Points

- In health care, advocacy is the active informing and supporting of persons so that they can make the best decisions possible for themselves. In cancer survivorship, advocacy is a continuum. It begins at the personal level, but it may encompass organizational and political advocacy.
- Survivorship is not only about long-term survival or cure. Rather, cancer survivorship is a term used to represent the state of living with the challenges of the cancer experience. It is a dynamic concept that avoids creating unnecessary and inaccurate boundaries in the lives of people with cancer. Equating survivorship only with cure fails to take into account those persons who live for many years with cancer as a chronic disease, those who indefinitely require maintenance therapy, and those who experience recurrences, or second or tertiary malignancies.
- There is little consensus as to what underlying processes explain different levels of long-term functioning after cancer diagnosis, but many researchers believe empowerment plays an important role. Empowerment assumes that individuals typically understand their own needs better than do others, and that it is optimal for individuals to have the greatest possible control in determining various aspects of their lives and in making informed decisions about actions that will shape the quality of their lives. Patients' need for empowerment emphasizes the importance of education as a part of health advocacy.
- Nationally, interest in end-of-life issues has centered on issues of physician assisted suicide, but many cancer advocates feel that policy makers and the cancer community should concentrate first on improving the quality of life of terminally ill individuals, in part by ensuring that they receive adequate pain treatment and psychosocial care.

Additional Research Needs and Other Recommendations

- We need to ensure that elderly people with cancer have Medicare coverage for the full range of quality cancer care—from screening and access to specialists' care, to pain management and psychosocial care, to long-term and hospice care. As increasing numbers of Medicare beneficiaries are covered under managed care plans, it is increasingly critical that these plans provide access to all necessary cancer care.
- Older cancer patients must have access to clinical trials when such care offers the opportunity for the best possible outcome.
- Cancer care includes not only therapies designed to extend an individual's life but also care focusing on improving the cancer patient's quality of life. Therefore, people with cancer, including the elderly, must have access to the full spectrum of cancer care, including palliative treatments like pain medications and antiemetics.
- The phrase "quality of life" must be used with some caution. It has been discussed as a tool for assessing which older patients (i.e., those with the expectation of a good quality of life for the next five years) should receive cancer screening. But questions remain as to how quality of life is being measured and who should make the determination as to whether an individual's quality of life is good, or good enough, to merit screening or treatment. Quality of life research is still largely uncharted territory concerning elderly populations, and we are only just beginning to conduct research in long-term cancer survivorship.

- Elderly persons with chronic conditions such as cancer require access to long-term care. Public policies must ensure quality nursing home care, home health care, and hospice care. As the number of our elderly citizens who are survivors of early cancer diagnoses continues to rise, advocates and policy makers must consider the special needs of these long-term survivors. Medicare must cover long-term follow-up care, including appropriate screening and treatment for secondary diagnoses for these survivors. Research on the late and long-term effects of cancer and cancer treatment on long-term survivors is becoming increasingly important.
- Health care professionals need to be more creative and assertive in fostering consumer empowerment. This is especially critical for the elderly person with cancer who may already be disempowered due to other psychosocial factors.
- Practitioners also must become more informed advocacy partners with their patients in the public debate about health care and health care delivery.

SURVIVORSHIP FOR AGING PATIENTS WITH CANCER—DR. Barbara Given

Key Points

- Much of cancer care is now provided in ambulatory or short-stay acute care settings; elderly patients are discharged with the expectation that they will rely on their own resources and family members for the care they need. Improvements in diagnosis and treatment have extended the survival period of many older patients with cancer. Therefore, there are many survivorship transition points at which the family and patient must work in partnership with health professionals. Health care professionals need to have a better understanding of the antecedents to positive long-term survivorship so that they can work effectively with the patient and caregiver.
- Unmet needs of the older cancer patient include symptom control; assistance with regaining mobility and function; emotional support and mental health needs; caregivers' need for knowledge and skills related to care, surveillance, and monitoring; coordination of care, and more effective family assistance.
- Desired outcomes for positive survival include continuity of care, return to physical and role function, mental health, symptom management and control, early detection of problems and complications, and continued and supportive care.
- In a community study of newly diagnosed lung, prostate, colorectal, and breast cancer patients over age 65 years, the average age of the patient's caregiver was 65 years and 48 percent of patients had three or more comorbid conditions. Of patients eligible for the study, 37 percent had no caregiver; these patients in particular represent a population at risk for less than optimal recovery and rehabilitation.
- In this study, patients were interviewed (after four to six weeks of treatment and again after 14-16 weeks of treatment) about the number and type of cancer- and cancer treatment-related symptoms they experienced. After 14-16 weeks, more than 50 percent of those interviewed still reported a high number of symptoms or had even deteriorated (i.e., reported more symptoms than at the earlier interview). Chief among the symptoms reported were pain, fatigue, and insomnia; there were no significant differences by cancer site. Further, measures of physical functioning and depression showed that physical functioning was still reduced, and depression still greater, at the second interview.
- This study suggests that cancer patients with continued unmanaged symptoms, particularly pain and fatigue, are at risk for negative survivorship. Symptom experience is related to

depression and functional status. Mental health needs of these patients continue into their survivorship experience; situational depression may be a particular issue. Patients in the study were provided few formal skilled care services and none focused on mobility, mental health, recovery, or physical function. Services that were provided were short-term and related to discharge from an acute care setting (e.g., catheters, wound dressing) rather than an overall rehabilitation or recovery plan.

- In this study, some caregivers were more ill than the cancer patient; in other cases, a cancer patient in the study was called upon to be a caregiver for someone sicker than they were. This reality highlights a major issue in chronic illness management.

Additional Research Needs and Other Recommendations

- Prevention of disability in the highly heterogeneous older cancer survivor population is critical to avoid major long-term care needs. We need to focus on maximal recovery and return to function in this population. Families need guidelines on how to help with recovery and manage symptoms.
- We need to develop risk profiles for all phases of survivorship to examine how age, stage, treatment, disease site, and comorbidity influence completion of treatment, symptom control, functional status, and mental health.
- Evidence-based guidelines for survivorship that include the patient and family are needed to address issues related to completion of treatment, symptom control, functional status, and mental health.
- These risk profiles and guidelines should be tested in randomized clinical trials to determine their impact on families, resource usage, health costs, and the clinical outcomes and recovery of patients.

SUPPORTIVE CARE MODELS—Dr. Kenneth J. Pienta

Key Points

- The transition that occurs when a patient is transferred from active treatment (with curative intent) to symptom palliation only is jarring to the patient, the family, and the health care provider. In the case of advanced prostate cancer patients whose disease has not responded to hormonal therapies, a choice must usually be made between trying chemotherapy to extend life beyond the typical six-month average remaining life span of these patients, or supportive care through a hospice program. This choice is a difficult one, since chemotherapy is hard on these patients, but choosing hospice may be perceived as surrender. Traditionally, hospice programs do not accept patients who are being actively treated.
- The goals of the oncologist and the hospice team in treating these patients are essentially the same—control of pain and other disease-related symptoms, helping patients and family cope with psychological issues of terminal disease and death, emphasis on palliative care and quality of life. The major difference is that the oncologist is also trying to help patients live longer and typically has less time to attend to the patient's supportive and psychosocial care needs.
- To address all of these needs, Dr. Pienta and colleagues developed a supportive care program that enables patients to choose both to actively fight the disease and at the same time get the best possible supportive care. Combining the medical care model (disease oriented, with an emphasis on recovery, disease eradication, and prolongation of life) and the hospice model (which is symptom oriented and emphasizes quality of life), the goals of

the program included elimination of abandonment, improved patient care, improved quality of life, and cost effective health care delivery.

- The supportive care program involves a patient care team that includes the oncology team (the primary care providers, consisting of the oncologist and nurse practitioner or physician assistant), hospice social worker, hospice nurse, and a program coordinator who oversees the patient's inpatient and outpatient care and serves as a liaison between the oncology team, hospice team, and patient.
- Patients are offered enrollment in the program when they enter chemotherapy; those who enroll are visited by the program coordinator and hospice team in their home. They are seen routinely in the clinic by the oncology team and as needed (even daily at the end of life) by the hospice team. All team members meet monthly to discuss each patient.
- Outcomes being tracked through the program included quality of life, cost, symptom management, and patient and provider satisfaction with care. In one (non-randomized) study of enrolled patients and a control group, all of whom had advanced metastatic prostate cancer, surveys and anecdotal feedback demonstrated high levels of patient and family satisfaction in level of support, timely assessment of potential side effects and toxicity, and decreased emergency room and clinic visits (made possible by the 24-hour availability of team members for home visits to assess symptoms). Providing patients with access to the hospice supportive care network through which they could deal with the issues of terminal disease and dying also proved to be an important benefit for the patients' care givers and family. Importantly, the supportive care program provides patients and family with six months of such support in the home environment, instead of the average of two weeks most patients receive hospice care in southeastern Michigan. Ongoing bereavement support was also important to family members. Patients enrolled in the program and others not enrolled also were assessed using a Functional Assessment of Cancer Treatment—Prostate (FACT-P) quality of life assessment instrument. The FACT-P indicated that patients in the program had a better quality of life than those not enrolled.
- It was also demonstrated that by enrolling patients for the hospice benefit, through which noninvestigational chemotherapy drugs used for symptom relief, CT scans, and palliative radiotherapy could also be provided, it was possible to provide a more comprehensive level of total care at a cost commensurate with (three dollars per patient day more than) the cost of care provided to the control group patients.
- Based on these results, Dr. Pienta and colleagues have partnered with the Robert Wood Johnson Foundation and several community hospitals in Michigan to conduct a randomized study of the supportive care model versus standard care, and track quality of life, health outcomes, and cost in both the community and academic setting. Approximately 600 advanced prostate, breast, and lung cancer patients, and patients with congestive heart failure, will be included in the study, which is expected to begin in the spring of 1998.

EDUCATION—Dr. Harmon Eyre

Background

The American Cancer Society (ACS), the largest voluntary health agency in the Nation, was established more than 80 years ago. Its current budget is \$400 million. Its staff number 4,000, plus two million volunteers working in 3,400 communities in the United States. The ACS estimates that this combination of paid and volunteer effort brings to bear the equivalent of \$3-4 billion on the Nation's cancer problem. The ACS is currently

reorganizing to maximize its efficiency and effectiveness. Approximately 50 percent of the budget supports programs and services delivered in the community. The ACS enjoys exceptional public recognition and trust—95 percent of Americans surveyed recognize its name, and 50 percent cite the ACS when asked to name a voluntary health agency. The principal mission of the ACS is to educate the public and health care professionals. The agency also funds approximately \$100 million of research and maintains an active program in cancer epidemiology and surveillance. Its Cancer Information Program receives an estimated one million calls per year; approximately 60 percent of callers are patients or family members, and information on breast cancer is most frequently requested.

Key Points

- ACS's Cancer Prevention Study No. 2 (CPS-2), a cohort study of 1.2 million Americans with an average age of 60 years at enrollment in 1982, continues to generate data. Among its findings were that individuals aged 60 and older between 1982 and 1995 who smoked, ate a diet low in fruits and vegetables, had a low activity level, and were overweight had a four-fold increased risk of death from all causes and a three-fold increased risk of cancer death. Follow-up surveys of this population demonstrate that changing these lifestyle parameters and body weight can modify these negative outcomes. ACS is currently following up on the diet studies in this cohort to accumulate more data in this area. CPS-2 data suggest that preventive behaviors may be of benefit throughout life, not only up to age 50 or 60, as has been suggested. Data are needed to help older individuals make healthful lifestyle choices. The ACS Behavioral Center is planning a 50,000-100,000 person cohort longitudinal study of cancer survivors that will sample age groups including the elderly population; further, the study will over-sample certain minority populations to generate more accurate data about these groups, and will also include cross-sectional studies.
- The average age of callers to the ACS Cancer Information Program 800 number is around 48 years. Less than 10 percent of callers are over age 65. To help callers become more effective self-advocates, the ACS is striving to individualize the pamphlets, printouts and other information sent to those requesting such information. This will include listings of American College of Surgeons and NCI-designated cancer centers to address the issue of older individuals with cancer receiving treatment in small community hospitals that lack systematic processes for ensuring quality cancer care.
- The evolving health care system poses one of the biggest threats to the quality of health care across the country. The ACS is concerned that the SEER program inadequately captures data on health system effects on cancer care, particularly in the southern region of the Nation. The ACS is exploring the possibility of establishing a population-based national cancer care surveillance program to help gather these data so they can be provided to the public.
- ACS is also increasing its advocacy program; recent efforts have included advocacy for colorectal cancer screening reimbursement, currently being considered by the Congress.
- Cancer control activities of the ACS are ongoing across the country; in smaller communities these are run by volunteers only, while larger communities also have paid staff with diverse expertise. ACS provides support programs, transportation, and targeted programs such as Look Good, Feel Better for women cancer patients. Though resource-intensive, these programs are important in a health care delivery environment in which resources for ancillary support services are diminishing.

Additional Research Needs and Other Recommendations

- In the area of prevention, several areas warrant further investigation: What preventive interventions are possible in the elderly population, specifically concerning smoking control, diet and exercise, and clinical trials participation?
- In screening and early detection, we need to determine the best use of resources to effect behavioral change in older populations.
- Ongoing national monitoring of quality of care is needed to ensure that the elderly are receiving appropriate cancer treatment; monitoring care provided in small community hospitals will be particularly difficult.
- There is a need to better catalog available patient support services and other community resources so that unmet needs can be identified and the most appropriate mechanisms for delivering needed services can be determined.

DISCUSSION—Drs. Given, Pienta, and Eyre

Key Points

- Physicians should avoid referring to cancer patients as terminal, since this term has a negative impact on patient attitude. It is important for patients to have a realistic understanding of their disease, but avoiding this term better enables them to address issues that occur any phase of disease in a more positive way.
- It was clarified that cancer itself does not cause depression, however, cancer patients are vulnerable to situational depression and should be evaluated periodically for clinical depression.
- Treatment cost is a major issue for older cancer patients, who may have to choose between buying food or medications. Physicians' choice of medication may be constrained by health plan and Medicare requirements to select the least costly alternative that may not always represent the best choice for the patient.
- Physicians do not always provide complete information about treatment options, including clinical trials; this deprives the patient and family of the opportunity to make an informed choice.
- Concern was expressed about the effect of managed care on the doctor-patient relationship. Dr. Kennedy suggested that it will be up to patients, not doctors, to insist that current restrictions on the duration of office appointments be modified. Dr. Clark indicated that while patient advocates are becoming more sophisticated and activist in their approach, a partnership between patients and health care professionals will be needed to ensure quality cancer care.
- The ACS's I Can Cope program for cancer patients and their families has been incorporated into the hospice system in some areas; this application of the program should be more widely considered.
- Joint funding and joint treatment and training programs in geriatrics and oncology should be pursued. For example, the ACS has a new clinical research training grant that would be highly appropriate for such dual focus studies. In addition, ACS targeted research in prostate cancer is focusing on quality of life and age-related issues; part of the goal of this targeted research is to attract behavioral and other investigators who have not necessarily been working on aging or cancer issues.

CLOSING REMARKS—Dr. Calabresi

In closing, Dr. Calabresi noted that:

- The magnitude of the problem of cancer in aging is great and will be increasing in the future. Accordingly, in its charge to report to the President blockages or delays in the execution of the National Cancer Program, these issues will be given high priority.
- He shares the view of the presenters on basic science issues that fundamental research in cancer and aging are intrinsically related; molecular and genetic insights can be expected to come from either field of research.
- Pharmacologic studies of drugs and the elderly are essential; such studies will probably be best conducted in specialized centers rather than in large Phase III Cooperative Group clinical trials.
- As the older population is at high risk for cancer, prevention and early detection interventions should have rewarding benefits.
- Choice of therapy, including bone marrow transplant and other aggressive therapies, should be based on physiological rather than chronological age. New and better growth factors and other agents are needed to mitigate treatment toxicity in the older population. It should be remembered that cure (eradication of the disease) may not be necessary in the older patient in whom effective palliation and control of the cancer may be just as desirable. There are many diseases (e.g., hypertension, diabetes, pernicious anemia) that cannot be eliminated but can be controlled effectively.
- Survivorship will be a major topic of a planned future meeting of the President's Cancer Panel. These issues are important because the survivor population is growing (more cancer patients are now surviving than are dying) but is at high risk for second and third cancers.
- Joint programs and funding for professional and public education in geriatric oncology are much needed. Dr. Calabresi congratulated Drs. Halter and Wicha for their vision and collaboration in establishing a center for geriatric oncology at the University of Michigan.

CLOSING REMARKS—Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- The geriatric oncology center at the University of Michigan will serve as an organizational model for the rest of the country in addressing the questions of cancer and aging.
- We should not automatically accept that cancer comes with aging. The scientific and biological reasons that older people get more cancer must be elucidated; finding these answers will have a major impact on the total cancer problem. It is natural that as people age, they have more medical conditions, but these comorbidities should not necessarily be a barrier to participation in clinical trials.
- The issues of cancer and aging raised by the presenters have received relatively little attention. The Panel will carry these issues to the President with vigor, and its report will be made available to the public.

CONCERNS OF SPECIAL POPULATIONS IN THE NATIONAL CANCER PROGRAM

SEPTEMBER 29, 1997
BETHESDA, MD

PRESIDENT'S CANCER PANEL

NATIONAL CANCER PROGRAM

NATIONAL CANCER INSTITUTE

CHAIRMAN
HAROLD P. FREEMAN, M.D.
HARLEM HOSPITAL CENTER

MEMBER
FRANCES M. VISCO, J.D.
NATIONAL BREAST
CANCER COALITION

MEMBER
PAUL CALABRESI, M.D.
BROWN-TUFTS CANCER CENTER
RHODE ISLAND HOSPITAL
NEW ENGLAND MEDICAL CENTER

EXECUTIVE SECRETARY
MAUREEN O. WILSON, Ph.D.
ASSISTANT DIRECTOR
NATIONAL CANCER INSTITUTE

Concerns of Special Populations in the National Cancer Program The Real Impact of the Reduction in Cancer Mortality September 29, 1997, Bethesda, Maryland

Opening Remarks	<i>Dr. Harold Freeman</i>
Director's Report	<i>Dr. Richard Klausner</i>
The Cancer Picture	
Incidence, Mortality, and Survival—An Overview	<i>Dr. Brenda K. Edwards</i>
Cancer in the Whole Health Context	<i>Dr. Edward Sondik</i>
Using Data for Cancer Control Planning	<i>Dr. Phyllis Wingo</i>
The Leadership Initiatives	
National Black Leadership Initiative on Cancer	<i>Dr. Louis W. Sullivan</i>
National Hispanic Leadership Initiative on Cancer	<i>Dr. Greg Talavera</i>
Appalachian Leadership Initiative on Cancer	<i>Dr. Gilbert H. Friedell</i>
Native American Initiatives	<i>Dr. Linda Burhansstipanov</i>
Consumer Concerns for the Future: The Voice of Advocacy	
National Coalition for Cancer Survivorship	<i>Dr. Elizabeth Clark</i>
US-TOO International, Inc.	<i>Mr. John Campbell</i>
National Asian Women's Health Organization	<i>Ms. Mary Chung</i>
North American Brain Tumor Coalition	<i>Dr. Susan L. Weiner</i>
Intercultural Cancer Council	<i>Dr. Lovell Jones and Ms. Susan Shinagawa</i>
Issues for Research and Medicine	
American Medical Association	<i>Dr. Priscilla Short</i>
American Society of Clinical Oncology	<i>Dr. Allen S. Lichter</i>
Oncology Nursing Society	<i>Ms. Pamela J. Haylock</i>
National Medical Association	<i>Dr. Nathaniel H. Murdock</i>
American Association for Cancer Research	<i>Dr. Donald S. Coffey</i>
Closing Remarks	<i>Dr. Harold Freeman</i>

Speakers List

Concerns of Special Populations in the National Cancer Program

The Real Impact of the Reduction in Cancer Mortality

September 29, 1997, Bethesda, Maryland

Dr. Linda Burhansstipanov

Director
Native American Program of Cancer Research
AMC Cancer Research Center

Mr. John Campbell

Communications Counsel
US-TOO International, Inc.

Ms. Mary Chung

President and Executive Director
National Asian Women's Health Organization

Dr. Elizabeth Clark

President
Coalition for Cancer Survivorship

Dr. Donald S. Coffey

President
American Association for Cancer Research

Dr. Brenda K. Edwards

Associate Director, Cancer Control Research Program
Division of Cancer Prevention
National Cancer Institute

Dr. Gilbert H. Friedell

Director for Cancer Control
University of Kentucky Markey Cancer Center

Ms. Pamela J. Haylock

President
Oncology Nursing Society

Dr. Lovell Jones

Intercultural Cancer Council
M. D. Anderson Cancer Center

Dr. Allen S. Lichter

Department of Radiation Oncology
University of Michigan Medical Center

Dr. Nathaniel H. Murdock

President
National Medical Association
Barnes Jewish Hospital

Ms. Susan Shinagawa

Intercultural Cancer Council

Dr. Priscilla Short

Director
Biomedical Science and Clinical Research Division
American Medical Association

Dr. Edward Sondik

Director, National Center for Health Statistics
Centers for Disease Control and Prevention

Dr. Louis W. Sullivan

President
Morehouse School of Medicine

Dr. Greg Talavera

Assistant Professor
Graduate School of Public Health
San Diego State University

Dr. Susan L. Weiner

Chair
North American Brain Tumor Coalition

Dr. Phyllis Wingo

American Cancer Society

CONCERNS OF SPECIAL POPULATIONS IN THE NATIONAL CANCER PROGRAM

The Real Impact of the Reduction in Cancer Mortality

September 29, 1997, Bethesda, Maryland

OVERVIEW

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. The purpose of this meeting, the third in a series of four meetings focusing on the concerns of special populations in the National Cancer Program, was to review recent statistical indicators of reductions in the Nation's cancer burden, to assess how and if these reductions affect various population groups and cancer sites, and to identify key issues for research and medicine.

Eighteen speakers representing varied disciplines presented testimony to the Panel on these issues and offered specific recommendations for measures needed to extend reductions in cancer mortality to broader segments of the population, for improving data collection on specific populations to support intervention planning and surveillance of the cancer problem, and for needed research and funding in a variety of areas.

OPENING REMARKS—Dr. Harold Freeman, Chairman, President's Cancer Panel

In opening the meeting, Dr. Freeman stated that:

- The final meeting in this series of four, to be held in Tampa, Florida on November 21, 1997, will examine the responsiveness of the health care system to the needs of special populations.
- Our best measures of progress against cancer in all populations have been empirical data on cancer incidence, mortality, and survival, but cancer comprises a complex number of diseases, and interpreting the data measuring reductions in cancer burden is equally complex. While mortality rates for total cancers appear to be declining in the United States, incidence rates for total cancers are increasing. These trends are not uniform across populations, however, or across disease types. Generally, the burden of cancer remains higher among minorities and other special populations such as the elderly and the poor, but this is not true for all populations or all cancers.
- Existing data raise questions as to how they should be interpreted in terms of setting research and health care priorities. In particular, unique issues exist in interpreting cancer incidence and mortality data for special populations and assessing the meaning of these data in terms of health needs of the Nation as a whole. These interpretations are complicated by different methods of defining special populations, especially with regard to race and ethnicity, and can lead to differences in reported mortality rates among these populations. As we become a more multiracial society, it becomes less clear how we should classify populations. Further, the status of a group as a "special population" can vary when considering cancer as a whole compared with specific cancer sites. Important differences also exist within subgroups of defined special populations; for example, cancer incidence and mortality rates differ among Mexican, Cuban, and Puerto Rican Hispanics.
- Other factors influencing cancer rates include environmental and behavioral factors that can create geographic disparities within populations. Taken together, it is not clear what all

of these factors mean in terms of the real impact in the reduction of cancer mortality, particularly for special populations.

- The increase in cancer incidence can be interpreted in different ways. Some of the increase may be due to better detection methods, outreach efforts that are achieving success in promoting early detection, or the fact that the baby-boom population is getting older and surviving longer. We need to understand the underlying reasons for the increases in cancer incidence. Although we should not diminish efforts that have led to mortality reductions, we also need to focus energies on decreasing the incidence of cancer and dealing with issues of survival after cancer treatment.

DIRECTOR'S REMARKS—Dr. Richard J. Klausner, Director, NCI

Dr. Richard Klausner, Director, NCI, indicated that:

- Cancer mortality and incidence statistics, the subject of much discussion at the NCI over the past year, are very informative, but as with all statistics, have a power that is at once mathematical, emotional, conceptual, scientific, and political. Statistics must be treated with extreme care and caution to ensure that they serve as much as possible to answer real questions about the burden of cancer. Mortality and incidence rates, while extremely important, are not the only measures of the cancer burden.
- Changes in cancer statistics are complex; it is necessary to understand the systems that generate them to understand the numbers themselves. Recognizing the importance of this issue, a task force, to include members from NCI, the National Center for Health Statistics (NCHS), and other agencies, is being convened to evaluate surveillance systems and the statistics they produce. The task force will be asked to assess whether the questions now being asked, the populations being monitored, and the methods of data collection and interpretation being used enable us to produce numbers that are real and useful for informing science and public policy. We need a deeper and richer system of surveillance that includes a wider array of parameters, including the nature of diagnostic and detection approaches and treatment followup. It is extremely important that as cancer statistics change, we can be assured that they are reliable and that they are accompanied by a richness of information that allows us to generate sound hypotheses about the basis for observed changes in mortality, incidence, survival, treatment response and complications, and other quantifiable changes, and how these changes can be addressed.
- We must also realize that cancer statistics have a great influence on public perception of the cancer problem, and that these statistics inevitably will be used and abused.
- It is important that cancer statistics are able to answer questions posed by individuals, groups, and organizations regarding the cancer burden in particular population groups. The cancer surveillance system must also be able to identify how the burden of cancer is distributed in the population. Viewed in this manner, the burden of cancer and the true variables that are associated with altered burden themselves define the population groupings. This is not to say that individuals who self-identify for historical, political, or social reasons should not want to know how cancer affects them in terms of that identification. But we cannot assume that a social, historical, or political identification itself defines the parameters of cancer burden. Such identifications may be valuable surrogates or, alternatively, confounding or confusing surrogates.
- As we begin to understand the fundamental nature of human variability (e.g., genetic variation or genetic polymorphisms), it becomes increasingly clear that ethnicity and race

are poor, if not totally inadequate, surrogates for biologic and genetic differences. As our knowledge increases, we must beware of the potential "genetification" of race; we must not fall prey to unsound thinking purporting that race or ethnicity is biologic. There are biologic differences that relate to cancer. These polymorphisms distribute differently among different geographically derived, historically defined populations, based upon their mating patterns. But that is not the same as how an individual self-identifies, and this distinction is extremely important. The idea that race is biological is at the core of the misuse of human variation, and we must be driven to determine how the burden of cancer is distributed, so that its differing burden, rather than politics, defines the variables.

PRESENTATION HIGHLIGHTS: The Cancer Picture

INCIDENCE, MORTALITY, AND SURVIVAL—AN OVERVIEW—Dr. Brenda K. Edwards

Background

The surveillance programs of the National Cancer Institute are based on the mandate contained in the 1971 National Cancer Act requiring the collection, analysis, and dissemination of all data useful in the prevention, diagnosis, and treatment of cancer. This mandate is carried out principally through the Surveillance, Epidemiology, and End Results (SEER) program that monitors the cancer burden on the population through the measurement of cancer incidence, survival, and mortality. Cancer incidence and survival data are derived from SEER's sample of approximately 14 percent of the U.S. population (with oversampling of selected populations); mortality data for the entire U.S. population are generated by the NCHS. In addition to incidence, survival, and mortality data, work is under way to develop data on cancer prevalence and the issue of multiple primary cancers.

NCI has developed a program of applied research for the assessment of individual, societal, and health services factors that mediate measures of the cancer burden both directly and indirectly. Applied surveillance research is currently exploring issues related to patterns of care, outcomes, and survivorship; the cost of cancer; health behavior and status; risk factors and susceptibility; data linkage and the use of extant data systems; and methodology and modeling studies.

Coordination, collaboration, and liaison in the development of cancer data occurs within NCI and the National Institutes of Health (NIH), with other Federal agencies and voluntary and private organizations, and with national and international consortia. Program evaluation efforts are exemplified by those assessing the impact of the ASSIST tobacco control initiative the 5-A-Day nutrition intervention, NCI's Cancer Leadership Initiatives, and usage of the Physician's Data Query (PDQ) cancer information database.

Dissemination of cancer information is carried out in large part through NCI's Office of Cancer Communications. SEER's standard data set, published annually, is also available on NCI Web sites. In addition, the first of a planned series of monographs was published a year ago.

Key Points

- SEER estimates that more than 1.2 million new cancer cases will be diagnosed in 1997. More than a half million cancer deaths are expected to occur.
- The 1970s and 1980s saw an increase in cancer mortality, with the rate of increase declining in the late 1980s. Beginning in 1990, we have seen a slow, steady decline in cancer mortality for the population as a whole. These declines are consistent for many sites and for many age groups, and are due in large part to cancer interventions and to scientific

advances. These benefits have not accrued equally for all populations. In fact, the cancer burden will continue to grow because cancer now represents a larger portion of all occurring deaths; thus, it is essential that we do not become complacent.

- Despite some exceptions (e.g., increases in non-Hodgkins lymphoma, prostate, and lung cancers), overall, we are seeing an improvement in the cancer mortality profile. The extent of the decline varies by site, but declines have occurred (though not consistently) across all age groups as well as in all race/gender subpopulations (e.g., white males, white females, black males, and black females). These improvements notwithstanding, cancer incidence, mortality, and survival rates differ substantially for blacks and whites. Compared with the white population, African-Americans experience 30 percent higher incidence for some tumor sites, and lower overall survival rates.
- Lung cancer deaths continue to increase, but at a slightly slower pace. Mortality from lung cancer now represents about 28 percent of all cancer deaths. Mortality rates for men are beginning to drop, though mortality is still much higher for black males compared with white males. Lung cancer mortality for women is increasing, although cancer incidence and mortality rates overall are still substantially higher among men than women.
- Cigarette smoking is a principal cause of lung cancer. Dramatic declines in the prevalence of cigarette smoking have been achieved over the past 20 years, reflecting effective cancer control efforts. However, careful examination of the prevalence data reveals that the decline is now leveling off, and rates may actually be increasing, depending on the measurement technique used.
- Cigarette smoking levels among the teen-aged population have been relatively stable for more than 20 years. Prevalence in this population is not declining and has been the impetus for cancer control initiatives directed towards tobacco and youth.
- Data on colorectal cancer are complex. Many factors affect both incidence and mortality, such as risk due to familial predisposition, dietary habits, and survival benefits due to early detection. The data show declines in mortality among the white population, beginning as far back as the 1950s, but rates are only just starting to decline for the black population, for both men and women, with rates higher for men than for women. There is considerable variability in rates among population groups. High incidence rates are seen not only in the black population but also in such subgroups as Alaska Natives and Japanese residents in the western United States.
- Colorectal cancer has been understudied. Much research is needed to understand the various components that are linked not only to diversity in rates but also to differences in rates over time.
- Substantial differences persist in breast cancer rates for white and black women. Incidence rates are higher in white women, although mortality rates are lower and declining. Mortality rates are also declining among black females. Declines vary by decade, with greater declines in the younger population, modest declines in women aged 60 to 69 years, but no change in mortality among those aged 70 and older. Considerable variability is also seen in other populations: for example, Native Hawaiian women have among the highest rates of breast cancer.
- Many factors must be examined in interpreting breast cancer data. Trends by disease stage show dramatic increases in incidence rates for Stage O (in situ) and Stage 1 disease; these are a direct reflection of screening and early detection practices that began in the 1980s. The benefit of screening is often measured in rates for advanced disease; although some

decline in rates can be seen for Stage III and IV disease, these have been relatively small. Distribution of cases by the stage of disease indicates that a larger proportion of cases are diagnosed at an advanced stage for both black and Hispanic populations. This suggests that not all populations are benefiting from early detection.

- Changes in breast cancer incidence can also be tracked by tumor size at diagnosis. Tumor size tends to be smaller in white women, although declines are occurring in diagnosis of mid-size tumors in both white and black females. These data indicate that early detection and screening are occurring in these populations.
- Survival, or outcome by stage of disease, varies among white, black, and Hispanic women. Less favorable rates for black and Hispanic populations indicate the importance of treatment and access issues.
- Although data from the National Health Interview Survey (NHIS) show that, over a 5-year period, overall rates for screening mammography have increased, particularly in the last 2 years, much remains to be understood about early detection and screening in different population groups.
- Considerable regional variation exists in radiology practice patterns and the delivery of mammography services. The Breast Cancer Surveillance Consortium is a major initiative for the 1990s, with the goal of understanding the operation and conduct of breast screening in the United States and its effect on breast cancer rates. Funding has come primarily from NCI, the Centers for Disease Control and Prevention and the Department of Defense. The Consortium fosters collaboration among researchers investigating the practice of mammography. By the year 2000, the database from nine highly diverse population sites will include over 2.3 million screening mammograms and over 24,000 breast cancer cases. The FDA will use these data to assess the quality of mammography and the performance of the nine research sites. The Consortium focused initially on defining terms (e.g., false positive, false negative), core data items, and standard guidelines for interpreting radiologic history. The group also addressed significant issues regarding confidentiality for both patients and practitioners.
- Prostate cancer data are highly controversial. Data for the mid- to late-1980s showed a rapid increase in incidence. In the last few years, however, declines in incidence and mortality for both white and black men have been observed. The estimate of 1997 prostate cancer incidence has been revised downward from 334,500 to 209,900 expected new cases. The relationship between incidence and mortality is hard to interpret; there is currently a lack of knowledge about the factors that contribute to this decline and whether or not they are transient. Recent declines in mortality have been linked to increases in detection and screening; it is not clear, however, whether increased screening or other factors are responsible for the observed changes.
- There remains, however, a significant, twofold difference in prostate cancer mortality in black men compared with white men. Measures of disease stage also differ; distant disease is more frequently seen in the black population. It is important to note that differences in how disease stage has been defined have affected reporting. Agreement on disease stage definitions will help lead to better understanding of the data. Similarly, survival rates in the black and white populations differ in part because of the way stage mix is determined. When stage is controlled for, lower survival rates are seen for black prostate cancer patients compared with white patients.

- Because of the controversy surrounding early detection and treatment, and difficulties in interpreting available prostate cancer data, SEER initiated the Prostate Cancer Quality of Life study. This study included 33,000 white, Hispanic, and black men diagnosed in 1995 in six areas: Atlanta, Connecticut, New Mexico, Los Angeles, Seattle, and Utah. Patients have been interviewed at 6, 12, and 24 months following diagnosis. The study has attempted to characterize disease at diagnosis and to obtain information on diagnostic patterns, initial treatment, clinical sequelae, the use of secondary therapies, and, importantly, health-related quality of life throughout the 24 months. Data analysis has just begun.
- Non-Hodgkins lymphoma is a significant cancer site; both incidence and mortality rates have been increasing. Rates are higher for the white population than for the non-white population. The disease has many etiologies, ranging from viral to chemical exposures. The NCI Division of Cancer Etiology, Epidemiology, and Genetics has recently begun a major study of this significant and poorly understood cancer.
- Cervical cancer is a designated cancer control site. There are differentials in incidence and mortality, with rates substantially higher in women age 50 and older compared with younger women. Younger women are more likely to be screened for this disease. In the older population, there is great variability in incidence and subsequent mortality. High rates are seen in native populations, as well as in Hispanics and some newer immigrant population groups, especially in California.
- Recent SEER monographs present data on other important cancer sites, such as the stomach, liver, and gall bladder; these can be significant sites for some populations. The top five cancer sites differ among population groups.
- To date, SEER has not emphasized the tracking of health practices and cancer risk factors. Most of these data come from the 1987 and 1992 NHIS. SEER is working with NCHS to explore adding a cancer control supplement to the Year 2000 NHIS. Comparison of the 1987 and 1992 NHIS data on cancer control reveals several important points: (1) There has been little change in the percentage of women reporting having a Pap smear in the previous 3 years. There is an age and education gradient, and, even among older women, those women with a higher education level use this test more frequently. The test is less frequently used overall among older women, in whom cervical cancer rates are relatively high. (2) The percentage of women reporting having had a mammogram has increased, with the gradient increasing by age, and with older women having lower utilization rates compared with younger women. (3) For this 5-year period, the percentage of men who reported having had a digital rectal exam changed little. Utilization increases with age and level of education. (4) The fecal occult blood test is widely used. Utilization of this test declined in the 1992 NHIS reporting period, with differences in use linked to education. (5) Although specific questions regarding utilization of the proctoscopic exam were not included in the 1987 and 1992 NHIS, the survey reports an increase in use over the time period, with utilization differing by income level.

DISCUSSION—Dr. Edwards

Key Points

- Dr. Edwards clarified that melanoma, as one of the major cancer sites, is included in SEER reporting. The SEER data set does not include basal and squamous cell cases because these cases are often not pathologically diagnosed. There are an estimated 900,000 cases of these types diagnosed annually.

- Data can be presented in several ways (e.g., 2-, 5-, 10- or even 15-year rates). When the reporting period is long, it includes cases diagnosed in a much earlier time period; more recent data include information on more recently diagnosed cohorts. The 5-year time period chosen by SEER is used for convenience.
- The coding of cancer disease and cause of death on a death certificate, particularly when other factors are involved, is a discipline with formal rules. NCI analyzes data by the underlying cause of death.
- Several attributes of breast tumors have been measured by pathologists; however, measures of aggressiveness, such as the presence of tubules or nuclear atypia, are not routinely found in pathology reports. When these data are needed, slides are re-read by a central pathologist. Thus, some of this information is available but is not routinely collected.
- SEER is always interested in obtaining more data; for example, the program is cognizant that some populations are not well represented in terms of incidence reporting. NCI is particularly interested in collecting more information on the diagnosis path, treatment, and followup. These data are difficult to obtain, since many diagnostic workups occur outside hospital settings and may be missing from medical records. A project to explore ways to capture additional data coupled to cancer cases, such as insurance information, is under way.
- SEER files can now be linked to Medicare data on the population aged 65 years and older. Analysis of these data suggests that most of the rise in reported prostate cancer is driven by the first PSA, leading to biopsy and earlier detection.
- It was noted that while SEER data are excellent, they have limitations, and certain key geographic areas (e.g., Appalachia) are not well represented. Capturing good data on melanoma cases is difficult and resource intensive. Regarding cervical cancer, grouping data on the entire white population misses significant local area differences. For example, in Kentucky, West Virginia, Virginia, and Maine, white women have rates very similar to black women. CDC has enabled the key State cancer registries to collect data on malignant melanoma; in Kentucky, this has led to a 50 percent increase in incidence estimates for melanoma.
- SEER data on Native Americans come primarily from four Indian Health Service (IHS) areas in Arizona/New Mexico. In some ways, these data are not representative of the Native American population as a whole. The highest Arizona/New Mexico rate for breast cancer is around 11 percent compared with a national rate of 27 percent. Breast cancer data from four other Native American sites in the northern Plains area, e.g., Aberdeen, Blackfeet, Bemidji, and Nashville, differ by less than one point from the U.S. rates for all races combined. This is a major difference. As a result, research efforts may rely on data that are not representative and thus undercount the problem. In Oklahoma and California, two States with the highest proportion of Native Americans, racial misclassification is a severe impediment to effective breast cancer surveillance, exceeding 50 percent in Oklahoma and reaching an estimated 82 percent in California. Similarly, misclassification of Native Americans in the CDC-sponsored State registry databases has led to undercounting of AIDS-related deaths. Tribal leaders have made major efforts to correct errors in classification; these efforts should be supported. This problem is being addressed by both SEER and the IHS.
- Data on Hispanics for cancers other than breast cancer are available.

Additional Research Needs and Other Recommendations

- The President's Cancer Panel should support enhancement of the SEER data collection efforts and those of the CDC National Program of Cancer Registries. State registry data collection efforts should be expanded to capture treatment and followup data, as this would provide critical local-level information not presently captured through SEER.
- The SEER database should include sites from the northern Plains to improve surveillance data on American Indian populations.

CANCER IN THE WHOLE HEALTH CONTEXT—Dr. Edward Sondik

Background

The National Center for Health Statistics (NCHS) focuses on evaluating the health status of all Americans, an activity with four principal dimensions. First, NCHS assembles data on the incidence and death rates for various diseases, together with associated morbidity. Second, NCHS evaluates the health care system in terms of how well it works; how people flow through the system; ease of access; and whether the system works differently for different types of problems or groups. Third, NCHS examines interventions that alter health, prevent disease, cure disease, or find it early. Finally, NCHS collects data on social and environmental people issues, e.g., birth patterns, family patterns, marriage and divorce rates, and how and where we live. Determining how these data relate to cancer diseases is a great research challenge.

Key Points

- The U.S. population totals 263 million. The principal minority groups represent a relatively small proportion of the total population, yet this does not mean that they are unimportant. Rather, this fraction of the population presents a challenge in terms of how NCHS resources are used to get accurate information on each and all minority groups and subgroups.
- Life expectancy at birth averages 6 years less for black males compared with white males. Overall death rates for Asian or Pacific Islander populations (75 percent of total) concentrated in seven States exceeds the death rate for the Asian/Pacific Island population in total; the reason for this is not fully understood. The high death rate for Hawaiians is also noteworthy.
- The distribution of the four major U.S. population groups (white, black, Hispanic, and Asian American/Pacific Islander) is changing radically, both overall and within each group. Between 1990 and 1995, the Asian/Pacific Islander population grew by just over 20 percent; but between 1990 and the year 2010, this population is expected to increase by about 90 percent. The Hispanic population is expected to increase by about 80 percent overall over the same period. These enormous increases are not distributed evenly across the country. To illustrate, by the year 2015, the white population in California will become a minority.
- National data may not be useful for identifying local problems. It is a challenge to get the degree of detailed information that is needed at the local level.
- Death rates vary across different population groups. In white males, cancer accounts for about 30 percent of total deaths; heart disease accounts for about 25 to 28 percent of all mortality; and HIV and unintentional injuries account for much smaller percentages. Cancer has a somewhat different impact for each of the major population groups, though the differences are not as large as might be expected. Relative to other health problems, the

mortality impact from all cancers combined is the greatest in the black population; this is true for both black females and black males.

- Heart disease is the leading cause of death for all major population groups; cancer is second; stroke and unintentional injuries or accidents are third. The leading causes of death vary for different populations: chronic obstructive pulmonary disease (COPD) among whites; HIV among blacks; and diabetes, accidents, HIV, pneumonia, and influenza for Asian American/Pacific Islanders. These differences reflect diverse influences and factors that affect different population groups.
- Patterns of disease and related mortality typical of the home countries of rapidly growing immigrant populations (e.g., Asians) are starting to be observed in the United States. There is already evidence of this in California. We need to be cognizant of these patterns to understand the current and future health problems of the Nation.
- One way to understand the impact of cancer in the context of other causes of death is to calculate potential years of life lost due to death from this disease; the current standard approach is to calculate years of life lost up to age 75. For white males, this is estimated at about 20 percent; for black males, it is about 15 to 18 percent. Death from cancer has the greatest impact on potential years of life lost for white females at about 30 percent; for black females, the figure is about 20 percent. For females, the greatest impact on years of life lost is due to breast cancer. Disaggregated data suggest the impact of particular cancers on years of life lost and the priority with which these problems should be addressed. Importantly, however, these data do not reflect morbidity from cancer as a chronic condition, which should be considered as well.
- Socioeconomic (SES) factors, particularly education and income, play a major role in differences in cancer experience among different groups, though they do not explain all of the variation in cancer rates among different populations. Significant differences in cancer experience are observed for different categories of income (e.g., poor, near-poor, middle, high) and household status across all major population groups.
- Similarly, the rate of mammography screening, as reported in the NHIS, shows great differences in rates of utilization by category of income. However, these differences are much smaller than they were a decade ago, with much of the gap closing between 1990 and 1993. This represents a significant public health gain over a relatively short time period.
- Data on smoking prevalence from 1987 and 1994 do not show much overall difference for the various population groups; however, if SES data are factored in, different pictures emerge. For example, smoking prevalence data for 12 to 17-year-olds indicate large differences between the various populations. Black teenagers, both boys and girls, have much lower rates of smoking compared with white and Hispanic teenagers. The differences become even more striking when they are broken down in terms of SES variables, particularly income. Smoking tends to be more prevalent at lower income levels. Though important, income is only one variable affecting smoking prevalence; people with more education tend to have a lower smoking prevalence rate independent of income.
- It has been suggested that wealth, rather than income, is a better measure of socioeconomic status, particularly among older persons. Current income may be less important than the actual resources available to an individual.
- Cancer-related variables, both risk factors and actual cancers, seem to vary with respect to income and education as surrogates for socioeconomic status. It has been less clear

whether the same is true for other diseases. Self-reported data for those with controlled hypertension show little difference among men regardless of income category, but there is a gradient with respect to income for women (i.e., a lower percentage of women with high incomes define themselves as being hypertensive than women who define themselves as being poor, although the percentage whose hypertension is controlled is approximately the same).

- Another measure of health for a country as a whole is the infant mortality rate. Overall, the United States ranks in the second decile of all of the countries in the world. Even though the infant mortality rate has been decreasing uniformly across the board, this represents a serious public health problem for the United States.
- The dimensions of health are broad, and it is important to look at the prevalence of non-cancer health problems to adequately understand how people perceive cancer risk and the need to change or adopt behaviors that may affect cancer rates. For example, about 5 percent of persons aged 12 and older have been involved in a violent crime in some way; this rate is surprisingly stable for income level. Such concrete problems may, for instance, influence individuals' response to advice about screening for cancer or changing their diet. The total context of peoples' lives is factored into determining what is important. Moreover, in developing interventions, factors such as insurance coverage and the health care system must be considered. Understanding cancer epidemiology is valuable but is only one part of a much broader picture of health and health status.

DISCUSSION—Dr. Sondik

Key Points

- The upcoming NCHS chart book will include poverty data broken out for American Indians/Alaska Natives, who are among the poorest populations in the United States. In publishing Asian/Pacific Islander data, it is important to separate out key subgroups, particularly in terms of income. High income rates for Japanese and Chinese groups mask very high poverty rates for smaller subgroups such as the Hmong, Native Hawaiians, Thais, and Cambodians.
- In the chart book, it will be valuable to break out smoking data for American Indians/Alaska Natives, because these groups have more elevated rates than other population groups. However, it is difficult to obtain disaggregated data on smoking habits. A Fort Collins, Colorado, researcher has gathered over 20 years of data on American Indian smoking rates. If this information could be integrated with other data sets, this would be helpful in planning interventions for these communities. Dr. Sondik noted that, currently, the NHIS only over-samples the black and Hispanic populations, which provides some data, but generally not the level of detail that is required for intervention planning. NCHS is working on ways to improve this.
- Behind each statistic are individuals, with lives and loved ones. It is predicted that by the year 2000, one in two people in America will develop cancer during their lifetimes. Cancer prevention has been a top-level objective of the National Cancer Program for many years, but since no reliable means of preventing cancer yet exists, risk factors continue to be examined to try to understand the fundamental causes of these diseases and improve the chances of intervening effectively.
- Individuals at higher income levels have a lower incidence of smoking; this has frequently been interpreted as being linked to higher educational levels (i.e., individuals with more education are better able to gather and evaluate data and may be less swayed by

advertising). Although the literature also suggests that smoking prevalence is highly sensitive to cigarette price (i.e., a 10 percent increase in price would result in a 7 percent decrease in smoking), it is difficult to predict whether this would hold true for adolescent populations.

- It was noted that no data on children's cancers were presented. Many lay people are uninformed and unaware that children can and do get cancer. An estimated 2,000 children are expected to die from cancer this year alone. Education in this area is critically needed. The NCI Web site has information on incidence, mortality, and 5-year survival rates for children; the American Cancer Society (ACS) also publishes statistics on childhood cancer.
- Nearly 40 percent of all Asian Americans and Pacific Islanders reside in California; the next highest percentage reside in New York (9 percent). Other States with substantial Asian/Pacific Islander populations include Hawaii, Washington, Texas, Illinois, and New Jersey.
- For the first time, the NCHS will publish a chart book focusing on SES factors and health; this is a landmark step. However, NCHS still does not know enough about which factors are most relevant, how SES issues contribute to the generation of disease, and how this then relates to health care access and treatment. Measures are quite crude and much more research is needed.

USING DATA FOR CANCER CONTROL PLANNING—Dr. Phyllis Wingo

Background

Certain types of statistics are used to plan cancer control prevention programs that are sponsored by State health departments and by units and State divisions of the American Cancer Society (ACS). The data used by ACS comes from activities supported by NCI and CDC. The recent downturn in cancer mortality forces program planners to think about how to continue to make progress in cancer control efforts. ACS is using the Healthy People 2000 (HP 2000) goals as a planning benchmark. It guides planning in four areas: reducing tobacco use in youth and adults; reducing other behaviors that increase the risk of developing cancer; increasing access to and utilization of screening procedures; and increasing access to and use of state-of-the-art, stage-appropriate treatment.

Key Points

- Cigarette smoking is a risk factor not only for lung cancer but for other cancers as well. ACS estimates that in 1997, 94,400 men and 66,000 women in the United States will die from lung cancer and that an additional 46,000 men and 34,000 women will die from the other smoking-related cancers. To make progress against cancer mortality, these numbers need to be reduced.
- About 30 percent of all cancer deaths can be attributed to tobacco use, including 87 percent of lung cancer deaths. The extent to which tobacco use contributes to death from other cancers is more variable; ranging from 8 percent for cancers of the kidney and other urinary organs in women, to 92 percent for cancers of the oral cavity and pharynx among men. These percentages also vary by race and ethnicity.
- The HP 2000 goal for adult smoking is to reduce the percentage of adults who smoke to 15 percent by the year 2000. This goal is adjusted for current smoking levels of different racial/ethnic groups (e.g., for blacks, 18 percent; Hispanics, 15 percent; American Indians and Alaska Natives, 20 percent). Currently, smoking is most prevalent among American

Indian and Alaska Native populations and least prevalent among Asian/Pacific Islander men and women.

- Tobacco use data from the CDC Behavioral Risk Factor Surveillance System (BRFSS) present a picture at the State level. Only Utah has met the HP 2000 goal of 15 percent for cigarette smoking for adults. Several States are within 5 percent of the goal: Hawaii, California, Washington, Idaho, and New Jersey. The median percentage of adults who reported current smoking in 1995 was 22 percent. These data suggest that smoking control programs still have a long way to go.
- The status of tobacco use by youth is not encouraging. Research shows that lifelong tobacco addiction begins during childhood and adolescence. Between 1991 and 1995, frequent cigarette use among high school students increased by 3 to 5 percent in all racial and ethnic groups except black females. This has occurred despite intensive smoking cessation education efforts in the schools. The HP 2000 goal for this group is to reduce the percentage of young persons aged 12 to 17 years who currently smoke to 6 percent. Data from the 1995 Youth Risk Behavior Survey (YRBS) show more white youth currently smoke than either black or Hispanic youth. Smoking levels reported on the YRBS were highest among white females and lowest among black females.
- Nineteen States do not participate in the YRBS. Of the States that do report, for the variable "tobacco use by youth," all were more than 10 percent away from the HP goal of 6 percent. More than 30 percent of high school students were currently smoking in 1995.
- About 35 percent of all cancer deaths are related to nutrition. For Americans who have never used tobacco, modifying diet and physical activity habits offers the best opportunity for reducing cancer risk. In 1996, ACS revised its dietary guidelines to say: "a diet high in vegetables and fruits, low in fat, combined with physical activity, helps to achieve and maintain a health body weight." Limiting alcohol intake is also key. To affect cancer mortality, cancer control programs need to increase these kinds of behaviors in the community.
- One dietary goal is to eat five or more servings of fruit and vegetables each day; another goal is to increase to 50 percent the number of persons who eat five or more fruits and vegetables each day. Data from the 1995 BRFSS indicate that all States were more than 10 percent away from this goal. The median percentage of U.S. adults consuming five or more fruits and vegetables each day was 22, a long way from the goal of 50 percent.
- Obesity has been associated with the risk of developing several cancers, including breast cancer in postmenopausal women, endometrial cancers, and cancers of the colon and rectum. The HP goal is to reduce the percentage of adults who are obese to 20 percent. According to the 1992 BRFSS data, black females had the highest levels of obesity (38 percent); among males, Native American men had the highest level (34 percent). Alaska Native and Pacific Islander men and women had the lowest level of obesity of all racial and ethnic groups. The percentage of persons who are obese has been increasing.
- In no State surveyed in the BRFSS did the percentage of adult men who were overweight meet or fall below the 20 percent goal. The median percentage of U.S. men who were overweight in 1995 was 31 percent. Only five States are within 5 percent of the goal: Hawaii (which has a large Asian/ Pacific Islander population), Utah, Colorado, New Mexico, and Massachusetts. The data are only slightly better for women; the percentage of adult women who were overweight was at or below 20 percent in three States: Hawaii, Massachusetts, and

New Jersey. The median percentage of U.S. women who were overweight in 1995 was 26 percent.

- Breast cancer is the most common cancer in women and is second only to lung cancer as the cause of cancer death in women. Early detection through mammography screening and timely treatment could result in one-third fewer deaths from breast cancer. The HP 2000 goal is for at least 60 percent of all women age 50 years and older, regardless of race or ethnicity, to have a screening mammogram every 1 to 2 years. This goal is considered achievable for all ethnic and racial groups, except possibly women of Asian and Pacific Islander origin. In this latter group, only 48 percent reported having had a mammogram in the past 2 years, 7 percentage points lower than any other racial or ethnic group.
- State comparisons on the mammography measure indicate that most States have already met, or are within 5 percentage points of, the HP 2000 goal. Only Wyoming, Louisiana, Missouri, and Pennsylvania have rates for mammography screening that are more than 5 percentage points away from the HP goal. The new ACS screening guidelines for breast cancer detection in asymptomatic women recommend annual mammography beginning at age 40.
- In 1997, 66,400 men and a similar number of women are expected to be newly diagnosed with colorectal cancers; 27,000 men and a similar number of women are expected to die from these cancers. The HP goal for colorectal screening is for least 40 percent of adults to undergo a sigmoidoscopy at some time in their lives and for 50 percent to have a fecal occult blood test every 1 to 2 years.
- According to 1992 NHIS data, a higher percentage of whites have had sigmoidoscopy and digital rectal exams (DRE) than have blacks or Hispanics. The percentage of persons who reported ever having had a fecal occult blood test was uniformly low for all three major racial and ethnic groups. The HP 2000 goal is for 40 percent of adults to have a proctoscopy at some time in their lives. Most States met the goal or were within 5 percent of the goal; the median percentage was a high 37 percent.
- Differences in access to care across racial and ethnic groups are important. Whether a family has health insurance is a key issue. The observed differences in risk factors and screening practices may in part be related to access to care and specifically to insurance status. Of those surveyed in the 1991-1992 BRFSS, a higher percentage of men than women across all groups had no coverage by insurance, an HMO, or from Medicare or Medicaid. Native Americans and Hispanics were without health coverage more than any other racial and ethnic groups.
- Most States participating in the CDC program of cancer registries are presently collecting only incidence data and not detailed information on treatment or outcome. There is limited information in this country as to whether cancer patients are receiving stage-appropriate, state-of-the-art treatment. At the national level, neither population-based nor other baseline data are available regarding actual use of state-of-the-art treatments. To illustrate, postoperative chemotherapy is indicated for Stage 3 colon cancer patients, but anecdotal data from clinicians suggest that many of these patients are not receiving this adjuvant treatment.
- Some areas of promise include significant progress in screening for breast and colon cancers. Breast cancer mortality is declining. The percentage of women over age 50 who received mammography in the preceding 1 to 2 years was 25 percent in 1987 and has more than doubled to 56 percent by 1994. Colorectal cancer mortality is declining and the percentage of adults who have ever had a sigmoidoscopy increased from 25 percent in 1987 to 33

percent in 1992. The latest BRFSS data indicate further improvement to 37 percent. A strategy of increased screening with fecal occult blood tests and flexible sigmoidoscopy every 5 years has the potential for further significant reductions in colorectal cancer mortality.

- Tobacco use and poor nutrition continue to be areas of concern. Taken together, these factors account for more than two-thirds of cancer deaths. Smoking levels in youth increased between 1991 and 1995. Further, the Nation is getting fatter. In 1960-62, in 1970-74, and in 1976-80, about 25 percent of the population were obese, not far from the HP 2000 goal. Data for 1988-94 showed that around 35 percent of the population were obese; rather than making progress, we are losing ground in this area.

Additional Research Needs and Other Recommendations

- To achieve a long-term, continued reduction in cancer mortality, cancer control programs should put their energies into four areas, with particular attention to the needs of special populations: curbing tobacco use, particularly among youth; expanding efforts to increase screening and desirable dietary behaviors; improving access to state-of-the-art cancer treatment; and collecting surveillance data at the local level.

DISCUSSION—Dr. Wingo

Key Points

- If the HP goals are to be achieved, we need to focus on more than just racial and ethnic populations; for those with low income and educational levels it is going to be a long time before the HP goals can be attained for the key areas under discussion. The problems of good racial or ethnic data and the availability of data at the local level are distinct issues. It is important to remember that national data on the white population are often not relevant for poor whites in remote geographic areas (e.g., Appalachia).
- The HP goals and objectives for tobacco use include Southeast Asian males, but the nationalities included under this definition could not be specified.

PRESENTATION HIGHLIGHTS: The Leadership Initiatives

NATIONAL BLACK LEADERSHIP INITIATIVE ON CANCER (NBLIC)—Dr. Louis W. Sullivan

Background

One interpretation of the data demonstrating continuing disparate rates of cancer in our poor and minority populations is that the Nation still has a two-tiered health care system C one that serves affluent groups well, but poor and minority groups not nearly as well. The data reflect a complex web of choices in health behavior and diet, as well as greater exposure to cancer-causing agents in the workplace or the environment. One solution is the development of targeted, sustained, and comprehensive programs focused on those populations most at risk of cancer and other diseases. The NBLIC is an example of this type of outreach program. It was started by the NCI Advisory Board in 1986.

From the outset, the purpose of this initiative has been to conduct cancer outreach programs through volunteer coalitions in the Nation's African-American communities. The NBLIC is particularly concerned with reducing the high death rates in this community from breast, colorectal, and prostate cancers. The NBLIC targets the 98 percent of the Nation's African-Americans who reside in 42 States and the District of Columbia.

While NCI continues to exercise program oversight, the NBLIC's administrative office recently has been moved to the Morehouse School of Medicine, becoming an integral part

of the campus community. The move is expected to bring many efforts at the School of Medicine into closer harmony, and enhance effective education for health professionals and patients about cancer prevention, early detection, and treatment.

Key Points

- The NBLIC has been able to rapidly coordinate and expand several important activities. First, an electronic information network for the exchange of relevant data has been established. This network provides for ongoing interactions between NBLIC and advocates, patients, and physicians. The network has proven to be a good forum for distributing information to the African-American community. Secondly, NBLIC is developing publications and news releases. These include educational pamphlets concerning colorectal cancer, breast cancer, prostate cancer, and the role of diet and nutrition in cancer prevention.
- The NBLIC steering committee had its first meeting in March 1997. At the meeting, the NBLIC intervention guidelines, fact sheets, and messages were formally approved. Copies were mailed to the 55 coalition chairpersons in four regions of the country in June and July. A program management document was completed in May. It provides a clear framework for how the national NBLIC office will work with its regional offices and local coalitions.
- NBLIC mobilizes African-American leaders in four regions of the country: the western region, based in Los Angeles was, until recently, chaired by Dr. Reed Tuckson at the Charles Drew University of the Health Sciences. The midwestern region is housed at the University of Illinois School of Public Health, and is chaired by Dr. Terry Mason. The eastern region is based at Harlem Hospital in New York and is chaired by Dr. Harold Freeman. The southern region (chaired by Dr. Sullivan) is based at the Morehouse School of Medicine.
- In each region, NBLIC fosters activities in cancer control, screening, media campaigns, outreach, and education. Clinical research initiatives are supported in the southern region. The regional units have been very active, increasing public knowledge of cancer prevention strategies, healthy behaviors, and healthy diets. These units also are increasing early detection efforts such as mammography and breast self-examinations (BSE), and are working to reduce exposure to environmental carcinogens. Further, they are working to increase resource referral efforts for followup diagnosis, treatment, and social support.
- Several NBLIC special events have been held. The midwestern regional staff at the Kennedy-King College on the south side of Chicago C the neighborhood with the highest incidence of cancer C held a town meeting, with more than 250 local participants. The event received extensive media coverage, thereby increasing awareness of cancer education and prevention programs, and provided an opportunity for feedback from the community. Two additional such events are planned in Chicago in the coming year C the Cancer Survivors Quilt Project and the Survivors Dinner Gala. Another regional event was Cancer Awareness Sunday, held in Louisville, Kentucky. This event was actually held on three consecutive Sundays in April 1997; it was the sixth year of such events organized by Kentucky African Americans Against Cancer, one of the NBLIC coalitions. Some 25 churches, each with more than 200 parishioners, participated in observance of Minority Cancer Awareness Week.
- The Leadership Initiative has also experienced challenges, but these have been minimized by the enthusiastic, energetic work of the regional directors, their staff, and coalition

volunteers. A need for better communications within and between the regions and the national office has been identified; NBLIC has contracted with Survey Research Laboratory to help address this issue.

- NBLIC is working hard to minimize community mistrust, for such mistrust could significantly undermine program efforts. So far, communities across the Nation have embraced the Initiative, viewing it as a partner in promoting improved health status. Work with community leaders has evolved the NBLIC into a series of local initiatives active in cities around the Nation and at the State level.
- Knowledge is power in the battle against cancer, in which knowledge may be life-saving. NBLIC is important in the Nation's campaign to reduce the devastation of cancer. NBLIC is a lifeline of information, prevention, and education efforts. This initiative is changing inner cities and rural areas, helping citizens to live longer, healthier lives.

DISCUSSION—Dr. Sullivan

Key Points

- Greater funding for the NBLIC and the other Leadership Initiatives would be extremely useful.
- NBLIC recognizes the key role of community leaders in making cancer prevention and treatment information relevant at the local level. Low income individuals are greatly influenced by local leaders such as ministers or community service agency leaders and are more likely to accept information that comes from them. Involving local leadership is effective in dispelling community distrust of State or national agencies and information or recommendations coming from them.

NATIONAL HISPANIC LEADERSHIP INITIATIVE ON CANCER (NHLIC)—Dr. Greg Talavera

Background

The National Hispanic Leadership Initiative on Cancer (NHLIC) is similar to the other Leadership Initiatives; it is community based, research oriented, and highly focused on evaluation. The work of the NHLIC is based on social learning theory; this framework, combined with cultural sensitivity, is having a positive impact in the community.

Key Points

- The Hispanic population in the United States is growing rapidly, approaching a double-digit figure, and is quite diverse. Mexico is still the predominant country of origin for Hispanic and Latin-American populations, but even within major nationality groups there is considerable diversity.
- The Hispanic population is young compared with other U.S. populations; this may explain why cancer incidence among Hispanics is relatively low. Racial/ethnic classification issues may also complicate efforts to develop an accurate profile of the Hispanic population and its disease patterns. In addition, it has been suggested that many Hispanics, especially Mexican-Americans, may return to their country of origin for terminal care or advanced cancer treatment. If so, this can be expected to skew the data on cancer morbidity and mortality in the Hispanic population.
- It is essential to dispel the myth that most Hispanics are welfare recipients. The Latino population, although mainly poor, is very much a part of the labor force. Latinos comprise a major segment of the working poor; many are employed as migrant farm workers or in

low-paying urban settings such as hotels and restaurants. Many Latinos lack health insurance, which creates a barrier to health care access.

- Data on Hispanics are often lacking. The NCI publication, *Rates of Risk*, 1996, does not include breakouts on Hispanics. When people consult major data sources and do not find racial and ethnic data for special populations, they may be unaware that other publications (such as the special publication on cancer risk in Hispanics referred to by Dr. Edwards) exist that could be useful. For example, NHLIC investigators and others collaborated on a little-publicized 1995 NCI monograph specifically addressing epidemiology, intervention, and diverse other issues related to Hispanics and cancer. A law is in place requiring that race and gender be considered in clinical trials; a corollary policy requiring that race and gender be part of the analysis of data at major U.S. institutions might also be in order.
- Cancer epidemiology data show that incidence rates for Hispanics overall are lower than those for the general (white) population. Some have questioned, therefore, whether cancer is really a major issue for Hispanics. A culturally sensitive analysis of recent data on cancer and Hispanics, contained in the NCI monograph cited above, confirmed that while Hispanics, rates for certain specific cancers and for cancer overall are lower than those of the general population, their rates for stomach, liver, and gall bladder cancer are higher in both men and women. In addition, Hispanic women have high rates of cervical cancer. Subgroup variations need to be studied, particularly factors associated with rate variations at different cancer sites.
- Often, minority populations are studied from the perspective of what is “bad” for them. It is somewhat of a paradox, given the increased cancer risk typically associated with the lower SES and education levels of many Hispanics, that Hispanics generally have lower incidence rates for cancer. What is it about this culture and these groups that account for these lower rates? This paradox exists for cardiovascular diseases and birth outcomes as well as for cancer. Despite high risk factors and the extent of poverty in the population, Hispanic incidence rates for chronic disease are lower than those for the general population. There may be protective factors at work, such as diet or certain cultural attributes; these should be explored.
- NHLIC evaluation data on the use of mammography screening, Pap smear, and smoking cessation have shown that when coalitions develop targeted intervention, desired changes in behavior in Hispanic communities can be achieved.

DISCUSSION—Dr. Talavera

Key Points

- Puerto Ricans resident in the Commonwealth are included in the U.S. census reports. The extent to which Puerto Ricans are included as a separate group within the overall calculations for the U.S. Hispanic population is unclear.
- The definition of “Latino” (or “Hispanic”) can be problematic. From a cultural point of view, these are the people who have predominantly come from Latin America, who speak Spanish. Beyond these parameters, Latinos are probably best defined on a geographic basis. For example, in San Diego, there is a melting pot that is predominantly Mexican; in other areas, Latin-American groups come together and form geographically based cultures. That type of pattern occurs in Miami where the dynamic forces of immigration in the Caribbean, political upheavals, and revolutionary situations in other countries have resulted in population influxes. What they have in common is that these groups come from Latin America and speak Spanish. After that, they are as diverse as the poor white U.S.

populations. NHLIC has consciously focused on targeting those who are low income and who speak Spanish. These are the people who are missing the message from the mainstream, English-speaking mass media and standard public health programs, which do seem to reach the Hispanic middle and upper classes.

Additional Research Needs and Other Recommendations

- Program planning for the Latino population is hampered by insufficient data collection and limited staff available to collect, analyze, and formulate both programs and policy based on the data. Additional funding is needed to address these issues.
- Since the Hispanic population is concentrated geographically far from Washington, D.C.C near the U.S./Mexican border C Hispanics tend to be unempowered politically. Funding for SEER data collection related to cancer in the Hispanic population needs to be concentrated in the areas where the population is clustered.

APPALACHIAN LEADERSHIP INITIATIVE ON CANCER (ALIC)—Dr. Gilbert H. Friedell

Background

Begun in 1994, the ALIC is a research program focused on the higher cancer mortality of the Appalachian population. The monograph *Sowing Seeds on the Mountain*, published by NCI in 1994, presents information concerning the social and economic history of Appalachia, health status and health care in the region, cultural characteristics of the population, theory-based information about community coalition building, and the proposed research approaches of the four projects that comprise the ALIC program. The monograph clearly shows that for the medically underserved in this predominantly rural, largely white population, the underlying problem is poverty, with “culture serving as a prism through which poverty exerts its effects on health.” (Freeman)

Cancer control in Appalachia must be seen as a social problem, not just as a medical problem. Both research and program development must have a multidisciplinary and interdisciplinary base, with the involvement of sociologists, anthropologists, and other social scientists, as well as cancer experts. Within this context, the ALIC has established three principal research questions: (1) Is there a general framework for developing and sustaining community cancer control programs in socioeconomically disadvantaged, rural communities through which specific cancer control efforts can be pursued? (2) What is the role, if any, of universities in developing sustainable, community-based cancer control programs and in developing and sustaining cancer control networks? (3) What is the role, if any, of the NCP in developing and sustaining community-based cancer control programs and in developing and sustaining cancer control networks?

Key Points

- The ALIC comprises four projects. Two are based in the cooperative extension services at Pennsylvania State University and North Carolina State University, and exemplify the private-public partnerships central to the ALIC. The other two programs, one based at the University of Kentucky, the other in West Virginia, are part of NCI cancer centers. Thus far, there are no programs based in Alabama or Mississippi. At present, there are 75 coalitions across the ALIC region, and each of these coalitions includes community-based, private-public partnerships. The population of interest is primarily rural, aging, and of low income. Interestingly, in the four ALIC projects, the non-white populations under study are predominantly urban.

- Appalachia presents many personal and systemic barriers to cancer screening, diagnosis, and treatment. These include poverty, isolation (due to geography, transportation issues, low literacy, cultural issues, and age-related factors), fear, and the availability, accessibility, and acceptability of services. Lack of continuity of care is not a new problem in the U.S. health care system, but it is a real problem in Appalachia, particularly when repeated cancer screenings are needed.
- Appalachia is a remarkable laboratory for studying those who are underserved, have relatively low education and income levels, and are predominantly white. There is little or no confounding effect of race and ethnicity. This is not to say that there is no African-American population, particularly in the Southern part of the region; however, the area of Appalachia currently served by the Initiative is about 95 percent white.
- Medical research tends to focus on the individual and strategies for effecting individual behavior change. However, the social context of individuals, lives must be taken into account, particularly when conducting cancer control research.
- In 1993 testimony to the President's Cancer Panel, Dr. Friedell stated that "if the problems are in the community, the solutions are in the community." After 5 years with the ALIC program, he is more convinced than ever that this is true. It also appears true that even as individual communities find ways to deal with their own cancer control issues, they want to connect with other communities. They value networking, and when they need help in overcoming an obstacle, they want a designated place to turn.

Additional Research Needs and Other Recommendations

- To sustain community cancer control efforts, there needs to be an enabling entity C a governmental or non-governmental agency C that can provide the encouragement, technical support, and connection with other community cancer control efforts, interstate or intrastate, and with other resources as needed.
- Continued and expanded cancer control research at the local level is needed.
- Community-focused cancer control research and implementation efforts at the Federal level should be integrated and have a high priority. At present, several agencies deal separately with similar issues.
- Goals and objectives should be set at the Federal level, and program oversight should be conducted at the Federal level. However, flexibility in implementation is important; for example, the CDC works with State health departments, which in turn are quite variable in the way they deal with community-based cancer control research efforts.
- Private-public partnerships in both research and program implementation at the community level should continue to be fostered.
- Improved cancer data collection and analysis at the State level through the continued and expanded support of the National Program of Cancer Registries and SEER is very important, and SES data are badly needed.
- Expanded collection of followup data is needed in State registries; some States are already doing this and can serve as pilot sites for others to emulate.
- Grant announcements should be developed addressing special populations other than minorities as currently defined (e.g., rural, low income, or low education), as this is where the burden of cancer lies.
- Increased coordination of the National Cancer Program is needed, at least at the Federal level. The NCP should set national goals and priorities, monitor progress towards goals,

and have the capability to move the overall program forward. There must be designated leadership for the NCP, and a focal point for accountability.

DISCUSSION—Dr. Friedell

- Common to all of the Leadership Initiatives is the need to work at the community level in order to engage underserved populations in program activities. Getting the message out is not enough. A behavioral response must be engendered. This can only occur in a social context in which the community supports individual change. All of the Initiatives are working towards this goal in different ways (e.g., demonstration projects, research). The common denominator is the recognition that different populations have distinct cancer problems that must be addressed in their communities.
- All of the Leadership Initiatives deal with poor populations. A common thread that must be recognized is that those who are poor, and who are often less well educated, are not as effective in assimilating for themselves information that is widely available to the public. Frequently, these populations rely on local institutions for cues regarding their behavior; this underscores the importance of involving credible local leaders to impart information that would not be accepted or understood from reading a monograph or from the recommendation of a national or local official. For example, women from the community have been trained as health advisors, in some areas, and have been instrumental in conveying health messages and increasing cancer screening rates in a wide variety of local programs.
- NHLIC and other Leadership Initiative minority investigators, as well as the ALIC, are developing and showcasing technologies that reach special populations. These models need to be adopted and institutionalized by major organizations, such as the ACS, so that they can be continued when the special funding used to develop them has expired.
- It was underscored that there is no “one-size-fits-all” approach to cancer control efforts at the community level. Concepts have to be modified to accommodate specific community needs.
- The emphasis over the years that poverty is a common denominator in cancer mortality statistics is valuable.
- Coordination of the large and amorphous undertaking that is the National Cancer Program has proven extremely difficult. In the early 1970s, this was the responsibility of the NCI Director. More recently, however, with many agencies now involved in cancer-related activities, this is no longer the case. The far-reaching goals of the NCP can sometimes run counter to those of the NCI, which is primarily a research organization. It was suggested that the President’s Cancer Panel or an external advisory body should be charged to develop a badly needed strategic plan, goals, and methodology for monitoring progress toward those goals.
- The lack of coordination between cancer control research and cancer control implementation illustrates the overall coordination problem within the NCP. NCI is concerned with research, while the CDC, working primarily through State health departments, focuses on implementation. This approach leaves a large crack into which important activities may fall. Concern was expressed that the Leadership Initiatives, which have only 2 years of funding remaining, are at risk of such a fate. Although it is not expected that NCI will fund the Initiatives forever, it is important for the successful activities of the Initiatives to be continued. If this charge falls to the CDC, it will have to develop a culture of research in addition to its current implementation orientation. In

addition, there is need for an amalgamation of effort among the Federal Government, the ACS, and other private sector organizations to adequately address the cancer control issues of special populations. Fundamentally, however, there must be agreement that there should in fact be a National Cancer Program; such a consensus is not currently evident.

- It is extremely difficult for two distinct agencies (i.e., NCI and CDC), with different charters, to share parallel leadership roles. One possible locus for coordination of the NCP is the Office of the Assistant Secretary for the Public Health Service (PHS), since established relationships exist with all of the PHS agencies; an alternative placement could be the Office of the Secretary, Department of Health and Human Services. It is difficult to impose leadership and coordination of activities on an agency at a parallel level and with parallel functions. Thus, placing responsibility for coordinating the NCP at a higher level may make sense.
- Cancer control needs to have a very high and visible priority; it must be placed organizationally where there is a commitment to its success, and where both research and implementation needs can be met.

NATIVE AMERICAN INITIATIVES—Dr. Linda Burhansstipanov

Background

Native American populations have never had a formal initiative similar to the NBLIC, NHLIC, or ALIC. Although there is strong interest in establishing an initiative to develop and implement innovative projects for Native American populations, this opportunity has been denied. Instead, the Network for Cancer Control Research Among American Indian and Alaska Native Populations has been established, but unlike the various Leadership Initiatives, which have been funded in the millions of dollars, annual funding for the Network has never exceeded \$42,000 a year. This lack of long-term support has been a major obstacle to the development of community trust and to sustaining community interventions.

The Network has published a plan detailing what is needed at the Federal level to control cancer in American Indian/Alaska Native populations. A separate strategic plan aimed at CDC-based State programs will be published in the *UCLA Journal of American Indian Issues* within the next 3 months. Three Native American conferences have been held; their proceedings have been published in peer-reviewed journals. In addition, the Network has conducted national surveys of all Federal reservations, urban Indian clinics, and State organizations, to gather information on current cancer prevention and control activities for Native Americans. Findings from these surveys have been published.

Key Points

- In 1992, the Congress passed legislation to support a Native American initiative; funds were approved, but never released. Focus groups were held to identify what was needed to address growing cancer problems in Native American communities. The need for data was identified, but more importantly, the need for special research initiatives for Native Americans, many of whom are medically underserved, was emphasized. The needs of the underserved population are related to poverty, but they also include psychosocial and sociocultural issues, as well as the need to change counterproductive policies (e.g., unavailability of breast cancer screening for women under 50 years of age).
- Whether for a Leadership Initiative or a Network, internal leadership C someone within NCI who is willing to make decisions, provide long-term direction, and be involved with

the funding agency C is crucial. The Network is housed at NCI; Dr. Edwards of SEER has provided direction for support in this area and was instrumental in bringing Dr. Lillian Tom-Orme to NCI, who can speak to special Native American concerns.

- Cost-effectiveness as a grant review criterion can have negative effects on program success in hard-to-reach populations. For example, in Los Angeles, where the Native American Cancer Research Program (Pine, CO) has a screening project, there are 500 licensed mammography providers. It took 8 months to access screening for Native American women living in LA county, however, because of the cost of bringing them to the screening facility. Since the project staff could not guarantee providers a minimum number of women (e.g., 40 patients), screening for the population was deemed not cost-effective. Inconsistent access to screening erodes program credibility and trust in the community. Further, cost-effectiveness criteria tend to result in the medically underserved becoming "unserved." It is more expensive to involve them mutually (i.e., first 3 years of the project) in screening programs. Projects targeting "hard-to-reach" communities often are not funded in favor of those that can screen a higher number of underserved individuals for the same level of funding.
- There is concern in the Native American community that the National Cancer Program (e.g., Department of Defense [DoD]) places a higher priority on the needs of underserved populations overseas than on those of underserved populations living in the United States.
- NCI has, through the RO1 mechanism, funded the Native American Women's Cancer Initiative; however, funding for some of the grantees expires this year, and next year for the remainder of the awardees. It will be important to continue these efforts through another initiative. The Native American Research and Training Program, which provides training for young investigators, may provide such a vehicle. Few Native American researchers work in the cancer area; most focus on diabetes, alcohol, or HIV problems. It is important to bring Native American investigators into the cancer field, so that the growing cancer problems of the population can be addressed. Dr. Edwards has been of enormous assistance to the Network in finding resources to provide training for young Native American investigators.
- NCI supports a Network meeting every year. The Mayo Clinic supported a meeting in 1993 and will sponsor another in 1997. NCI has also provided supplemental funding to the Mayo Clinic for infrastructure development for the new Native American Resource Center to be called the "Native Circle." This Center will be in a central location and will house data collection instruments that have been modified and used successfully with Native American populations. It also will include summaries of previous research and successful service projects, educational resources, and a speakers' bureau.
- CDC has supported Native American initiatives, funding 12 tribes and an urban Indian Center. The Indian Health Service (IHS) has had a special cancer prevention and control program; however, funding for this initiative has recently been cut by 50 to 75 percent, and the agency's cancer focus has been broadened to include all chronic diseases. Further, there is speculation that the IHS may cease to exist within the next few years. To date, the Department of Defense has funded no Native American breast cancer projects. The Health Resources and Services Administration (HRSA) has expressed an interest in future Native American initiatives, as has the ACS, which published proceedings from the Network's cancer conference in its journal, *Cancer* (Oct 1996).

- The Agency for Health Care Policy and Research (AHCPR) conducted a survey of Native Americans in the late 1980s as part of the National Medical Expenditures Survey. Survey design and data collection effectively involved trained interviewers; however, data analysis was conducted by non-Natives and is of limited utility.
- Support for community-based service, education, and research programs is eroding, including programs for Native Americans, largely as the result of a Federal freeze and budget cuts.
- Cervical cancer patterns differ in Native American women compared with women of other races. In Native American women, the disease is much more aggressive and is found in younger women. The reasons for this are not known. A similar pattern for breast cancer has been observed, but insufficient data exist to support development of a hypothesis.

Additional Research Needs and Other Recommendations

- Addressing access barriers related to poverty is important, but insufficient to effectively recruit and retain medically underserved populations in state-of-the-art cancer care projects.
- Psychosocial and sociocultural interventions are needed to recruit and retain populations that hold belief systems that differ from the "majority" cultural values.
- Greater support is needed for community-based and community-driven cancer research interventions.
- Cancer survivors need greater visibility and leadership opportunities.
- A cancer registry is needed that collects data about cancer patterns in indigenous populations.
- Culturally relevant and competent interventions are needed to increase Native cancer patients, survival from cancer.
- Special initiatives are needed to ensure that Native American cancer patients have access to state-of-the-art cancer prevention and control services, interventions, clinical trials, and support services.
- Special initiatives are needed targeting medically underserved and "unserved" populations (e.g., small tribes urban clinic).
- Health care facilities should train and support culturally relevant "navigators" to facilitate patients, interactions with the health care system.
- A central clearinghouse of culturally relevant Native American cancer resources is needed (and is in its formative stages through the "Native Circle" located at Mayo Clinic).
- Medically underserved populations and cancer survivors should be included in cancer research projects in paid, rather than voluntary, positions.
- Racially specific and accurate databases are needed. Age-adjusted disease data from Federal agencies needs to be racially specific and based on the same standard population (e.g., "1970 Std Pop" or "Yr 2000 World Pop") so that comparisons can be made.
- Cost-effectiveness as a research grant criterion should be applied only after a project has become established in the community (e.g., after 3 years).

DISCUSSION—Drs. Sullivan, Talavera, Friedell, and Burhansstipanov

Key Points

- The reasons underlying disparate cancer rates among minority groups (e.g., lower cancer incidence rates among Hispanics) should be an important focus of the Panel.
- The Department of Defense Web site contains information on the proportion of DOD funds allocated to minority issues, which remains comparatively “small”; a committee provides continual oversight to ensure that proposals are funded according to both merit and need.
- Racial misclassification is a significant issue in attempts to determine cancer rates for Native American groups. Rates are highly diverse in different parts of the country (e.g., in the northern Plains tribes, rates for lung and breast cancer are very high compared with other Native population groups and other racial groups). Rates for colorectal cancer in Alaska Natives are puzzling, and within that population vary substantially for Aleut, Athabascan, and Eskimo subgroups. Very limited data are available for these populations and are not well understood. Survival percentages for childhood cancers for Native Americans/Alaska Natives are the lowest for any racial or ethnic group.
- Parents and families of children diagnosed with cancer shoulder a heavy burden of care. With the advent of managed care, it is especially important to link those families with all available services and with each other.
- The ALIC is presently conducting both process and outcome evaluations. Findings will be available for review by the research community to determine effectiveness. Research output from the projects will justify the importance of funding these initiatives.
- For the NBLIC, evaluation will measure changes in behavior, using such variables as the percentage of women who do breast self-examination or have mammograms and the percentage of men who have had a digital rectal examination (DRE) or a fecal occult examination within the past year. Through linkages with the 5-A-Day program, the NBLIC will measure the percentage of the target population who are consuming five servings of fruit and vegetables a day. Levels of awareness about cancer and cancer screening are being studied.
- In contrast to much of the research typically funded by NCI, the Leadership Initiatives have discovered that it takes several years to establish projects and have some degree of organization in place in the various participating communities.
- The Hispanic and Native American populations are each comprised of a number of distinct cultures; these subgroups need to be accessed through culturally appropriate cancer control messages. This suggests that funding smaller, more focused initiatives may be more effective than larger efforts. At the same time, there are many benefits associated with working as a group. The Leadership Initiatives enable investigators to share resources, models, and strategies; in addition, investigators develop a valuable, shared perspective they would not have obtained working in isolation.
- Subgroup variation can be evaluated when a unified protocol regarding knowledge, attitudes and behaviors, as these relate to interventions, is used to compare distinct groups (e.g. Cuban-Americans in Miami, Mexican-Americans in the San Diego area). When this approach is used, variations in different groups emerge and distinct, geographically based problems are seen. This approach is not being used on a national level to study variation in chronic diseases other than cancer, yet it is invaluable for identifying what works across the Nation as a whole as well as locally.

- Lack of resources prevents the Leadership Initiatives from being able to develop specific programs at a local level that reach out to families dealing with childhood cancers. Coalition volunteers refer families to local health authorities or regional offices; however, this approach is not very effective. Limited resources have limited the focus to cancers with the highest incidence.

Additional Research Needs and Other Recommendations

- The Leadership Initiatives would benefit from having some centralized activities (e.g., training programs) and a network of mentors around the country that could help investigators at the local levels implement programs and address local problems as they emerge. An example of this is a Native American pilot project to develop a survivors' database and related support system. Sites in Santo Domingo Pueblo, the northern Plains, Alaska, Arizona, California, and Wisconsin are participating and will share data. Initial findings suggest that many subgroups are not able to access state-of-the-art treatment (e.g., very few women with breast cancer are on tamoxifen). A central coordinating organization would be of significant benefit. Having an actual "leadership" initiative, rather than only a "network" with funds limited to one meeting of 13 members per year, has delayed collaborative initiatives such as the survivor's database.

PRESENTATION HIGHLIGHTS: Consumer Concerns for the Future—The Voice of Advocacy

NATIONAL COALITION FOR CANCER SURVIVORSHIP—Dr. Elizabeth Clark

Background

Founded by and for survivors, the NCCS mission is to advocate on behalf of people with all kinds of cancer. The term "cancer survivorship" is used to represent the state of living with the challenges of the cancer experience. This population is not bound by biological, genetic, or geographic factors, but by many other problems, such as increased risk of developing second and third cancers. This population is at risk for long-term and late effects of cancer treatment. NCCS' works to generate a nationwide awareness of cancer survivorship (e.g., through publications, education to eliminate the stigma of cancer, advocacy for insurance and employment rights, and empowerment of individual survivors in the communities where they live and work). Illustrative of NCCS success is the increasing responsibility survivors are taking to ensure that their views are heard.

Key Points

- Only in the past decade has advocacy been recognized as a legitimate strategy for influencing the policies that shape health care, and it has only been in the recent past that health care professionals have become aware of the need to stand with the patient advocacy groups to ensure the provision of quality cancer care.
- In the classic sense, advocacy means summoning to one's assistance, calling to one's aid, or defending. In health care, advocacy is the act of informing and supporting persons so that they can make the best decisions possible for themselves. In cancer survivorship, advocacy is a continuum that spans personal, organizational, community, and public advocacy.
- Personal advocacy entails empowerment. For cancer survivors, empowerment can mean the difference between maintaining a positive future outlook or feeling helpless and less sure of the desirability of survival. Cancer-related self-advocacy is essential in the current

health care delivery system. Despite some legislative successes (e.g., the Family and Medical Leave Act, the Health Insurance Accountability and Portability Act), much needs to be done to teach patients how to obtain quality cancer care in a managed care environment.

- Patients and their caregivers need to be educated about advances in cancer care, such as participation in clinical trials. Not all HMOs will cover costs associated with clinical trial participation, and many physicians are uninformed about trials. Some patients erroneously believe that the control group in a trial receives no treatment, but is given only a placebo with no active ingredient.
- Clinical trial insurance coverage issues are confusing to payers, physicians, and patients alike. Patients and physicians report that they avoid telling the health plan that care is being provided under the auspices of a trial in order to obtain reimbursement for services. Some physicians may be reluctant to refer patients to trials because they fear losing a patient, are unaware of trials that may be relevant to the patient's disease, or are skeptical about the care provided in trials.
- At the organizational level, advocacy for coordination of services and for the provision of support services is important. Institutions are cutting back on providing the services of oncology social workers, oncology nurses, and pastoral care counselors. As hospital lengths of stay decrease, there is less opportunity for preventive interventions that previously were used to help patients adapt to living with cancer. Cancer survivors can help in advocacy efforts by speaking at medical schools, in the media, and at professional meetings about the needs and issues of cancer survivorship, and by educating employers, unions, and community groups about the need for better managed care plans.
- Followup care is another important area for community advocacy; followup clinics for long-term survivors are urgently needed. The NCCS publication, *Imperatives for Quality Cancer Care: Access, Advocacy, Action, and Accountability*, identified needs for quality cancer care, physiologic long-term effects of cancer treatment, and psychosocial issues of cancer survivorship. One of the most significant needs identified was for clinics that focus on health promotion, disease prevention, rehabilitation, and physiological and psychological problems.

Additional Research Needs and Other Recommendations

- As advocates for their own care and the quality of their lives, cancer survivors must have a collective voice in helping to shape health care policy and standards of quality cancer care.
- At the community advocacy level, there is an urgent need for the development of new models of cancer control for the medically underserved. These programs must be culturally and educationally appropriate. Many excellent examples are available; however, many more are needed.
- Access and coverage for clinical trials participation often becomes a political advocacy issue. Despite their potential for improved survival or an enhanced quality of life, many insurance plans arbitrarily refuse to cover routine patient care costs associated with clinical trials, leaving many individuals without the means to afford the best treatment available. NCI must join with advocacy groups to develop a joint plan of action to maximize leverage with both public and third-party payers for clinical trials.
- Increased funding for behavioral research, particularly survivorship research, is needed.

- Cancer survivors have a great deal to contribute to advocacy, and to further oncology research, education, and practice. They need to be included in the design of research studies and clinical trials. They have much to contribute to institutional review boards, hospital ethics committees, and commissions and advisory groups. They should be included in negotiations with managed care companies and with those writing legislation about cancer care. They belong as partners in teaching institutions and community organizing efforts. The establishment of the Director's Liaison Group within NCI is an excellent example of the partnership that needs to exist between the professional oncology community and the consumer.

US TOO INTERNATIONAL, INC.—Mr. John Campbell

Background

In existence for 6 years, US TOO is the largest men's cancer organization, with more than 100,000 members and over 550 chapters. The recent increases in prostate cancer incidence rates are due in part to the aging of the population, but are related primarily to the increased diagnosis of asymptomatic men as a result of the prostate specific antigen (PSA) test. Between 1988 and 1991, physicians increased their use of this test for men over age 65 from 1,430 tests per 100,000 men to 18,000 tests per 100,000. Prostate cancer incidence now appears to have peaked, as many men now receiving the PSA test have already received at least one prior test.

For organizations like US TOO, and for many individuals facing even the possibility of prostate cancer, early detection has become a mantra. The majority of American men are already aware of the importance of testing. The challenge now is to inform them of their options after they have been tested and/or diagnosed. Different treatments impact greatly on men's quality of life. The decision to seek treatment, and what kind of treatment, is as much personal as medical.

Key Points

- Reports of a decline in prostate cancer mortality may be premature, and the attribution of any such decline to early detection may also be premature. NCI researchers indicate that any drop in mortality rates is occurring too soon to be related to increased screening; it will be a few years before the impact of screening on prostate cancer mortality can be assessed. The 5-year prostate cancer survival increases may be easier to explain. A man diagnosed as having Stage B prostate cancer in 1985 would, by 1995, have been considered a Stage C or D prostate cancer patient. This shift reflects improvements in diagnostic techniques and technology. This individual's chances of survival would not be estimated to be nearly as good as a Stage B in 1995. Controversy over early detection continues, but may be moot, since it is now estimated that more than 50 percent of men over age 50 have had at least one PSA test, and that more than 20 million men will have the test this year.
- Adequate information on the natural progression of prostate cancer is lacking (i.e., whether a tumor will be indolent, aggressive, or potentially lethal). According to some, three out of four men diagnosed with prostate cancer do not really need to be treated. Either their cancers will not be aggressive or the treatment will not be effective, or they will die of something else first. The fourth man, theoretically, can benefit from treatment. Unfortunately, we cannot yet distinguish reliably who should or should not be treated.
- Physicians bring different perspectives to the decision regarding treatment, based on their training, experience, and other factors. Oriented to ensuring survival, the physician may place less importance than the patient on the potential for treatment-related impotence,

incontinence, or other complications. The patient, however, must ask, "What is my life going to be like if I take this particular route?"

- On diagnosis, men are frequently presented with a relatively simple picture and are encouraged to act more rapidly than is necessary. Men need time to overcome the fear that accompanies a cancer diagnosis so they can make informed decisions based on medical factors as well as personal preferences.
- US TOO has joined with NCI to establish the National Prostate Cancer Education Program, an initiative aimed at men with or at high risk for prostate cancer. A newly diagnosed patient should become a member of a support group, which can be instrumental in showing him the importance of actively participating in decision making, understanding the medical factors involved, and accessing information.
- While survey data show that a majority of men prefer a passive role in treatment decision making, they still want to be informed and have their opinions considered by their doctors. It is important to realize that patients and their families differ in their preferences. Some want their doctors to tell them what to do, some want to collaborate, and some want to make the decision. What is less clear is the extent to which the physician's handling of the interaction influences the decision that is made; this area requires investigation. Questions that need to be asked include: Is denial the typical response to a cancer diagnosis? Do patients really want physicians to hide uncertainty or bad news from them? How can patients get the information they need to participate fully in the treatment decision? What impact does better communication between patient and doctor have on health status? Do patients who participate in treatment decisions have fewer problems with impotence or incontinence? Is it possible to link medical outcomes to decisions made as a result of specific communication approaches?
- Since the treatment decision may impact a man's daily life for 30 years or longer, assuring that the patient's preferences are considered is absolutely essential. Conducted in tandem with medical research efforts to improve diagnosis and treatment, psychosocial research could result in identifying ways that patients and physicians can collaborate, to the benefit of millions of cancer survivors, their families, and their doctors.

Additional Research Needs and Other Recommendations

- Applied research that would benefit men and their physicians struggling with complex treatment decisions includes a better understanding of the natural progression of prostate cancer. This knowledge would enable patients and their physicians to better predict prognosis.
- Better data on the risks or likelihood of treatment-related impotence and incontinence and on alternative methods of addressing these problems are needed. Studies on decision making in the medical literature typically focus on issues faced by physicians. Most psychosocial research in the health field addresses patients, coping skills, compliance with doctors, orders, or behavior modification in response to promotional or educational initiatives. Research on the dynamics of clinical consultation regarding diagnosis, treatment, and prognosis would be most timely.

DISCUSSION—Mr. Campbell

Key Points

- The position of US TOO regarding PSA screening is that men should be informed about the pros and cons of screening and should make their own choices as to whether to be

screened. The organization, working with NCI, is trying to develop educational initiatives and other ways of intervening outside the medical setting so that men not in the health care system or without physicians (e.g., the poor or otherwise disadvantaged and special populations) can learn about the issues surrounding screening and make informed choices.

- US TOO maintains a site on the World Wide Web at www.ustoo.com.

NATIONAL ASIAN WOMEN'S HEALTH ORGANIZATION—Ms. Mary Chung

Background

The National Asian Women's Health Organization (NAWHO) is a nonprofit organization committed to improving the health of Asian-American women and girls. NAWHO focuses on bringing people together to create strategies that will close existing gaps in health care for this underserved population. The specific health care needs of Asian-Americans have often been overlooked because of stereotypes; among the most misleading being the "model minority" myth that all Asian-Americans are wealthy, educated, and healthy. This is simply not true for vast numbers of Asian-Americans in this country and masks the enduring barriers and problems that Asian-Americans encounter.

In the fall of 1996, NAWHO brought together 45 leaders at the first National Asian-American Breast Cancer Summit. This meeting was a joint effort between Government agencies, such as NCI and CDC, the private sector, health care providers, community-based organizations, and advocacy entities. From this meeting, a National Plan of Action on Asian American Women and Breast Cancer was created that systematically addresses all aspects of access to and involvement with breast cancer education, detection, and treatment services. This plan has been created to assist other agencies serving Asian Americans in national efforts to advance research on breast cancer and to encourage women's proactive consumer involvement in these processes.

Key Points

- Some people wrongly assume that Asian-American women do not get breast cancer. Data presented earlier showed that heart disease was the leading cause of death for all female populations; however, Asian-American women are the only group for whom cancer rather than heart disease is the leading cause of death. Rates vary widely among population subgroups: Hawaiians have a breast cancer incidence rate of 105 per 100,000; in Japanese women the rate is 82 per 100,000; for Korean women, the rate drops to 28.5 per 100,000.
- Changing demographics call for a new perspective. It is not possible to adjust statistics for breast cancer on the basis of immigration status. While breast cancer incidence and mortality rates for immigrant Asian women are the lowest of all women in the United States, the longer Asian women are in this country, the more likely they are to develop breast cancer.
- Vietnamese women have the highest rate of cervical cancer in the United States. There are no data, however, on cervical cancer mortality rates for either Vietnamese women or Korean women, who have the second highest incidence rate for this disease (15.2 per 100,000). We do not even know the number of women from Asian/Pacific Islander populations who are dying from cervical cancer or if they are receiving appropriate treatment.
- Asian-American women have the lowest rates of Pap test screening, mammography, and clinical breast examination of all racial and ethnic groups in the United States. Asian women are greatly underrepresented in breast and cervical cancer research and in screening and

outreach programs. Low screening rates result in too many women being diagnosed at later stages of disease.

- Most Asian women do not perceive themselves as being at risk for health problems and are not getting sufficient baseline information from their providers about screening and preventive health care. Maintaining personal good health is not a cultural priority. Health professionals need to become advocates in changing gender-based and culturally based attitudes toward preventive care, including breast and cervical cancer screening.
- NAWHO conducted a knowledge, attitude, and belief survey regarding reproductive health care services involving 734 Asian women between the ages of 18 and 35 in six California counties. More than 25 percent of these women had never had a gynecologic exam. Over 49 percent had not had a physical or gynecological exam in the past year. Of those who were sexually active, 69 percent were not always protecting themselves against sexually transmitted diseases (STDs). When asked why, they said they felt they were not at risk for STDs. Of these women, 50 percent had private insurance; however, even among this educated and insured population, utilization of preventive health care was very low. Outreach and screening efforts must incorporate cultural competency to increase Asian women's perceptions of the value of interacting with the health care system, and to overcome the lack of information, fear, misconceptions, and cultural barriers that currently result in underutilization of available services.
- The HP 2000 targets aim for an 80 percent rate of clinical breast exam and mammography among Hispanic and black women; however, Asian women have not been included, nor have they been included in Pap test special population targets.
- National studies show that Asian-Americans have the lowest rate of smoking (13.9 percent) of all racial groups. However, subpopulation studies have shown much higher prevalence rates C over 50 percent C for certain ethnic-specific populations, including Laotians and Cambodians. Since many studies use telephone surveys in English, with mostly middle-class respondents, it is quite possible that many immigrant and refugee communities have been overlooked.
- Since most Asian-Americans are immigrants, smoking behaviors in their countries of origin must be studied. While smoking rates have fallen in the United States, Great Britain, and Australia, in Asian countries tobacco use has increased by 22 percent. Cigarette advertising is pervasive in Asian countries, encouraging practices such as handing out boxes of cigarettes at weddings, and using tobacco as a healing tool in Laotian communities. Studies in California show that tobacco billboard advertising is most prevalent in Asian-American neighborhoods compared with other racial groups.
- Tobacco control is a crucial issue for Asian-American women that has received inadequate attention. Lung cancer is the second leading cause of death for Asian-American women, and ranges between second and third among different Asian ethnicities as the most commonly diagnosed cancer. This has particular implications as the relatively young Asian-American female population ages. The majority of these women are of reproductive age. As children of immigrants, in the home girls grow up in smoking environments that are carried over from Asian countries. Outside the home, they face the media image of thin, beautiful women C beautiful women smokers C as social ideals, combined with pressure to acculturate and fit in with their American peers.
- NAWHO has organized a series of cultural competency training sessions for health care professionals in California. The core message is to recognize language as a primary barrier

to effective breast and cervical cancer screening outreach to the State's Asian population. Language barriers, however, are not the only concern. While Asian-American community-based clinics can provide comprehensive, culturally sensitive, and bilingual care, it is not realistic to expect that all Asian women will be served by these providers, nor to expect that every provider has the resources to provide translation for every Asian language. Rather, compassionate and respectful efforts to provide information and services is critical to increase utilization and bring about changes in behavior.

Additional Research Needs and Other Recommendations

- Expand investigations into the increase of breast cancer in Asian women, with an emphasis on risk factors and intergenerational risk. Studies to gain a better understanding of the lower risk for women residing in Asian countries and the increase in the risk over time after migration to the United States hold immense potential for understanding how breast cancer might be controlled. This research would benefit all women.
- Strengthen the capacity of the NCP and SEER for the collection and use of ethnic-based data on breast and cervical cancer incidence and mortality among Asian-American women.
- To address tobacco use among Asian-American women, NCHS and the national vital statistics system should expand their efforts to collect ethnic-specific and gender-specific data among Asian immigrant and refugee groups. Further, Government agencies should target tobacco control education resources towards younger Asian-American women and girls who are at risk for tobacco use.
- HP 2000 goals should be updated to include Asian-American women in all priority areas.

NORTH AMERICAN BRAIN TUMOR COALITION—Dr. Susan Weiner

Background

The North American Brain Tumor Coalition (NABTC) comprises eight brain tumor research and patient service organizations. The statistics on children and adults with brain tumors are disheartening. The incidence of brain tumors seems to be increasing, a fact not explained by the aging of the population. The death rate is increasing rather than decreasing.

The statistics on brain tumors mask the complexity of the disease and the challenges associated with its treatment and aftermath. Brain tumors include many subtypes of disease. Different tumor types grow at different rates and respond differently to treatment. This year, 17,600 Americans will be diagnosed with primary malignant brain tumors, the most aggressive type. Only 25 percent of those with this diagnosis survive for 5 years. For the more than 10,000 adults who are diagnosed with primary benign brain tumors each year, many will not survive because the location of the tumor precludes surgery. Benign tumors may recur and may become malignant. Another 80,000 individuals are diagnosed each year with metastatic brain tumors. Individuals with either primary or metastatic brain tumors face similar treatment hurdles and side effects.

For children, the picture is even more complex. Brain tumors in children are very different from those in adults in their origin, growth, and response to treatment. Brain tumors are the most common solid cancer in children, and, depending on the type, pediatric brain tumors are among the most aggressive. Brain tumors are the second leading cause of death in children up to the age of 15 years as well as for young adults between the ages of 15 and 34 years.

Key Points

- The location of the tumor directly and indirectly affects every system of the body, complicating and limiting treatment. Treatment involves consideration of the impact of the treatment itself on the surrounding tissue and on the functions the tissue subsumes. Surgery, while often the most effective treatment, may not be an option for many, because the location of the tumor may affect functions critical to the quality of life or to life itself. Improvements in surgery, radiation, and chemotherapy have reduced deaths and boosted survival for other cancers, but these trends have not been achieved for brain tumors.
- Treatment presents another serious challenge in that the relatively small numbers of brain tumors (as compared to other types of cancers) are not an attractive target for private-sector investment and new product research and development. This year, the FDA approved a new delivery system for chemotherapy, the first new treatment for brain tumors in 7 years.
- Although the survival rate for children is higher than for adults (60 percent versus 25 percent), survival rates for children with brain tumors have not improved as dramatically as they have for many other childhood cancers. Treatments for children raise difficult ethical as well as medical issues. These include the potential toxic and damaging effects of therapies on a child's developing brain. Families must evaluate the impact of treatment on their children's quality of life and future. While children with certain types of tumors may respond well to treatment with relatively few side effects, children with other types may be seriously disabled by the disease and its treatment.
- The individual organizations comprising the NABTC have awarded more than \$18 million in brain tumor research funds for solid, creative research on basic science questions related to brain tumors.

Additional Research Needs and Other Recommendations

- A two-pronged approach to brain tumor research is needed. There must be a greater sense of urgency regarding the development of new treatments, and there must be focused basic research to uncover the causes of brain tumors. NCI has acknowledged the need for this dual approach in planning its research agenda.
- Discovering the genes and growth factors associated with many different types and sites of cancer holds potential for developing therapies that may apply across cancers. Research also must be conducted to deepen our understanding of specific cancer types so that new therapies can be tailored appropriately using new knowledge as it becomes available.
- For brain tumor patients and their families, time is often measured in days and weeks, rather than in months and years. As a result, this special population is impatient with the bureaucratic response to date to pleas for better treatment. While it is appreciated that scientific discovery cannot be rushed, NABTC urges policymakers to take a fresh look at old and seemingly insoluble problems in an effort to create the best possible environment for basic and clinical research and accelerate the translation of basic science discoveries into improved therapies. Coordination between basic researchers and clinicians is essential.
- The Federal Government should target basic research on brain tumors in both children and adults.
- Incentives for industry and for private-public collaboration should be enhanced to develop better therapies; there should be incentives in the form of additional exclusivity to expand

labeling of drugs for pediatric use. Ready access to information about off-label drug use may be of particular importance for children.

- Both private-sector and Medicare insurance programs should be encouraged to allow enrollees to participate in clinical trials, with coverage for routine patient care costs.
- Continued strong support for the pediatric clinical trials network for brain and other solid tumors is needed.
- A new and efficient national clinical research strategy should be created to develop and assess new treatments for children with brain and other solid tumors.

INTERCULTURAL CANCER COUNCIL—Dr. Lovell Jones and Ms. Susan Shinagawa

Background

The Intercultural Cancer Council (ICC) is a unique organization that brings together leaders and experts from minority and medically underserved communities, along with experts from mainstream cancer medical, scientific, and survivor organizations to focus on the cancer problem in minority and medically underserved communities. It is clear that individuals from racial/ethnic minorities, the poor, and/or the medically underserved have not shared equally in the progress that is being made against cancer. ICC works to reduce the high incidence of cancer and its associated suffering and death by promoting policies and programs that address this imbalance. While poverty does have a great impact on cancer, it is by no means the only significant issue. In looking at the problems we face, we need to think “outside the box.”

Key Points

- For consumer advocates for minority and medically underserved populations (with a personal stake in the issues), the belief that cancer research will yield results that are relevant to these populations, their families, and their communities, is of utmost importance. While it is understood that a great deal of information is not yet known, the cancer problem is urgent, and is growing more so in America's increasingly diverse and disenfranchised racial and ethnic populations.
- An effective interface between science and public health systems is critical. The heart of the issue is the speed at which research results are applied to cancer prevention and control programs in communities. How this is approached, along with the priority assigned at the national level, determines how many lives can, in fact, be saved.
- There is a lack of central, baseline data on the cause of the disproportional cancer rates among minorities. These differences cannot be attributed solely to “inadequate access.”
- ICC supports enhancement of the State Cancer Registries so they can collect necessary data addressing relationships between environment and cancer. The ICC also is encouraged by NCI's current efforts to create a task force to review surveillance data collected by SEER.
- Data on dietary habits and minority populations are constantly changing, as subgroups move around the country. Surveys conducted at one point in time may not be representative or accurate for specific geographic areas or for particular groups. This presents a continuing challenge for those conducting research on the effects of diet on cancer.
- Being aware of the subtleties inherent in data on cancer rates is essential. Geographic differences, dietary habits, immigration status, and many other factors must be taken into

account. For example, Hispanic Americans in Illinois have the highest breast cancer incidence in the Nation, yet nationally, Hispanic women have among the lowest breast cancer rates. Similarly, in Texas, more than 30 percent of breast cancer deaths among Hispanics and blacks were in women under age 50, twice the percentage for white women in the State.

- Although the notion that health risk often varies by race/ethnicity was considered potentially inflammatory a decade ago, it is now widely accepted. We should not be ashamed to notice differences in health risk; the shame is in not noticing them. From the ICC's perspective, the issues in addressing cancer risk in minority populations are not issues of social change, but of investing in America and its people.

Additional Research Needs and Other Recommendations

- The NCP is more critical than ever in terms of program planning, integration, implementation, and accountability across all Federal agencies and the private sector. Who is in charge of the program? Finding a locus for the NCP, where turf issues, funding, and program priorities can be agreed upon, is critical. The ICC would like to be a part of discussions aimed at revitalizing the NCP in this way.
- The Asian American/Pacific Islander group is the only racial/ethnic minority population that is not served by a Leadership Initiative on Cancer. The Panel should take action to rectify this inequity.
- Recent funding decisions to increase resources for the ALIC and decrease them for the NHLIC are not acceptable. Funding for all of the Initiatives should be increased, not increased for one at the expense of another. This issue must be addressed.

DISCUSSION—Drs. Clark, Weiner and Jones, Mr. Campbell, Ms. Chung, and Ms. Shinagawa

Key Points

- One example of providing incentives for private industry to pursue brain tumor research can be found in the recent FDA reform legislation that provides 6 months of market exclusivity for developers of drugs for the treatment of pediatric brain tumors. The success of this incentive in spurring drug development efforts for this small patient population remains to be seen, but it is a step toward improving the environment for brain tumor research.

PRESENTATION HIGHLIGHTS: Issues for Research and Medicine

AMERICAN MEDICAL ASSOCIATION—Dr. Priscilla Short

Background

As part of its mission to improve public health, the American Medical Association (AMA) supports educational initiatives to educate minority populations with regard to their cancer risk. In its advocacy role, the AMA consistently supports funding for the NIH. The AMA also recognizes and is highly invested in addressing the need for coordination of clinical research and clinical trials. To this end, the AMA, along with the American Association of Medical Colleges (AAMC) and Wake Forest University, is convening a summit on the future of clinical research. The AMA also supports the goals of HP 2000, and is highly involved in tobacco use issues, supporting Smokeless State Programs and funding for smoking cessation programs.

Key Points

- The educational poverty of physicians with regard to cancer genetics, particularly given the accelerating trend toward marketing cancer-related marker tests directly to physicians and patients, is a major concern. To illustrate, a study reported in a 1997 article in the New England Journal of Medicine indicated that a significant proportion of the providers studied would have misinterpreted a test for APC, a colorectal cancer gene. Currently, there are only about 2,000 genetic counselors, most of whom have been trained principally in prenatal genetics, and only about 1,100 medical geneticists. The AMA believes this situation represents a major crisis in cancer genetics education in this country.
- In response, the AMA has joined with the National Institute for Human Genome Research, the American College of Medical Genetics, the American Society of Human Genetics, and primary care provider organizations to sponsor a March 1998 conference on genetics and genetic testing. One-half day of the 2 day program will be devoted to cancer genetics. A strong impetus for the conference was the recognition that the medical school education of some physicians may not have included genetics. In addition, physicians need to know what questions to ask patients who have family histories or potential predispositions to cancer. Physicians need to know how to interpret data in the literature on the penetrance of specific cancer genes, the cancer risk associated with them for specific populations, and the performance of new gene tests. Misinterpretations of risk (e.g., Ashkenazi Jewish women with BRCA gene mutations) may lead to inappropriate treatment. In addition, patients are now, through access to the Internet, becoming informed about cancer genetics issues; physicians must be able to knowledgeably discuss these matters with their patients. In a related activity, the AMA, the National Coalition on Education of Health Care Providers, and the American Nurses Association have joined forces to provide reliable Internet resources on genetics, including cancer genetics.
- In the drive to collect better demographic and followup data on various populations, privacy and confidentiality concerns must not be forgotten.

AMERICAN SOCIETY OF CLINICAL ONCOLOGY—Dr. Allen S. Lichter**Background**

The American Society of Clinical Oncology (ASCO) represents more than 12,000 physicians involved in the day-to-day care of people with cancer, and is dedicated to reducing the impact of cancer on the American public. ASCO is concerned that reductions in cancer mortality rates and other advances are not being shared across all segments of our population. It is critical to understand why these differences exist and correct them.

Key Points

- Socioeconomic differences, while important, do not account for all variations in cancer outcomes. For example, African-American men are at higher risk for prostate cancer mortality and less favorable survival than are white men. A large study of military personnel found that even with equivalent stage of disease at diagnosis, equal access to health care, and treatment by the same group of physicians, the African-American prostate cancer patients had lower disease-free survival. This study suggests that biologic issues might explain some of these differences, both in prostate and other cancers. Any such differences should be sought out and if they exist, they should be well-characterized and therapeutic strategies should be developed to circumvent them.

- Certain prognostic markers for cancer have been identified. One of these is the erb-B2 growth factor for breast cancer, the overexpression of which is associated with poorer outcome, especially if chemotherapy dosage is modest. However, it has been discovered that the adverse outcome of erb-B2 disappears when patients receive high-dose chemotherapy. Many other markers exist; these may be randomly distributed in the population or they may cluster. If they are clustered, different therapeutic approaches may be indicated for certain populations. This is an area ripe for research.
- Advances in molecular genetics have changed our ability to detect individuals at risk for certain cancers from mutations in specific genes. These advances have the potential to lead to new screening and treatment strategies. It is already known that some mutations are not randomly distributed; certain populations (e.g., the Ashkenazim) have unique spectrums of genetic change. Screening of a specific population is made easier if researchers know where gene mutations of interest are clustered.
- Other so-called “founder” mutations have been discovered in subpopulations and could explain some of the observed differences in cancer incidence and, perhaps, outcomes. Access to these populations for research purposes is greatly needed. Considerable suspicion toward genetic testing exists in some communities. These attitudes must be understood, studied, and overcome so that research can go forward. The Panel could help in this regard by endorsing the application of molecular biology and molecular genetics as part of the systematic study of possible population differences in cancer appearance and outcome.
- Clinical trials are the accepted vehicle for assessing the efficacy of treatment for any population. If clinical trials are large enough, subpopulations can be studied and compared to other populations in the trial. Many trials, however, are not large enough to generate sufficient statistical power on special populations to support conclusions. In addition, less than 3 percent of adults with cancer participate in trials, limiting our ability to gather subpopulation data and conduct trials in a reasonable length of time. Exclusion of coverage for experimental therapies included in most insurance contracts, including Medicare, further limits participation. Patients are afraid to go into studies and physicians are reluctant to place them on trials.

Additional Research Needs and Other Recommendations

- Bipartisan legislation is being sponsored to require Medicare coverage for cancer clinical trials approved by NCI, the Food and Drug Administration, the Veteran’s Administration (VA), and the DoD. The Panel’s endorsement of the Rockefeller-Mack legislation could provide a boost to advocacy in support of the bill.
- Comprehensive solutions to socioeconomic problems of access to the health care system are needed. Screening is of little value if there is no payment mechanism to provide followup or treatment when an abnormality is discovered. Many low-income patients have access problems, leading to treatment delays and poor prognostic outcomes. ASCO advocates for adequate and affordable health insurance coverage for all Americans, a crucial step toward persuading patients to participate in screening and obtain appropriate treatment when it is needed. In addition to treatment of identified cancers, cancer care coverage should include screening, prevention, access to oncology specialists, and oral pain medications after hospital release. It is unconscionable to provide adequate pain medication in the hospital setting, only to release patients to suffer needlessly because their

insurance will not pay for orally administered pain medications and they are unable to afford the out-of-pocket cost of purchasing them.

- We must remove the barriers erected by health insurers that discourage patients and their physicians from participating in clinical trials, and we must encourage more racial and ethnic minority patients to enter trials. Suspicion about clinical trials and genetic testing must be addressed.
- Tobacco use is the number one preventable cause of cancer deaths; we must redouble our efforts in tobacco control.

ONCOLOGY NURSING SOCIETY—Ms. Pamela J. Haylock

Background

The membership of the Oncology Nursing Society (ONS) numbers approximately 25,000 registered nurses and approximately 70 associate members who are not registered nurses. A core value of the ONS is the right of all individuals to the best possible cancer care. Incorporating multiple world views and preferences into every aspect of care will benefit patients and families. Cultural competence enhances a nurse's ability to provide quality cancer care; this is defined as being sensitive and responsive to issues of race, culture, ethnicity, gender, age, socioeconomic status, and spiritual and sexual orientation.

Key Points

- In their work with diverse populations, ONS members have noted that cancer patients from different populations frequently report substantially different symptoms of cancer disease and highly variable responses to treatment, including the willingness and/or ability to comply with treatment and supportive care regimens. This is both perplexing and disturbing.
- Cancer means different things in different population groups. Communication styles and preferences differ and need to be considered in all informed-consent processes. Social support differs within and between different ethnic groups. Symptoms, concepts of death and dying, and survivorship mean very different things to different populations. Issues of trust and credibility have to do with the "insider/outsider" phenomenon, with outsiders often being researchers. Access to trusted providers who are skilled in cancer care services is another real issue. Many variations in home and community care exist. It is important to explore and understand these variations.
- What is meant by "race" is not clearly defined. This confusion creates barriers to effective research and impedes our ability to generalize study results across groups. Heterogeneity within racial and ethnic groups needs to be better understood, since variations and taboos exist that are related to age, gender, and, in the case of Native American populations, to tribe.
- Minority populations have reason to mistrust research, (e.g., the Tuskegee Syphilis Study); and this historic backdrop must be considered when attempting to develop trust.
- Methodologic problems can arise when the language of the dominant group is different from that of the study population. Tools used in research are often created for and by members of dominant groups and do not translate well to members of other population groups.
- It takes time for researchers to become accepted by a community. Folk healing and alternative approaches to health and wellness are often dismissed or ignored by researchers, leading to a perception of arrogance and ignorance on their part. Often, there

is no end product or sense of something being given back to the community. A lack of reciprocity. In many cases, the end of a grant means the end of the program, which can lead to a feeling of abandonment by the group being studied.

- Qualitative research methods are generally used to address cultural and ethnic variables; however, these approaches are still not as well accepted as are quantitative methodologies.

Additional Research Needs and Other Recommendations

- The integration of a world view throughout the cancer trajectory should be promoted. Questions of cultural competence must be asked and answered. Cultural assessment skills and tools should be promoted and integrated into clinical practice.
- Racial definitions require clarification, both for use in the grant process and in reporting.
- Approaches that focus on wellness rather than on illness should be fostered. Approaches that incorporate lay health workers whenever possible and draw on insider/outsider research teams should be encouraged.
- Support within the research process is needed that truly considers population needs and is accepting of qualitative research. The grant rating and review processes should be aligned with the cultural, ethnic, and community norms, nuances, and expectations. There is a need to integrate concepts of mutual reciprocity and to incorporate intervention grants, funding for ongoing programs, information sharing, and the involvement of community organizations.
- Study results should be shared with the group under study as well as health care providers, researchers, and policymakers. As Dr. Burhansstipanov has noted on other occasions, many ethnic and cultural nuances are not described in books; we must learn from being in the community.

NATIONAL MEDICAL ASSOCIATION—Dr. Nathaniel H. Murdock

Background

The roles of the National Medical Association (NMA) include promoting policy to address the imbalance in cancer mortality among populations; supporting efforts to ensure continuity and portability of health benefits; promoting increased research participation by minority scientists; increasing consumer participation in clinical trials; fostering provider education on the merits of clinical trial participation; targeting health interventions to the needs of minorities; and providing prevention education programs in a variety of health care settings.

NMA has developed several successful educational programs, including a PSA screening program that offers a musical concert as a participation incentive; a smoking cessation program called "Stop Active Smoking and Take Charge," currently under way in 130 NMA chapters; and a breast and cervical cancer screening project that has given physicians the tools and the ability to reach the underprivileged and underserved.

Key Points

- While cancer deaths have declined nationwide, cancer incidence in minorities and the medically underserved continues to increase. Survival rates in these populations are lower than those for the majority population. Cancer rates are highest among African-American men and among Alaskan Native women. Of the 560,000 Americans who will die of cancer this year (1,500 per day), 62,000 will be African-Americans, and 14,300 will be members of other ethnic minority groups.

- There are scant data to prove or disprove that screening and improved health care access will significantly reduce cancer mortality in minority populations. Professional organizations, advocacy groups, associations, and community organizations must provide strategies to address the needs of minorities and the underserved. All health measures must be improved to produce a decrease in minority cancer mortality rates.
- Minorities and culturally diverse individuals should be involved in the development of policies and programs that may impact their communities. Equal representation of minority population groups in research is needed. This includes addressing disparities in data collection and surveillance of high-risk groups, and developing programs to counteract fear, ignorance, and denial with confidence, knowledge, and involvement.
- Barriers that limit minority participation in clinical trials include: lack of awareness of existing protocols by local physicians; the amount of time required for physicians and staff to explain protocols and consent forms; patients' fear of research; the amount of patient time involved, detracting from home and family responsibilities; and the lack of bilingual providers. Protocols must be set up at convenient times (e.g., evenings and weekends). Providing support for travel-related expenses and financial costs associated with certain diagnostic procedures can be very helpful and should be encouraged.
- Tumor incidence differs among populations, which must be kept in mind when recruiting minorities for clinical trials. Specific protocols for cancers seen in minority populations may be lacking. A lack of understanding of minority knowledge, attitudes, and practices can result in poorly planned protocols.
- Future research should be directed at isolating genes responsible for the development of specific cancers. Once identified, we can develop methods of modifying these genes to prevent disease.

AMERICAN ASSOCIATION FOR CANCER RESEARCH—Dr. Donald S. Coffey

Key Points

- The Panel's focus on the concerns of special populations intrinsically involves consideration of genetic, racial, gender, religious, and policy concerns. These are controversial issues. Although some believe that race and race differences in cancer are social and political, rather than biological, Dr. Coffey expressed the belief that biologic differences exist and should be studied.
- Research conducted at Johns Hopkins University has examined androgen receptors in relation to prostate cancer. Androgen receptors contain variations in glutamine repeats. The repeat sequences have been observed to be shorter in cancer patients than in people without cancer. Among cancer patients, these sequences were found to be the shortest in African-Americans, of moderate length in Caucasians, and longer in people from Asia. Further, several distribution curves have been identified within different races, suggesting that there may be subpopulations within racial groups. Research at Johns Hopkins and by other investigators suggests that the shortest glutamine repeat links are associated with the race that experiences the most aggressive forms of cancer.
- From an anthropological perspective, it is difficult to classify people by race. All human groups are polymorphic. There is no one human genome, just as there is no one common human. Variations in the noncoding regions of the gene affect gene stability. Thus, polymorphism has a tremendous effect. Genetic differences between various groups exist (e.g., lactose intolerance in some Asians, sickle cell anemia in some African-Americans).

Controversy aside, fundamental research should go forward to understand these critical racial differences.

- Young cancer scientists are fearful of being unable to find jobs. This is not surprising, since currently only 23 percent of approved grants are funded. In the early 1970s, when the war on cancer began, 40 percent of approved grants were funded. Yet, despite the delay in progress against cancer and the disincentives to pursue cancer research careers that are being caused by inadequate funding, there is little support, even in the scientific community, for vastly increasing cancer research funding. Those who suggest that funding should be doubled or tripled are considered naive.
- Dr. Coffey noted that in the time required to conduct the afternoon's meeting, eight people in the United States would be murdered, 11 people would die of AIDS, and 163 people would die of cancer. The toll of death from cancer is equivalent to five fully loaded Boeing 747 aircrafts crashing every day. Despite the public's perception, there has never been a real war on cancer; what has been done to date represents only a skirmish.
- Government representatives, specifically the Congress, appear to be uninterested in minority and cancer issues. Likewise, Government policy on tobacco is counterproductive and does not address the need for research in this area.
- Investments in cancer research have paid off (e.g., finding a cure for testicular cancer). Can funding be found to solve the riddle of the six leading cancers? Finding effective prevention and cures requires a major policy shift, including greatly increased funding for research C a real war on cancer.

DISCUSSION—Drs. Short, Lichter, Murdock and Coffey, and Ms. Haylock

Key Points

- The NMA believes that increasing physician awareness and understanding is one way to increase the number of adults in cancer clinical trials, and has partnered with the Eastern Clinical Oncology Group (ECOG) in this regard. ASCO is focusing on the passage of legislation to cover clinical trial care costs. It also supports the cooperative group research programs, such as ECOG, that can also make a key difference in easing barriers to trial participation for both physicians and patients. The AMA believes that patient empowerment can be effective in increasing understanding and confidence in the clinical trials mechanism. Support organizations that track the availability of clinical trial programs are providing an important source of information for patients.
- ONS members are aware of and actively support patient access to clinical trials. ONS is collaborating with NCI on a workshop to help nurses provide patients with consistent information about clinical trials generally, and with regard to specific protocols. In addition, the ONS Clinical Trials Special Interest Group is working with NCI to assess the informed- consent process for clinical trials. ONS also supports reimbursement for direct care costs of clinical trials participation.
- Dr. Coffey expressed his view that should funding for cancer research be dramatically increased, the funds should be put into existing programs (e.g., in biology, epidemiology, molecular research). The number of Specialized Programs of Research Excellence (SPORes) should be increased for cancers such as prostate. At the same time, there is a need for fresh thinking to accelerate progress.
- It has been known for 20 years that prostate and breast cancer rates increase in populations that move from Japan to Hawaii, and jump again when these same populations then move

to the U.S. mainland. The scientific reasons for the associations are not known, but with adequate resources applied at the levels of basic research, prevention, and therapeutics, questions such as these should be answerable.

- The patient accrual rate by physicians participating in clinical trials is about 9 to 10 percent of all patients seen. Minority participation in NCI-sponsored trials is proportionally representative to the burden of cancer in these populations relative to the population as a whole. Dr. Brawley expressed his view that the tendency of blacks and other minorities to be suspicious of medical research is more likely to be related to their personal encounters with the medical system than fears engendered by the Tuskegee Syphilis Study. Remedies being pursued by the NMA include conducting regional outreach, emphasizing prevention, teaching healthy lifestyles to school-aged children, and promoting clinical trials.
- The advent of managed care has increased problems with patient accrual to clinical trials. Rhode Island has passed legislation that requires managed care entities to support routine care costs of any patient on approved Phase II, III, and IV clinical trials. Approximately 12 other States are exploring the passage of similar laws.
- If alternative and less toxic therapies were given the same value and respect as surgery, chemotherapy, and radiation, there might be greater public interest in research participation. The need for less toxic therapies is well recognized; researchers are looking for naturally occurring factors, such as cytokines, and other biologicals that will affect cancer cells without harming normal cells.
- Categories used in the United States to define race are not biologically determined; rather, they have come out of the Nation's history. Eighty-five percent of genetic variation occurs within a given race; 15 percent occurs between races. Groups of people are different; but race is not the classifier that determines the difference. However, stating the issue in this way can suggest that there are no genetic differences between African-Americans and Caucasians when clearly there are. Differences in polymorphism are seen in different racial groups. There is at once a tendency to de-emphasize race distinctions and to believe that racial and cultural differences are unique and important in understanding cancer causation. These two perspectives are not necessarily diametrically opposed.
- For the cost of one B2 Stealth bomber, we could double the budget of the NCI.

CLOSING REMARKS—Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- The Nation's cancer problem is large and involves all populations. This year, there will be more than a million new cancer cases and more than a half million deaths. While there has been a 2.6 percent reduction in cancer mortality over the past 5 years, this reduction has not been evenly distributed across all parts of the population. We need to determine the reasons for these discrepancies and, at the same time, attempt to improve conditions for all populations.
- The testimony provided at this meeting, and the Panel's recommendations based upon it, will be incorporated into a report to the President.

CONCERNS OF SPECIAL POPULATIONS IN THE NATIONAL CANCER PROGRAM

NOVEMBER 21, 1997
TAMPA, FL

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

N A T I O N A L C A N C E R P R O G R A M

N A T I O N A L C A N C E R I N S T I T U T E

CHAIRMAN
HAROLD P. FREEMAN, M.D.
HARLEM HOSPITAL CENTER

MEMBER
FRANCES M. VISCO, J.D.
NATIONAL BREAST
CANCER COALITION

MEMBER
PAUL CALABRESI, M.D.
BROWN-TUFTS CANCER CENTER
RHODE ISLAND HOSPITAL
NEW ENGLAND MEDICAL CENTER

EXECUTIVE SECRETARY
MAUREEN O. WILSON, PH.D.
ASSISTANT DIRECTOR
NATIONAL CANCER INSTITUTE

Concerns of Special Populations in the National Cancer Program The Responsiveness of the Health Care System to the Needs of Special Populations November 21, 1997, Tampa, Florida

Opening Remarks	<i>Dr. Harold Freeman</i>
Director's Report	<i>Dr. Maureen Wilson</i>
The Programs of the H. Lee Moffitt Center	<i>Dr. John C. Ruckdeschel</i>
A Community Clinical Oncology Program (CCOP) Perspective	
Mt. Sinai Medical Center	<i>Dr. Enrique Davila</i>
Montana Cancer Consortium	<i>Dr. Neel Hammond</i>
LSU Medical Center	<i>Dr. Robert Veith</i>
San Juan City Hospital	<i>Dr. Luis Baez</i>
Bay Area Tumor Institute CCOP	<i>Dr. Jay K. Harness</i>
South Texas Pediatric Minority-Based CCOP	<i>Dr. Javier Kane</i>
Kings County MBCCOP [SUNY]	<i>Dr. Constantin J. Rosenthal</i>
An Advocacy Voice	
Coalition of Hispanic and Health and Human Service Organizations	<i>Dr. Deborah Duran</i>
National Ovarian Cancer Coalition	<i>Ms. Susan Wallace</i>
National Prostate Cancer Coalition	<i>Mr. Robert Samuels</i>
Patient Advocate Foundation	<i>Ms. Nancy Davenport-Ennis</i>
National Hospice Organization	<i>Mr. John Carney</i>
Rural Research Issues	
Rural Linkages	<i>Dr. Charles W. Given</i>
On Behalf of Working America	
AFL-CIO	<i>Ms. Nadra Floyd</i>
Closing Remarks	<i>Dr. Harold Freeman</i>

Speakers List

Concerns of Special Populations in the National Cancer Program

The Responsiveness of the Health Care System to the Needs of Special Populations

November 21, 1997, Tampa, Florida

Dr. Luis Baez

Chief, Hematology/Oncology Section
San Juan VA Medical Center and San Juan City
Hospital

Mr. John Carney

President, Hospice Inc.
Chairman, National Hospice Board of Directors

Ms. Nancy Davenport-Ennis

Founding Executive Director
Patient Advocate Foundation

Dr. Enrique Davila

Mount Sinai Medical Center

Dr. Deborah Duran

Senior Research Advisor/Cancer Project Director
National Coalition of Hispanic and Health and Human
Service Organizations

Ms. Nadra Floyd

Assistant Director for Community Action
AFL-CIO Field Mobilization Department

Dr. Charles W. Given

Michigan State University

Dr. Neel Hammond

Principal Investigator
CCOP
Montana Cancer Consortium

Dr. Jay K. Harness

Professor of Surgery
University of California at Davis
Bay Area Tumor Institute

Dr. Javier Kane

Assistant Professor
Division of Hematology/Oncology/Immunology
University of Texas Health Science Center

Dr. Constantin J. Rosenthal

Long Island College Hospital
Division of Medical Oncology

Dr. John C. Ruckdeschel

Director
H. Lee Moffitt Cancer Center

Mr. Robert Samuels

National Prostate Cancer Coalition

Dr. Robert Veith

Principal Investigator
Louisiana State University Medical Center
Minority-Based CCOP

Ms. Susan Wallace

National Ovarian Cancer Coalition

CONCERNS OF SPECIAL POPULATIONS IN THE NATIONAL CANCER PROGRAM

The Responsiveness of the Health Care System to the Needs of Special Populations

November 21, 1997, Tampa, Florida

OVERVIEW

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. The purpose of this meeting, the last in a series of four meetings focusing on the concerns of special populations in the National Cancer Program, was to consider the responsiveness of the health care delivery system to the needs of these populations.

Fifteen speakers presented testimony to the Panel on the experience of Community Clinical Oncology Programs in providing cancer care to special populations, the perspective of patient advocates for various special population groups, rural cancer care issues, and problems experienced by working Americans. Speakers highlighted recent research and interventions focused on meeting the needs of different special populations for cancer screening, education, early detection, treatment, and supportive care, and offered specific recommendations on improving care for special populations for consideration by the Panel.

OPENING REMARKS—Dr. Harold Freeman, Chairman, President's Cancer Panel

In opening the meeting, Dr. Freeman stated that:

- This is the last of four meetings addressing the concerns of special populations in the National Cancer Program. Prior meetings in this series addressed the meaning of race in science and related considerations for cancer research, cancer in the aging population, and the real impact of the reduction in cancer mortality.
- Today's meeting is intended to identify areas of the current health care system that successfully serve the needs of special populations, and areas in which improvement is still needed.
- The health care system in the United States is in the midst of an extraordinary and rapid evolution. A principal feature of this evolution is a transition from traditional fee-for-service health insurance to varying forms of managed care. Health care costs are "managed" using structured service networks, negotiated provider-payer contracts, and common health care delivery guidelines, among other mechanisms. This transition is occurring in both the public and private sectors. More than 60 million Americans are now covered by private managed care organizations; further, both Medicare and Medicaid are rapidly converting to managed care systems as a central strategy for minimizing costs.
- In 1996, the Panel addressed the impact of the evolving health care system on the National Cancer Program, and reported its findings in its annual report to President Clinton. The Panel concluded, based on hearings in each quadrant of the country, that the impact of changes in our health care system has been equated, though not always correctly, with the introduction of managed care. These changes, under whatever organizational auspice (including traditional fee-for-service systems), pose a real danger to our progress in

reducing the burden of cancer for all people. Perhaps nowhere will the effects of the changing health care system be as pronounced as among the traditionally underserved populations, who are already disadvantaged by having the fewest resources and fewest proponents to advance their interests.

- One of the Panel's recommendations in 1996 was that measures should be taken to ensure that minorities, the poor, the elderly, the uninsured, and the underinsured are not excluded from access to appropriate health care as the health care system evolves. Every person now waging a personal war with cancer, or who may in the future do so, needs timely access to the diagnostic and therapeutic strategies and tools best able to fight his or her disease, and assurance that medical knowledge and care will be applied appropriately to each person as an individual. Thus, access, cost containment, and quality of care are currently the competing priorities, among which we are struggling to achieve a balance for all populations, and particularly for underserved populations. Today's meeting provides an important opportunity to focus at greater length on the responsiveness of the current health care system to the needs of special populations.

DIRECTOR'S REMARKS—Dr. Maureen O. Wilson, Assistant Director, NCI

Representing Dr. Richard Klausner, Director, NCI, Dr. Wilson indicated that:

- Over the past two years, many discussions have taken place at the NCI on the impact of the changing health care system on cancer research, particularly in the area of clinical trials. Many efforts to increase participation in clinical trials research have focused on expanding the populations to whom clinical trials are accessible. These efforts have resulted in agreements forged with the Department of Defense (DoD) and the Department of Veterans Affairs to make NCI-sponsored Phase III and IV clinical trials available to persons receiving health services through those systems. NCI is now working to expand this coverage to Phase I and II trials.
- Likewise, discussions have taken place with the Health Care Financing Administration (HCFA) to expand such coverage to populations eligible for Medicare. The Medicare population is at high risk for cancer, and is growing. These discussions are continuing, but NCI realizes that the populations that can be reached through such agreements (i.e., through Federally-sponsored health programs) are relatively limited compared with the population as a whole. The help of institutions across the Nation is needed to expand interactions with the wide range of populations affected by cancer and those at risk.
- NCI has continued to ask why less than three percent of adults participate in clinical research studies. Lack of health insurance coverage is only one of the many factors contributing to this low participation level. Others include a general mistrust of clinical research among special populations, nonresponsiveness of the clinical trials systems to the needs of special populations, physical barriers such as geographic inaccessibility, fiscally-based reluctance of local physicians to refer patients to clinical trials at major cancer centers, and the lack of an evidence-based system of support for clinical trials reimbursement (an issue related to insurance coverage problems).
- Recent statistics show that while we have succeeded in achieving a reduction in cancer mortality nationally and as a research community, we have not been able to achieve a similar result with respect to cancer incidence. NCI has recently launched several initiatives to address this concern. First, a task force has been established to examine one of the most widely used reporting systems in the country, the Surveillance, Epidemiology, and End Results (SEER) program. By reexamining SEER, we will assess the validity of

how we collect data on cancer incidence and mortality, and the populations that are affected. SEER data are also a crucial tool for tailoring cancer-related messages and the delivery of health care.

- Second, NCI has reorganized its Division of Cancer Prevention and Control into two distinct parts—a Division of Cancer Prevention, and a Division of Cancer Control and Population Studies. The extramural epidemiology and genetics program has been incorporated into the latter Division.
- Third, NCI is establishing a health informatics system that will be responsive to consumer needs, and plans to organize a network of cancer Web-masters to ensure that information available to one institution can be made available to all participating institutions.
- Lastly, NCI has recently created a consumer liaison group to bring more consumers and survivors into the NCI decision-making process.
- As Dr. Freeman has previously stated, changes being felt as the health care system metamorphoses threaten to disenfranchise further those who are already at risk in the system—the poor, the underinsured, the uninsured, minorities, and the elderly. Another group not often discussed in this category is much of America's working class. It is our responsibility to ensure that this further disenfranchisement does not occur by removing as many obstacles to access to appropriate cancer care as is humanly possible.

WELCOME—Dr. John Ruckdeschel, H. Lee Moffitt Cancer Center

Background

The H. Lee Moffitt Cancer Center was established 11 years ago with a single mission—to contribute to the prevention and cure of cancer. It was designed and constructed on a clinical imperative: Florida ranks number two both in number of new cancer cases, and in cancer mortality. The Center's primary catchment area is on the west coast of Florida. It has a huge population of retirees who have brought with them to the area their accumulated life experience and exposures.

The state legislature created the institution in 1983, which opened as a cancer hospital in 1986. It was funded by the cigarette tax. In 1986, the facility had 50 beds, about 3,500 outpatient visits, and no funded research. The research program was initiated in 1992, and as a result of an aggressive scientific recruitment program, nearly 80 new faculty have joined the Center in the last three years.

Clinical facilities at the Center currently include a full service, 162-bed hospital with the largest bone marrow transplant unit in the Southeast, and full radiation, surgery, imaging, and pathology services. The Moffitt Clinic is the Center's outpatient facility. Clinical facilities also include the Lifetime Cancer Screening Center that provides full screening, genetic screening, and counseling services. Research facilities are growing rapidly, with one addition under construction and another planned. In 1996, the Center had nearly 2,000 patients entered on cancer control, translational, and clinical trials.

The Center uses a multidisciplinary approach to cancer care. Breast, lung, and prostate cancers make up a significant portion of the cancer cases treated at the Center. Somewhat unique to the Center and geographic area, more melanoma patients are treated at the Center than either lung or colon cancer patients. Special populations in the Center's catchment area include Latinos, the elderly, migrant farm workers, African Americans, and children. To serve its large elderly population, the Center has one of the few multidisciplinary senior adult oncology programs, which also serves as a focus for clinical and basic research on

issues related to aging and cancer. Special programs for the underserved, low income migrant population focus on breast health; a breast health initiative is also in place for senior, primarily African American women. Programs for elementary school children and adolescents focus on smoking cessation and sun protection.

The Center has taken an aggressive and innovative approach to attracting patients and working with managed care providers in the area, with positive results. The H. Lee Moffitt Cancer Center has become an NCI-designated Cancer Center.

Key Points

- Populations with special needs that tend not to be addressed include women with cancer other than breast cancer, and men with cancer other than prostate cancer. In addition, academic health centers and the collective national clinical research effort both have unaddressed important needs.
- Advocacy is a double-edged sword. Focusing attention and funding on specific cancers or conditions is beneficial as long as it is not at the expense of patients with other conditions. Without an increase in overall resources, advocacy and fighting between advocacy groups results in politicians setting specific clinical and research priorities—this is wrong.
- Academic health centers, of which cancer centers are a component, are suffering as a result of unintended consequences. In response to concerns about U.S. health care costs, we have rushed headlong into managed care systems without first testing to determine their effect on quality of care. Marketplace forces that are reducing expenditures have led to inappropriately restricted access to care. The Center maintains a staff whose sole job is to argue with managed care companies about patient access. This is true even for patients with policies in which the Center is a participating institution, and for Center employees covered by the Center's health policy who require cancer treatment.
- Teaching hospitals are also suffering the consequences of actions to reduce government spending—Medicare, residency, capital, and Medicaid reimbursements have all been cut. In addition, student loan program changes that now require repayment to begin upon medical school graduation rather than at the end of training discourage individuals who would be the next generation of cancer researchers and caregivers from pursuing specialty training.
- Academic health centers in medical schools are increasingly dependent on the clinical practice of the faculty to support the institution. At the same time, access to specialists is being limited. This results in a highly precarious situation. Capricious funding of clinical research by managed care companies complicates an already difficult problem. Moreover, financial incentives and data management support provided to community physicians by commercial research firms to enroll patients on industry-sponsored studies are reducing accruals to NCI sponsored research.

Additional Research Needed and Other Recommendations

- A general increase in research funding is needed. Doubling the National Institutes of Health (NIH) budget would require only the cost of a single B-1 bomber.
- Access to NIH-approved clinical trials should be legislatively mandated.
- The messages of advocacy groups should be carefully weighed until the overall research budget is increased.
- The current trend toward training primarily generalists without specialty knowledge or training, and curtailing specialty and research training will decimate the Nation's academic

health enterprise. This must not be allowed to happen; the rebuilding of research system capacity and its workforce cannot be accomplished rapidly.

DISCUSSION—Dr. Ruckdeschel

Key Points

- To attract and support young translational investigators, the Moffitt Cancer Center provides from its core resources salary support and protection from clinical practice requirements. Core grant development funds are used to provide laboratory equipment and support. This assistance is available for up to five years. A more difficult group to support are predominantly clinical researchers who also need to know enough basic and translational science to cooperate intelligently in the design and implementation of translational trials. They, too, need general, central support. Deans or center directors need a larger pool of funds for such discretionary support. Without adequate support early in their careers, translational scientists are forced to spend their time writing grant applications for projects judged to be most readily fundable, instead of developing the working relationships with basic and clinical scientists necessary for their professional development.
- The commonly accepted statistic stating that only three percent of adults with cancer are treated on clinical trials may be misleading. Not every patient, because of comorbid conditions, lack of an ongoing study relevant to their disease, or other legitimate reasons (not related to funding) is appropriate for inclusion in a clinical trial. Instead of looking at the participation level of the universe of adult cancer patients, it may be more appropriate to assess the level of participation among patients who would be medically eligible for a study and for whom a relevant study is available; at the Moffitt Cancer Center, a study of lung cancer patients found that about 30 percent met these criteria and of these, about one in three entered a study.
- Cancer centers and other institutions should make extra efforts to reach populations in their areas that have special issues or needs. However, the focus on special populations has allowed policy makers, particularly Congress, to escape dealing with the larger, underlying issues (e.g., lack of access to care including clinical trials, lack of insurance coverage, inadequate research funding) that give rise to targeted programs for special groups.
- The Panel has heard testimony from other Cancer Center representatives indicating a shift toward industry-sponsored research compared with government-sponsored research. Dr. Ruckdeschel indicated that the Moffitt Center also grapples with this issue. In the past six years, the Center has de-emphasized reliance on this form of research support, and enters into pharmaceutical studies only as scientific partners with the company and when the study answers a scientific question of interest to the Center's investigators. He noted that at academic centers in which the faculty have heavy responsibility for generating clinical care income, they are likely to have little time for research other than relatively narrow, industry-sponsored studies.
- Until such time as funding for research is substantially increased, strong leadership at NCI and the NIH is crucial to avoid a conglomeration of programs dictated by advocacy support and political pressure. In the last two years, the benefit of such leadership at the NCI in particular has been evident. This underscores the importance of de-politicizing, to the extent possible, decisions regarding the selection of Institute leaders and of insulating these leaders from the whims and direct retribution of individual legislators so that they can be strong leaders. It was noted, however, that advocacy has been the avenue by which people whose health issues may have been ignored gain access to the system; it would not

be desirable to close that avenue entirely or filter the exposure of Congress to pressing health issues.

- Protecting the academic centers from fiscal failure due to the dual forces of government spending cutbacks and managed care may require legislative protection or designation of the academic centers as a "pecial population." The academic centers need to be saved not just for their own sake, but to ensure that needed research on cancer continues. If the medical schools fail, there will be no influx of new talent to continue research into the next century. This in turn can be expected to lead to failure of the cancer centers. The advocacy community has a vested interest and an important role in ensuring the continued viability of the academic centers. The next generation of cancer research will not be done in private practice, in the HMOs, large insurance companies, or large integrated health systems. It will only be done in the academic centers.
- Dr. Calabresi has noted in the past that currently, 50 percent of cancer patients are saved; another 25 percent could be saved with the knowledge and technology we have now. For the remaining 25 percent (those with still intractable disease like pancreatic cancer and most metastatic disease), the research enterprise holds the only hope for improving survival.
- Reiterating that applying the cost of a single Stealth bomber to cancer research would double NCI's budget, Dr. Freeman suggested that an appropriate slogan might be: "We do not need Stealth, we need health."

PRESENTATION HIGHLIGHTS: A Community Clinical Oncology Program (CCOP) Perspective

MOUNT SINAI MEDICAL CENTER—Dr. Enrique Davila

Background

Mount Sinai Medical Center, located in Miami Beach, is the largest private not-for-profit hospital in Florida, with the only clinical cancer research program sponsored by the NCI in South Florida other than the Moffitt Cancer Center.

Key Points

- Managed care patients often cannot be included in studies because of late referral, and denial of coverage by insurers is a continuing problem. In addition, HMOs and managed care programs resist providing complete work-ups that are necessary if a patient is to be included in a trial. Further, managed care companies require patients to receive tests at the facility with which they have contracted; these facilities are often not of the highest quality.
- Other factors that complicate efforts to include managed care patients on clinical studies are preauthorization requirements, difficulties in locating gatekeeper physicians, unproductive discussions with non-physician managed care personnel, and difficulty in obtaining answers to questions. In addition, many oncologists treating managed care patients are forced to substitute chemotherapy drugs included in the plan's formulary for those they believe are most effective.
- Managed care plans could be the ideal setting for large screening trials since they have large patient populations.
- NCI reimbursement for CCOP patient accrual activities is substantially less than that provided by industry studies, and does not provide any payment for patient follow-up. At the Mount Sinai CCOP, the 1997-98 budget (3.5 full time equivalents, \$180,000) is

expected to cover enrollment of 75 new treatment patients (100 credits); however, the CCOP is also following 400 patients on adjuvant trials. Income from the pharmaceutical industry-sponsored studies being conducted at the CCOP is in fact subsidizing almost in full the costs associated with the NCI-sponsored trials. Remaining CCOP costs are covered by the Medical Center and philanthropic gifts.

- National statistics indicate that the average annual salary for oncologists is \$175,000. Considering that most physicians work approximately 310 days per year, 10-12 hours per day, their hourly wage is less than that of their office managers. In addition, time is spent away from family at professional meetings. It should also be noted that participation in Federally-sponsored meetings may not cover the costs (e.g., travel expenses, slides) associated with attendance, unlike participation in industry-sponsored meetings. However, most oncologists continue to participate in clinical research because of the professional satisfaction it brings.
- The requirement to recruit a specified percentage of minorities to clinical trials has no scientific basis. It has not been proven that minorities, as currently defined, have cancers that behave differently than those of the majority population. It is more costly to recruit these populations, and the study data may have insufficient statistical power to support conclusions. The current requirement does not take into account important socioeconomic factors that have far more impact on health than race/ethnicity; in addition, the requirement does not acknowledge the difficulties in categorizing self-identified multiracial/multicultural individuals.
- The special populations of particular interest in Dade and Broward Counties, Florida, because of their greater numbers (compared with state and national percentages) include Hispanics and the elderly; the CCOP has been quite successful in recruiting these populations to trials, though the reasons underlying this success are unclear. It is noteworthy that efforts to recruit minorities have also resulted in an increase in accruals overall.

Additional Research Needs and Other Recommendations

- The American College of Surgeons has mandated that two to four percent of all new cancer cases be entered onto research protocols. HMOs and other managed care plans could be required by Federal or state mandate to enter a specified percentage of new cancer cases onto NCI-approved protocols. Such a mandate, which should be enforceable, could also include an informed consent provision that would enable the cancer center to conduct appropriate tests and refer the patient to the center and protocol best able to meet his or her needs.

MONTANA CANCER CONSORTIUM—Dr. Neel Hammond

Background

Over the past 20 years, the Montana CCOP, currently made up of three major clinical facilities and seven additional affiliates, has accrued about 2,500 patients to NCI-approved clinical trials. Some 830 trial participants are currently being followed. All 22 medical oncologists in the state participate in the CCOP, which is managed centrally from Billings. The CCOP's goals for the current grant period were to increase accrual onto NCI-approved studies, to improve knowledge diffusion in a remote area, to increase the availability of studies to physicians practicing oncology in this remote area, and to consolidate both data management and institutional review board (IRBs) activities.

Montana's geography is unique; a population of just over 850,000 people is spread over 145,000 square miles, and the weather and terrain are highly unpredictable. The Native American population is reservation-based, and has significantly different lifestyle and access to care issues than many other Native American populations.

Key Points

- Relative to the CCOP's goals, its most impressive achievement has been in accrual to cancer control studies, particularly the Breast Cancer Prevention Trial (BCPT) and the Prostate Cancer Prevention Trial (PCPT). The more than 200 participants in these studies form a nidus for future prevention trials in the region. From 1996-1997, the CCOP accrued 137 credits to these trials, with a dropout rate on the BCPT that is among the lowest in the country. However, only two men were accrued to the PCPT from the Reservation. The Indian Health Service was notably nonsupportive in the accrual effort.
- The CCOP holds twice-yearly oncology conferences and has both telemedicine tumor boards and tumor boards established in all of the major villages. IRB-approved priority lists are delivered every two to four weeks to all outlying participating physicians.
- Data management centralization in Billings has enhanced data quality. In addition, consolidating the IRB in Billings has provided greater access to legal, social worker, and professional support, and has allowed the IRB to have both regionally and ethnically diverse members.
- Breast cancer is only one quarter as prevalent among Native Americans as it is on average nationwide, but five year survival is 50 percent or less, compared with 62.5 percent among African Americans and 75 percent among Caucasians. Native American women with breast cancer are almost invariably diagnosed with late-stage disease.
- A locally famous Native American woman has been instrumental in increasing trust and participation in the CCOP's breast screening program. As a result, the clinics are now full, and for the first time, several stage one breast cancers have been detected.
- At the same time, it must be recognized that the medical plight of Native Americans on Montana's Cheyenne and Crow reservations is extreme. These maternally-directed reservation cultures are devastated by alcohol, domestic violence, lack of domestic structure, and a seeking of immediate gratification in a disinherited population. The medical providers are all white male physicians, whom the population does not trust. A survey of Native American women on the Crow reservation showed that 99.4 percent did not want to be examined by a white male doctor. Only half of the reservation population has a high school education; the survey indicated that most did not understand what is meant by "a painless lump" and most were unaware that the Indian Health Service (IHS) provided free mammograms. Most communications about health-related information are by word of mouth.
- In the past, NCI's funding to Native American populations has not been based on need. Native American populations differ substantially, and this must be recognized. Cultural differences among tribal nations are also significant; educational materials must be developed for each distinct culture.
- Similarly, rural populations have unique access and quality of care issues. Trying to maintain quality in outlying areas is difficult, and patients in the region do not travel to major metropolitan centers for care no matter how sick they are.

- The diffusion of medical knowledge into Montana is slower than it is into New York, California, or other more populous and accessible states. This is aptly illustrated by Montana's lumpectomy rates for breast cancer; statewide, the rate is 28 percent, compared with 45-50 percent for all National Surgical Adjuvant Breast and Bowel Project (NSABP) participating states and 87 percent in Pittsburgh. Rural women in Montana would rather have a mastectomy than a lumpectomy and radiation if the latter entails traveling 200 miles for the radiotherapy. Similarly, ductal carcinoma in situ (DCIS) incidence, an indirect measure of mammographic efficiency, is lower in Montana than NSABP-wide.
- Providing hospice care in Montana's remote rural setting also presents problems, and there is no hospice funding for the reservation Native American population or for veterans. It must also be recognized that it costs more to provide hospice services in rural settings.
- Unlike many other health services in Montana, radiation facilities are abundant, but their quality is questionable in some cases. Guidelines are needed to ensure adequate quality of these and other services.
- Managed care provides a unique threat in the rural environment; rural residents are very likely to be intimidated by managed care practitioners from major urban centers.

Additional Research Needed and Other Recommendations

- It is important that NCI distinguish between needy and non-needy minorities in its funding decisions and know where the money is going, especially in rural areas.
- Federal agencies including the Veterans Administration (VA) and IHS, should be supportive of NCI and NIH clinical research activities.
- To help involve rural residents in clinical trials, hospitals that support rural clinics should themselves be supported. Rural residents will not travel to Billings to see a medical oncologist and the cost of having the physician travel to the outlying areas is prohibitive.
- Managed care organization should be required to accommodate Montana's unique population and geographic requirements.
- Special efforts should be made to recruit and encourage female and minority physicians, particularly in organizations such as the IHS.

LOUISIANA STATE UNIVERSITY MEDICAL CENTER—Dr. Robert Veith

Background

The Louisiana State University (LSU) Medical Center Minority-based CCOP (MBCCOP) has been operational for three years. Its mission is to enhance cancer control in minority and underserved populations. The Stanley Scott Cancer Center at LSU has participated in the Southwest Oncology Group (SWOG) since 1965, in the Pediatric Oncology Group (POG) since 1980, and in the NSABP since 1974. The population served by the CCOP numbers 2.5 million, of whom about 35 percent are African American. Both community and university-based physicians participate in the CCOP.

To date, the CCOP has had more success in recruiting minority subjects for treatment trials than for prevention trials. Recruitment to the PCPT has occurred largely among the Caucasian population, because recruitment was tied strongly to existing prostate screening programs that were concentrated in areas with small minority populations.

Key Points

- To help identify areas for improvement in prevention clinical trials recruitment, the CCOP conducted two surveys of its cancer epidemiology group. One survey included 62 African

American patients (55 percent female) being treated in the Medicine Clinic at Charity Hospital for a variety of conditions. The second survey included 31 medical residents, of whom 23 percent were minorities; its purpose was to better understand the attitudes and beliefs of primary care physicians about cancer prevention trials. The residents perceived that getting to and from the clinic and taking time off from work were substantial barriers to patient participation. Patients did not indicate that these were significant problem areas, but it was recognized that the survey population may differ in its perceptions from a population not already being treated for a medical problem. Patients ranked altruistic reasons (e.g., helping community, mankind, children, and family) as strong motivators for participating in a trial.

- Residents indicated universally that lack of knowledge about available clinical trials was a major barrier to referral, pointing to the need for a major educational effort by the CCOP.
- At the beginning of its effort to recruit patients for the PCPT, the CCOP conducted a telephone survey of 300 lower income men aged 25-65 years in the New Orleans area; 60 percent were African American and none had a history of cancer. The purpose of the survey was to determine the sources from which these men sought out cancer-related
- information. Though no strong trends emerged, the African Americans indicated a greater reliance on television for this information that did not vary greatly with income level. The Caucasian men surveyed indicated a slightly greater reliance on print media compared with the African American men, and this preference increased with income (a possible surrogate measure of educational attainment).
- At a recent conference on recruiting minorities to cancer prevention and treatment trials, it was suggested that radio can be an effective tool for reaching African American urban populations; in particular, radio spots aired during the late night and early morning hours can be especially effective in reaching older African American men.
- Recruitment for prevention trials is more difficult because people who are not ill are being asked to interface with the medical system and alter their daily routine. It must be recognized that these recruitment efforts take time.

SAN JUAN CITY HOSPITAL—Dr. Luis Baez

Background

The San Juan Minority-based CCOP includes six participating institutions. The largest of these, San Juan City Hospital serves a population of 450,000, of whom 80 percent are medically indigent. Cancer is the second leading cause of death. Primary care is provided at Centers for Disease and Treatment that are distributed throughout the service area. Combined, the six CCOP facilities treat 25-30 percent of the cancer cases on the island of Puerto Rico. The relatively small number of patients who have medical insurance are likely to travel to the U.S. to receive treatment at one of the major cancer centers in Florida. For the remainder, the CCOP represents the only source of state-of-the-art cancer care.

Key Points

- Participation in the MBCCOP has provided several benefits. It has been possible to conduct pilot studies to improve management of cancer pain, laboratory evaluations and pathology reports have been improved, surgical and oncologic reporting has become more specific, a multidisciplinary approach to care has been adopted, and professional education opportunities have been expanded.

- Barriers to the success of the MBCCOP include those related to socioeconomic factors, ethnic/language differences, data management issues, administration, protocol availability, pharmacy limitations, physician issues, grant funding constraints, and the Puerto Rico health care reform effort. Perhaps the most problematic of these is the demand for cost-neutral studies. Demonstrating cost neutrality is difficult because no firmly established standards of care exist for activities such as staging studies and follow-up.
- Socioeconomic challenges derive from the limited state funding available to care for a large low income population, the limited educational level of most patients, the high percentage of single parent families, and poor telephone communications complicated by a highly mobile population within San Juan.
- Language and ethnic barriers, including the prevalence of different dialects, have made it difficult to use quality of life assessment instruments or existing educational materials.
- IRB issues are a major challenge. Currently, the CCOP must work with four IRBs; the result is nearly overwhelming paperwork, increased data management time, and delayed trial activation. For each protocol, eight informed consent forms must be approved; this is multiplied by the number of amendments to any given protocol. Informed consents are also needed in both Spanish and English.
- Pharmacy-related problems relate to use of non-formulary drugs, limited pharmacist and pharmacy technician manpower, storage issues, and most importantly, off-label use of drugs on clinical trials.
- Physicians tend to refer patients to trials late in the course of disease and often only as a last resort. They are not compensated for increased documentation associated with trials, and resent the "fiscalization" and monitoring of their practices associated with managed care. Some community physicians do not strictly follow the trial protocol; patients often have higher morbidity as a result.
- Data managers have difficulty performing their role, since they also serve as patient escorts, and perform scheduling, laboratory, x-ray, pathology, and chart retrieval duties. They are required to cover four hospitals, and their salaries are low.
- Puerto Rico is changing rapidly to a capitated system for providing care to the medically indigent population. The potential impact of this transition has not been adequately assessed and problems are expected.

BAY AREA TUMOR INSTITUTE CCOP—Dr. Jay K. Harness

Background

The Bay Area Tumor Institute (BATI) CCOP serves the Oakland-East Bay area; the population in Oakland, however, has a far higher percentage of minority, lower income, and poor residents than San Francisco or the State of California. African Americans comprise the largest racial/ethnic poverty group. One quarter of the Alameda County population is non-English speaking. Ninety percent of the CCOP's treatment trial accruals come from the Oakland area's minority, female, pediatric, or indigent populations.

Key Points

- The uninsured now number approximately 41 million in the United States, and should be considered a special population. It is somewhat shocking that 40 percent of working Americans are uninsured. Not surprisingly, a recent study from the Department of Health and Human Services demonstrates that the percentage of people who are insured rises as earnings rise.

- The public hospital sector cares for most of the uninsured in the United States; this is particularly true in urban areas. While community need and demand for services from public hospitals is rising, state and Federal dollars supporting these facilities are shrinking. As a result, care is being rationed in the public sector today.
- The private sector and managed care companies are competing for paying patients, including Medicaid patients, but no one is competing to provide care to the uninsured. Public sector hospitals need these Medicaid dollars to provide care to the uninsured.
- The number of new cancer patients seen annually at the Alameda County Medical Center, which serves a large poor and African American population, half of whom are uninsured, has doubled over the past ten years. These patients present with more unstaged and distant disease, less regional and localized disease, and have a 20 percent poorer five year survival rates compared with patients at other facilities in the county.

Additional Research Needed and Other Recommendations

- The social, economic, cultural, educational, and institutional barriers to cancer care for special populations are real and require attention. In particular, the Panel should bring the issues of the uninsured to the attention of the President.
- The loss of Medicaid dollars to private sector providers is crippling the ability of public hospitals to provide care to the uninsured, particularly as it is coupled with the loss of other state and Federal funding. NCI should directly support the public hospital sector cancer programs.
- The NCI should support innovative approaches to cancer control for the uninsured. The multidisciplinary, collaborative, and comprehensive approach used in breast cancer control in the private and university sectors can and should be adopted in the public sector. It can be applied to all cancer sites. This model also can be used to provide cancer control for special populations, focusing on patient education, screening of asymptomatic individuals, early and rapid diagnosis, prompt initiation of treatment, and retaining patients in treatment. In addition, supportive and long-term follow-up services are needed for these populations.

SOUTH TEXAS PEDIATRIC MINORITY-BASED CCOP—Dr. Javier Kane

Background

The South Texas area covers about 65,000 square miles inhabited by some 3.5 million people in 46 counties. None of the 41 counties in the western area has a population of more than 100,000, but population in this area is growing rapidly due to high birth rates and immigration. It is estimated that the lower Rio Grande Valley population will reach 2.5 million by the year 2025. The population in South Texas has just over one million people under age 18 years; this is the population served by the pediatric minority-based CCOP. There are an average of 141 cases of childhood cancer per year.

The South Texas area is considered medically underserved and a health professional shortage area; with 149 physicians per 100,000 population, compared with 173 per 100,000 in Texas overall, and 210 per 100,000 in the U.S.

South Texas has a large Hispanic population that derives from or has close ties with Mexico. The total population is about 60 percent Hispanic, but is up to 95 percent Hispanic in the border towns. Thirty percent of the population identifies Spanish as their primary language. While some of the population has been in the area for multiple generations, there

are also many recent immigrants. It is not uncommon for one parent and some children to be U.S. citizens, while the other parent and other children in the family are Mexican citizens. Families tend to be large, extended, and predominantly Roman Catholic.

Levels of acculturation vary widely. Literacy rates are low, while poverty levels are high. Parts of the population adhere to a migrant work lifestyle and folk concepts of health and disease, which complicates the provision of health care. In addition, patients must travel long distances to access pediatric oncology services, and transportation can be unreliable. Provision of care is also complicated by increased surveillance of this population by the Immigration and Naturalization Service (INS).

The overall goal of the minority-based CCOP is to reduce the incidence, morbidity, and mortality of cancer in the pediatric, primarily Mexican American, age group, and to accomplish this principally by enrolling patients in cancer prevention, cancer control, and cancer treatment protocols of the POG. The MBCCOP institutions care for about 75 percent of all pediatric cancer patients in the region. Of all patients enrolled in treatment protocols at the MBCCOP institutions, 87 percent are minorities (74 percent Hispanic, 13 percent African American).

Key Points

- The minority-based CCOP supports a clinical research office, data managers, expanded services to rural areas, clinics in medically underserved areas, continuing medical education for primary care physicians on the diagnosis and supportive care of children with cancer, and maintenance of a research-based affiliation with the POG.
- The pediatric oncologists in the area are located in San Antonio and Corpus Christi; patients in the smaller cities are reached through outreach clinics.
- Acute lymphoblastic leukemia (ALL) and relapsed ALL are the most common pediatric cancers treated in the MBCCOP. For all cancers combined, 80-90 percent of eligible patients are enrolled in clinical protocols.
- Historically, it has been difficult to obtain cancer control credits in pediatrics, since primary prevention of childhood cancer is limited in scope, incidence of many cancers is low, and identifiable risk factors are lacking. Recently, however, several secondary prevention and related prevention protocols have been activated.

Additional Research Needs and Other Recommendations

- Minority populations can be enrolled onto treatment and cancer control research protocols, but MBCCOP support is essential. Enrolling these populations requires extra coordinating efforts, and these efforts require funds.
- Additional emphasis on secondary prevention, cancer control, and minority affairs is needed.

KINGS COUNTY MINORITY-BASED CCOP—Dr. Constantin Rosenthal

Background

The Kings County MBCCOP serves the 2.5 million residents who reside on the 500 square mile borough of Brooklyn, New York. The population is approximately half Caucasian; the principal minority groups are African Americans and Hispanics. Median level of educational attainment approximates the national level, but the percent living in poverty is twice the national average. The percent elderly is slightly higher than the national average.

Like many minority and low income populations, the residents of Brooklyn tend to be diagnosed with cancer at later stages of disease. Where screening programs exist, earlier detection has been possible. The African American population has higher than average rates of multiple myeloma and cancers of the esophagus, prostate, cervix, and stomach. Kings County is medically underserved, with approximately 40-45 physicians per 100,000 population.

Key Points

- The rapid and aggressive development of managed care organizations has had a negative impact on the MBCCOP participating hospitals and has resulted in a shift to outpatient cancer care. To maintain accrual of managed care patients, the CCOP has attempted to establish agreements with the managed care organizations; it has been successful in doing so only with the Health Insurance Plan of New York (HIP), a large, not-for-profit plan.
- In addition to the NCI CCOP grant, support has been received from the nonprofit university hospital. This latter support, however, first declined and will now be terminated, due to reduced institutional income driven by the increasing market share of for-profit managed care organizations. The for-profit plans have been uninterested in collaboration with the CCOP.
- To help increase accruals, the CCOP has distributed informational pamphlets to physicians and the community, published a quarterly newsletter, and employed both radio and newspapers to disseminate screening information. In addition, the CCOP has assembled a team of survivors to help in recruiting new patients.
- Up to 40 percent of patients in clinical trials are lost to follow-up; lack of transportation and telephone communication, both linked to income level, are major contributors to this problem.

Additional Research Needs and Other Recommendations

- For-profit managed care operates to the detriment of cancer care for minorities; these plans should be required to participate in clinical research activities as a condition of operation.
- Grant funding should provide for transportation and related services needed by minority populations to enable them to participate in follow-up.
- For cancers in which there is no standard treatment and high mortality, Phase III studies should be incorporated into existing treatment regimens.
- A public relations campaign on clinical trials is needed to inform the public and enable the CCOP and other investigators to compete with managed care companies for patient enrollment.

DISCUSSION—Drs. Davila, Hammond, Veith, Baez, Harness, Kane, and Rosenthal

Key Points

- It is difficult to get consumer input or involve consumers in outreach activities in the smaller villages in Montana. Though IRB representatives distribute informational materials, many communities do not have newspapers. Outreach clinics distribute protocol booklets, and patient education sessions are held. Direct consumer involvement (e.g., a cancer survivor from a particular tribe or community providing information to the community) is possible in some of the larger communities, but small numbers make this impractical in the more remote areas.

- Dr. Kane suggested that the high level of accrual of pediatric patients, including minority patients, to clinical trials is the result of excellent organization and communication in the pediatric oncology groups. This organization has developed out of necessity; there is only one pediatric patient for every 150 adults with cancer, and institutions have needed to collaborate to ensure that enough patients are accrued to conduct meaningful research. The transferability of this model to adult patients should be explored.
- The MBCCOP support in Texas is necessary to enable outreach to remote areas, some of which can only be reached by air.
- In Montana, smoking prevalence is high, though not tied to cultural or religious ceremonies. A recent survey of reservation Native Americans indicated that more than 40 percent of the women surveyed used smokeless tobacco.
- Dr. Davila reiterated his view that the term "minority" is political and is being inappropriately applied to science. In doing so, the purity of science is being sacrificed. We do not know if the Federally-defined minorities should be applied to science, or if cancer incidence, etiology, or response to treatment differ at all between these groups. Moreover, far more data support the importance of socioeconomic rather than racial factors in cancer outcome. However, these factors are frequently linked; without correcting for socioeconomic factors, it is probably meaningless to apply racial categories in science. It was suggested that if studies are to be conducted to identify racial factors, if any, distinct from environmental or sociologic factors, such studies should involve only individuals whose known heritage is one third or more the minority group of interest. In addition, the possibility of important variations within the white population is seldom explored. Within Federally-defined minority/ethnic groups, differences in living circumstances and migration may be far more important than ethnicity. It was also noted that individuals can and do elect to change their Federally-defined racial/ethnic designation; studies to date have not attempted to control for this reality.
- Studies of minorities should first correct for socioeconomic factors. Recent immigrants should be studied separately as a severely disadvantaged group. Cultural aspects, particularly nutritional factors, may also be of significance in epidemiologic studies.
- Dr. Kane maintained that genetic racial differences may exist and should be explored if they appear to influence response to cancer treatment or disease risk. He believes data on different responses to methotrexate among white and black children with ALL illustrates this possibility. He agreed that social, cultural, and economic characteristics of a population are also important.
- Participants acknowledged that while the CCOPs count minority participation in accruals to comply with Federal requirements for funding, it is unclear if this is of scientific value. It does seem to be true, however, that designation of a group for emphasis leads to greater funding, which permits more outreach and more access for previously underserved populations.
- Though no one in Puerto Rico is denied access to health care because of lack of insurance, the state-sponsored system for the uninsured is underfunded and understaffed, resulting in a dual standard of care. It has a fixed annual budget which has to cover all care; funds for certain procedures may be exhausted before the middle of the calendar year.
- Managed care competition for Medicaid patients is diverting funds from public sector providers that need these funds to provide care to the uninsured. The loss of these funds has a particular impact on access to cancer care, which tends to be expensive.

PRESENTATION HIGHLIGHTS: An Advocacy Voice

COALITION OF HISPANIC AND HEALTH AND HUMAN SERVICE ORGANIZATIONS—

Dr. Deborah Duran

Background

The Coalition of Hispanic and Health and Human Service Organizations works with community-based organizations across the country; it does not accept either tobacco or alcohol industry funding.

The Hispanic population in the United States is the fastest growing population group. It is highly heterogeneous, and relatively young (average age 26.4 years). Two-fifths report that they do not speak English well.

Key Points

- Advocacy is needed by and for specific populations. Until they are afforded the same data coverage, the same quality of cancer care, the same opportunity to experience quality of life with and after a cancer diagnosis, and until language differences and cultural meanings of illness are integrated into programs, research projects and treatments (instead of as add-ons or dismissed as unimportant), advocacy will be needed to secure designated funding for these populations.
- Overall funding for health care and research should be increased, but it should not occur without concomitant increases in funding for special populations, for whom a disparity of data, care, and quality of life persists. If increased funding does not also occur for special population programs, these groups will remain invisible, and will continue to have limited tools and resources to fight cancer as a disease, or to fight disparities in research and health care systems.
- Only those who have not experienced discrimination and bias would negate the need for targeted cancer funds for special populations. If a special population representative is not at the decision making table, their issues are not included in funding or study design decisions. What comes out of a meeting depends on who is invited to participate.
- It is less important to know whether or not biological race exists; it is more important that there are racial disparities in treatment, care, and the collection of data.
- Hispanic populations have many of the high risk behaviors and characteristics (e.g., tobacco and alcohol use; different diets; low levels of exercise; low education, screening, SES, and insurance levels) associated with higher cancer rates. Yet Hispanics overall have low incidence rates for most cancers, and low mortality in general. Their cancer survival rates, however, are relatively low.
- In 20 years the rapidly growing Hispanic population will reach the ages at which cancer incidence escalates; an epidemic of cancer in this population may be the result and we must be prepared.
- Currently, only 50 percent of Hispanic children complete high school. Because of lower educational levels, Hispanics are concentrated in lower income occupations; however, Hispanics earn less at every educational level than the general population. In addition, Hispanics tend to be in jobs that do not offer health insurance benefits; at least one third of working, documented Hispanics have no health insurance.
- Hispanics visit the doctor less than the average. Since 81 percent report a preference for speaking Spanish, a lack of Spanish-speaking providers may be a cultural barrier to care.

- Cancer data on the Hispanic population is badly lacking. As a result, important questions about cancer prevention, intervention, treatment, and genetic differences cannot be answered either for Hispanic subgroups or the Hispanic population as a whole. The Surveillance, Epidemiology, and End Results (SEER) program did not begin collecting data on Hispanics until 1992, thus no trend data exist at this time. The Centers for Disease Control and Prevention (CDC) registries are relatively new, and have a distinct set of problems. In addition, the population growth denominators from the Census Bureau are problematic. In research studies, sample sizes of Hispanics are so small that conclusions cannot be drawn from the data.
- The National Hispanic Leadership Initiative on Cancer (NHLIC) began a focus on population-specific studies, but its funding has been cut. The only current national study on Hispanic women with breast cancer (sponsored by UNIDOS) has identified important differences in patterns of follow-up care, number of procedures and elapsed time to diagnostic completion, barriers to care, and treatment options offered. The five most frequently cited barriers to health care were: cost, long waits in medical offices, inconvenient hours, long waits for appointments, and long distances to travel for care. Of the 98 percent of women studied for whom surgery was recommended, 66 percent received radical mastectomy; 59 percent indicated that they were not given a choice on type of surgery.

Additional Research Needs and Other Recommendations

- Population-specific studies are needed, and Hispanics should also be included in all national studies.
- Extramural programs that include community-based research collaborations should be supported, since community-based organizations can best assess population needs and facilitate communication of research findings to Hispanic communities.
- Culturally competent cancer education, outreach, prevention, and screening programs should be fostered. Tailored community messages enhance the likelihood of behavior change.
- The Department of Health and Human Services' (DHHS) Hispanic Agenda and Office of Management and Budget (OMB) Directive 15 should be more fully implemented. More Hispanic professional and scientific staff are needed; the development of Hispanic researchers and scientific professionals should be fostered. Hispanics currently are underrepresented in these areas.

NATIONAL OVARIAN CANCER COALITION—Ms. Susan Wallace

Background

The National Ovarian Cancer Coalition (NOCC) is a grassroots effort envisioned and created by Gail Hayward, an ovarian cancer survivor, approximately one year ago. Its mission is to raise awareness about the disease, and to promote education for health professionals and the public on the facts and issues of ovarian cancer. The Coalition hopes to reduce morbidity from the disease. It operates a toll-free information line and a Web site. Volunteers distribute educational brochures and symptom cards.

A related organization, the Ovarian Cancer National Alliance, has as its mission to unite organizations and individuals to fight to overcome ovarian cancer. Based in Washington, D.C., its goals are communication and coordination of local, state, and national efforts, with an emphasis on public policy development and strategy, education of women and

health care providers, and increasing research attention to ovarian cancer. The Alliance now acts as an umbrella organization for a wide variety of support organizations for ovarian cancer. One of the Alliance's board members was recently chosen to participate in NCI's consumer liaison group.

The main goal of the NOCC and the Alliance is to save women's lives.

Key Points

- Ovarian cancer is the fifth leading cause of cancer death among women, and the deadliest of the gynecologic cancers. More than 50 percent of women diagnosed die within five years because 70 percent of cases are not diagnosed until they are advanced and incurable. In these advanced cases, the fatality rate is 80 percent. However, when diagnosed at stage 1 (less than 25 percent of cases), the five year survival rate is over 90 percent.
- Ninety percent of women who have had surgery for early stage ovarian cancer did not have tissue samples taken throughout the abdominal cavity to determine if the disease had spread. The knowledge gained from these biopsies can mean the difference between life and death. In addition, women whose initial surgery was performed by a gynecologic oncologist have been demonstrated to have longer survival; unfortunately, most women do not know these specialists exist.
- Awareness of ovarian cancer in the medical community is extremely limited. Because it affects only one in 55 women by age 60 years, it is not on the screening list of many obstetricians, gynecologists, internists, or family physicians. Symptoms can be vague (e.g., bloating, abdominal discomfort, menstrual problems, fatigue, painful intercourse, constipation); many women are told their symptoms are common to middle age or are referred to gastroenterologists while their ovarian cancer continues to advance.
- Another reason for the low five year survival rate for this disease is that middle aged and older women, who are at greatest risk, are relatively unaware of the disease. Even those with more explicit risk factors (e.g., women without children, those with a family history of breast, ovarian, or colon cancer) are not alert to the disease.
- The imperfect status of diagnostic tools for ovarian cancer and the lack of cost effective, simple, and reliable screening methods is the third problem that dooms so many women to late stage diagnosis. The CA-125 blood test for ovarian cancer has limited sensitivity.

Additional Research Needs and Other Recommendations

- Dramatically expanded awareness of ovarian cancer and resources devoted to improving early detection are urgently needed. A screening test with better sensitivity than the existing CA-125 test must be developed. The lower incidence of ovarian cancer relative to breast or cervical cancer is no excuse to delay developing a reliable screening test that will prevent thousands of women from dying.
- Vital research on ovarian cancer is taking place and has resulted in treatment improvements, but far more research is needed. Research funding for ovarian cancer should be increased in both the public and private sectors; research is needed on all aspects of the disease, including psychosocial issues.
- Challenges in the fight against ovarian cancer are to provide greater public and professional education, and to ensure that women are aware of the availability of CA-125 and transvaginal ultrasound, and the need for an annual bimanual rectovaginal pelvic examination. Further, better access to clinical trials is needed, and the trials need to be made understandable to patients.

- Ovarian cancer screening should be piggybacked onto breast and cervical cancer screening schedules, since women have become accustomed to receiving these tests.
- Medical school curricula should include more in-depth education on ovarian cancer.
- A Federal information program on ovarian cancer is needed to disseminate prevention, detection, and treatment information.

NATIONAL PROSTATE CANCER COALITION—Mr. Robert Samuels

Background

The National Prostate Cancer Coalition was formed in 1996 in recognition of the need for a unified voice to the Nation on the issues of prostate cancer. Made up of organizations both specifically and more broadly related to fighting prostate cancer, the Coalition's mission is the elimination of the disease as a serious concern for men and their families.

In 1997, 209,000 men will be diagnosed with prostate cancer, and 41,800 men will die from the disease; this means that a man is diagnosed with prostate cancer approximately every 2.5 minutes, and a man dies from prostate cancer every 12.5 minutes.

Key Points

- Prostate cancer accounts for 25 percent of all non-skin cancer cases annually, yet only 3.5 percent of cancer research funding is devoted to prostate cancer research.
- Prostate cancer has a particularly severe impact on minority populations. African Americans have the highest prostate cancer rates in the world; some 66 percent higher for African American men compared with white men. African American men die of prostate cancer at twice the rate of white males. African American men are often diagnosed at later stages of disease, but research is needed to identify other factors contributing to these disparities.
- Twenty percent of new prostate cancer cases are now diagnosed in men under age 65, dispelling the myth that this is an old man's disease. However, our ability to diagnose the disease has outpaced our ability to treat it. Earlier diagnosis in men at the peak of their professional and earning capacities also has serious economic implications.

Additional Research Needs and Other Recommendations

- The national financial commitment to AIDS research has made a major difference in the lives of those affected by that disease. A similar all-out attack on prostate cancer is needed. Research priorities in five major areas have been identified:
 - Identifying the causes of prostate cancer and its progression
 - Predicting the stages of prostate cancer
 - Eliminating the pain associated with prostate cancer
 - Determining the risk of recurrence
 - Determining why men under age 65 years are increasingly at risk for prostate cancer
- Addressing these research needs requires at least an additional \$250 million annually. The Federal government must play a more aggressive role in prostate cancer research funding.
- A more accurate and useful diagnostic test is needed for prostate cancer. In addition, a test is needed to identify which prostate cancers are aggressive and which are not.
- Early detection must be accompanied by treatment advances and assurance of access to competent therapy.

- In the African American community, research is needed to determine if prostate cancer differs biologically by race; what factors are hindering early detection and the delivery of adequate therapy for black men; and what cultural, economic, or other issues impact the development of an African American patient support system.
- The research funding pie is too small. Rather than divert resources from other diseases, the relative funding levels of defense and cancer should be re-examined. While we should not weaken our national defenses, arguably, the real war is against cancer. If we expect to prevail in that war, we must commit sufficient resources to it.

PATIENT ADVOCATE FOUNDATION—Ms. Nancy Davenport-Ennis

Background

The Patient Advocate Foundation assists cancer patients nationwide in the areas of managed care interface, legal support, and access to and funding for care. Patients are referred to the Foundation by cancer centers, research facilities, and national voluntary health agencies that have exhausted all avenues available to them to assist the patient.

Key Points

- Americans previously accustomed to indemnity insurance with major medical benefits are struggling to transition to managed systems of health care. Competent individuals, corporations, providers, policy makers, medical device, and pharmaceutical entities are increasingly confused by the requirement to conform to ever-changing sets of rules which they have not endorsed.
- The drive to contain health care costs has resulted in health care that serves fewer citizens and is delivered by less qualified medical personnel. Medical decisions are being made by computer specialists at managed care organizations rather than by the physician in consultation with the patient. Patients and providers are weary—their energies are no longer directed at battling disease; instead, they are expended in negotiations with providers for access to and funding for cancer care as prescribed by the treating physician.
- Physicians are demoralized by the closing of hospitals that cared for the underserved and, enforced by the threat of being deleted from the approved list of providers, by restrictions on the treatment options that can be offered to patients. Likewise, primary care physicians are reluctant to make referrals to specialists, since they are at direct financial risk for the cost of the referral, or subject to practice profiling that may have an impact on an end-of-year bonus. Capitation rates create even more restricted access to care.
- Clinical trials funding is threatening our Nation's leadership in health care. Cutbacks in hospital reimbursements have resulted in data collection cutbacks; thus, we are making patient management decisions based on less data. In addition, fewer patients are being enrolled on clinical trials, as fewer insurers are willing to participate in the costs. Patients are at risk of losing access to evolving therapies, while physician practices, hospitals, and research centers are at risk of closing. Many major pharmaceutical companies have chosen to conduct new drug trials in other countries.
- The Foundation's experience suggests that health plans are inconsistent in their interpretation of what constitutes investigational or experimental therapy; moreover, there often is inconsistency in coverage within a given plan.
- Every American diagnosed with cancer becomes a member of a special population. The insured are endangered by a lack of minimum standards for insurance coverage, the lack of an expedited appeals process, lack of or poor adherence to quality performance or

standards, and limited input in selection of physician, hospital and/or protocol for care. Special populations defined by age, socioeconomic, or ethnic factors share these concerns. Insured population concerns also include a lack of preventive care.

- The uninsured face delay in receiving acute care; 40 million, though employed, lack health coverage. The uninsured population also faces delays in support from medical public assistance, and delays and denials in obtaining Social Security and other benefits. As they struggle with these problems, their cancer is progressing.
- Senior citizens have cancer rates in excess of rates in the general population. The Medicare population is burdened by reimbursement reductions within the Medicare system. Physicians are restricted in the treatment options they can offer, and there are financial incentives to undertreat the elderly. This population is especially stressed by disruptions in continuity of care, particularly in the face of severe illness. Home health care funding is lacking. The elderly also are facing increasing copayments and deductibles, while living on fixed incomes. Transportation is a key issue for this population.
- Medicaid provides medical care coverage for more than 35 million Americans; of these, 10 million are enrolled in Medicaid managed care. Low income working adults do not qualify for Medicaid; they are the population that “falls through the cracks” if a serious illness occurs in the family. Medicaid eligibility requirements are rigid, and the enrollment process is extremely slow. Lower provider reimbursements for Medicaid patients cause these patients to be shifted to public hospitals, but these facilities are closing. The shift to Medicaid managed care means greater variation in coverage across this population.
- Delayed decisionmaking by insurers can lead to emotional and psychological distress, disfigurement, or death for patients. Insurers deny care prescribed by the physician, or refer the patient to a distant location, effectively deterring many from accessing needed services. Referral to specialists is restricted by gatekeepers, and there is no universal, consistent and timely appeals process for coverage decisions. Policy language describing benefits, exclusions, restrictions, and financial responsibility is confusing. Terms such as experimental, medically necessary, investigational, adequate, and peer review—pivotal terms in decisions made by insurers—are defined inconsistently.
- New technology assessment processes also vary and contribute to uneven access to innovative therapies.
- By the year 2000, one in 900 adults in the U.S. will be a survivor of a childhood cancer. The mean annual out-of-pocket cost of having a child with cancer now represents 52.4 percent of gross family income. Families are told that the only way their child can receive needed medical care through Medicaid is for the child to become a ward of the state; we must find a better solution than this.
- Children with cancer need access to psychological counseling. As they mature, they need information about possible late effects of their childhood cancer treatment. They also need assistance in securing health and life insurance.
- Among Hispanic Americans, 54 percent have no insurance, 32.6 percent of those employed have no insurance, and only 17 percent receive Medicaid health services.
- Employer-sponsored, or employer self-funded ERISA health plans are subject to little Federal regulation, and are immune from state regulation. In some cases, different categories of employees are offered varying levels of coverage. Appeals processes and utilization review may be particularly arbitrary or uneven.

Additional Research Needs and Other Recommendations

- Specific standards for health plan and technology evaluation processes are needed. Legislation recently passed in Maryland may serve as a useful model.

NATIONAL HOSPICE ORGANIZATION—Mr. John Carney

Background

The mission of the National Hospice Organization (NHO) is to be the voice of dying Americans. NHO is a national organization serving approximately 2,600 hospices across the country. The focus of hospice is on care rather than cure. Annually, one-half million Americans receive hospice care; about 80 percent have cancer. Thus, hospice providers care for nearly half of all Americans who die annually from cancer.

Most hospice care is provided in the patient's home; about 90 percent of hospice patients die at home. However, 60 percent of all Americans die in the hospital, most without benefit of hospice services.

In 1983, Congress adopted a benefit allowing a Medicare patient to elect hospice care for a terminal disease, in effect disenrolling from traditional Medicare for care for that terminal disease. However, regular Medicare part A coverage remains in force for treatment of other conditions. This hospice benefit provides payment for items not normally covered under Medicare, including palliative and comfort measures, supplies, and equipment. Payment under this benefit is prospective, and averages about \$100 per day. This covers all needed services at virtually no cost to the patient. The eligibility period is up to six months, however, the median length of stay for hospice patients is currently 36 days, reflecting a pattern of late referral to hospice care.

Key Points

- NHO has been working with the IHS and VA to develop agreements on models for hospice care for their covered populations. Funding mechanisms have yet to be established.
- Though not a research organization, NHO has established medical guidelines for determining prognosis in nine non-cancer diagnoses; these have been adopted by the Health Care Financing Administration (HCFA) for determining hospice eligibility of Medicare patients. Similar guidelines for cancer patient prognosis are under development. Recognizing that prognosis as currently defined by physicians may not be the best way of establishing readiness for hospice care, the NHO has established a Medicare task force to determine how prognosis should be redefined.
- Dying Americans do not want to be abandoned, and they do not want to die in pain. To date, we have not been able to meet these needs. The most comprehensive study of dying Americans, sponsored by the Robert Wood Johnson Foundation, was completed two years ago. A two-phase study conducted over eight years, found that despite a number of interventions with the study population (e.g., discussions with patients about their impending death, intervention of psychiatric nurses with families, discussion with physicians about advanced directives and living wills, additional assistance to patients and families), there was virtually no change in key outcome measures. Forty percent of the patients died in what their family members considered to be intolerable pain. One third spent their entire life savings paying for medical care. One half reported that their physician were not informed nor did the physician report knowing the wishes of the dying patient.

- We lack adequate language about dying in this culture, and we have not rejected the notion that death is a failure of medicine. Death will occur for every person at some point, but we cling to the notion that death is an optional event, and that the primacy of medicine is paramount. We are unable to distinguish between hope and expectation in discussing death with patients and families. We do not understand the importance and dignity of dying and the work that a patient does in the final stages of life.
- While the typical activities or duties of a well person or a sick person are clear to most people, few understand that the duties of a dying person include reconciliation, saying "I love you," and completing one's life story. These tasks take time. We tend to see death as an interruption rather than a completion. We have always viewed illness and death in this country as a disease or biological process rather than as part of a biography. Regardless of the age of the patient, death is still a completing event and families need time to discuss what they need and want relative to this completion.
- When we leave the world, disease is not necessarily the enemy; most of us will need a disease to make our exit. Therefore, while prevention and treatment of disease are important, at the time a patient is dying, the disease is a necessary component of the process.
- The American Medical Association is beginning to recognize and address the need for physicians to understand and develop language about dying.
- In this country, we do not usually view rituals of separation that are (or could be) sacred for most families as being an important health care issue in the final days of life. Honoring and conducting such rituals could be of significant preventive value to the loved ones of the person who dies by enabling them to deal authentically with the death before it occurs.
- For 20 years, hospice has prided itself on being separate and discrete from the medical system, and has not engaged in serious conversations or collaborations with the medical community. NHO now recognizes that to change the way most Americans die, these collaborations and conversations are necessary.
- Mr. Carney's local hospice organization participates in outcomes research in collaboration with the local CCOP, but study patients often do not complete participation in the trial. There is a need to find another model for conducting research on patient outcomes.
- A major challenge for hospice is to become more fully integrated into the health care continuum in this country.

Additional Research Needs and Other Recommendations

- We must teach that it is possible to die well; to be healthy in a terminal status. Accepting this idea would allow critical aspects of preventive care to be provided to family members.
- NHO has identified three key outcomes on which descriptive research in clinical trials is needed: effective grieving, safe and comfortable death, and self-determined life closure.

DISCUSSION—Dr. Duran, Ms. Wallace, Mr. Samuels, Ms. Davenport-Ennis, and Mr. Carney

Key Points

- Cost effectiveness analyses of hospice care may not lend themselves to prospective randomized clinical studies, since patients cannot be randomized to not die. A retrospective study completed in 1995, however, suggests that for every dollar spent by Medicare on care for dying patients, hospice saves \$1.52. The Institute of Medicine had planned a study of futile treatment at the end of life, but did not pursue this part of the study since

acceptable definitions of futile treatment is retrospective determination. Instead the IOM focused on end of life decision making processes.

- An Annenberg Foundation physician education program, Care Beyond Cure, recommends that at the time of diagnosis, the physician should begin discussion about the possibility of dying from the disease. In this way, conversation about dying is begun well before the event is imminent.
- Mr. Carney noted that the research on symptom management conducted to date by hospice organizations has consisted of small, focused studies. These tend to be discounted as anecdotal by insurers. In some areas, such as bereavement care, little data exist to demonstrate what hospice providers know from experience—that family members surviving hospice-involved patients are less sick after the death of the patient, and socialize more quickly after the death of the patient if they have been involved in the patient's care in the home setting prior to death.
- Twenty-eight percent of Medicare dollars are spent in the last year of life. Physicians are trained to prolong life, and families may demand heroic measures, when both may know that the patient cannot be cured and is dying. Physicians and nurses feel compelled to do everything possible for the patients because they have been trained to do so. Hospice maintains that you can always care for the patient, but the focus is on comfort and support rather than cure. One of the biggest fears of patients' and families' is abandonment, including abandonment by their doctor.
- Physicians are only beginning to address the needs of the dying patient and learn to have discussions with patients about death. This includes seeing the patient as a whole (that includes his/her family) rather than focusing only on the disease. These physician education efforts need to be initiated in medical school; we are good at teaching the science of medicine, but do a poor job of teaching the art of the practice of medicine.
- The Hastings Center (New York) in collaboration with the World Health Organization has recently adopted its New Goals of Medicine. One of these goals is the avoidance of premature death and the pursuit of a peaceful death.
- It was suggested that all of the advocacy organizations might be well served to unite under a single umbrella organization with sections devoted to specific diseases, a structure parallel to medical professional organizations. It was noted that this structure does not necessarily foster productive communication or collaboration among physicians (even those treating the same disease); therefore, this may not offer the best model for other, more disparate groups.
- Studies on specific minorities should be designed and funded as such and should be conducted by facilities that can attract those populations. Lumping unrelated or marginally related population groups under the term "minority" results in minority individuals being placed on studies that do not address issues specific to them. In addition, some "minority" programs have been heavily focused on African Americans; the result has been that other population groups are left to fight over an even smaller portion of funds than were allocated. The various groups should be studied individually, so that differences among them—whether genetic, biologic, behavioral, environmental—can be identified, if they exist, and beneficial or protective factors applied to other population groups when possible. More funding, not reallocation of funds, is needed.
- In the same way that Japanese-U.S. migration studies have shown increases in cancer rates within a very few generations to levels found in the U.S. white population, similar studies

of Hispanic populations show that the more Hispanics are acculturated, the more their cancer rates approach those of U.S. whites. Similar trends have been demonstrated for depression rates among Hispanics.

- The most relevant research questions vary among populations; we do not necessarily need to ask every question about every group. It is essential to involve the communities in study design and implementation; the communities know best what are the relevant questions.
- We still have the dilemma that resources are allocated based on racial and ethnic classifications that have been socially and politically determined; they are not based on science or anthropology. Recognizing that there are historic social and economic injustices that require correction, it remains unclear how to obtain scientific truth from studies based on social and political classifications of individuals who may share little more than certain cultural practices and social pride.
- Regardless of what actual biologic or genetic differences may exist, at this point in this country, health care access is determined substantially by phenotype. Populations experiencing discrimination in health care access or research attention need data to support their claim to resources. For some populations, such as Hispanics, these data do not yet exist.
- It is inappropriate to try to correct health care access problems through the research mechanisms, such as the MBCCOPs.
- A crucial difference between previous fee-for-service care and the current systems of managed care is the feeling of essential security and well-being that people had under indemnity care. People felt reasonably sure that if they became ill and went to a doctor or hospital, that care would be provided and would be provided as prescribed by the physician. This is no longer the case; insurance intermediaries now determine what protocol is appropriate and how long hospitalizations should be. Patients and physicians are demoralized and frustrated with attempts to deal with insurers in the current environment. It was also noted, however, that under the fee-for-service system, many patients probably received more services than they needed because there was the assurance that their cost would be reimbursed.
- At this time five Federal bills are pending on ERISA reform; each has a component dealing with the issue of patient access to reasonable care. Requiring health plans to define reasonable care is an important first step in restoring integrity and morality to the health care system and in relieving the frustration currently felt by patients, medical providers, and advocates. Advocates face strong opposition from health industry and corporate lobbies in this matter; Congressional action will be needed to resolve the problems now faced by the more than 60 percent of Americans covered by ERISA plans.
- Dr. Calabresi cited the Rhode Island legislation guaranteeing access to Phase II, III, and IV trials approved by the NIH, DoD, or FDA. Last year, 19 states introduced clinical trials funding legislation.

PRESENTATION HIGHLIGHTS: Rural Research Issues

RURAL LINKAGES—Dr. Charles Given

Key Points

- The National Commission on Quality Assurance (NCQA) and the HEDIS guidelines have had significant positive effects on screening and early detection in rural areas, particularly in mammography, prostate, and colorectal cancer screening in the past few years. Another

aid to screening in rural populations has been the availability of computer-generated reminder notices that can be produced from desktop computers using off-the-shelf software. Digitized data transmission (e.g., mammography images) has afforded people in rural areas access to high standards of care, since images can be transmitted for evaluation by experts at major medical centers. Standards for rural laboratories have also improved.

- Despite these improvements, the single greatest problem remains the number of rural families who are outside any system of continuous care; these vulnerable populations tend to receive only episodic care. Barriers to rural cancer care include travel distances to sites of specialty care; concentrations of poor, elderly, and less educated citizens; fragmented community services; lack of access to the full range of cancer services; inability to recruit and retain cancer specialists in rural areas; and reliance on informal systems of care.
- Rural America is an aging population, and therefore is at high risk for cancer. Lower education makes this population less likely to be engaged in preventive, screening, and early detection services. The rural population also suffers from low income and a poor economic base. Those who are insured are not usually covered for screening or preventive services.
- A 1992 study of cancer care in rural areas concluded that once rural residents became involved in cancer care, they generally were able to access high quality services in their locales; however, problem areas identified included a lack of supportive care for chemotherapy side effects, difficulties contacting oncologists, and a lack of integrated palliative care.
- A multi-community study was conducted to assess the impact of educational interventions for rural oncologists, primary care physicians, nurses, and pharmacists on cancer diagnosis and staging, treatment, and support. The data suggested that even in the non-intervention communities, patients were receiving appropriate care, as measured by cancer management scores devised for the study. The investigators in this study are now analyzing the data to determine if there were important differences in stage at diagnosis.
- Dr. Given and colleagues developed a nurse-centered intervention to deliver supportive care to rural cancer patients in four targeted communities. The intervention was linked with and developed in collaboration with community oncologists, rural surgeons, local family physicians, and the CCOP. Patient histories, treatment plans, and other study data were maintained on laptop computers; in addition, on-line access to PDQ and the Cancer Information Service enabled the nurses to locate and print needed information for patients. The nurses were heavily involved in early detection and management of treatment side effects, evaluating and monitoring patient health, educating families and patients, and provided other nursing services such as dressings and venous access maintenance. In addition, they facilitated referral and coordinated care including drug assistance programs, working with social service agencies, arranging transportation, and helping patients with Medicaid eligibility paperwork. Through this intervention, patients were better able to care for themselves, and family members and primary care givers became more active in patient care throughout treatment and follow-up. Among the strengths of the program were the relational database used, the development of quantifiable data on the nursing interventions, the use of procedure (CPT) and International Classification of Diseases (ICD) codes that permitted assessment of treatment complexity and billing for nursing services in one of the study locations, and improved care for these patients.

Additional Research Needs and Other Recommendations

- We need to find ways to extend state-of-the-art cancer care to rural populations. It is important to link patients with suspicious screening findings to definitive care, and to provide supportive care in the rural communities.

PRESENTATION HIGHLIGHTS: On Behalf of Working America

AFL-CIO—Ms. Nadra Floyd

Key Points

- The American Federation of Labor-Congress of Industrial Organizations (AFL-CIO) is greatly concerned about the problems faced by uninsured and underinsured workers. According to the National Institute on Occupational Safety and Health (NIOSH), of the half million cancer deaths occurring annually in the United States, four percent (20,000 deaths) are due to occupational exposures. While this figure reflects remarkable progress in reducing the effects of recognized carcinogens in the work place, it remains clear that far too many Americans are still being killed slowly by the work they do.
- As many as five million American workers are exposed to substances classified by the International Agency for Research on Cancer (IARC) as human carcinogens. NIOSH estimates that 10 percent of lung cancers and up to 27 percent of bladder cancers result from occupational exposures. In workers with documented exposure to established carcinogens, close to 100 percent of angiosarcomas of the liver can be traced to occupational exposure to vinyl chloride. As much as 50 percent of lung cancers in these workers can be attributed to asbestos exposure.
- By the late 1970s, when compelling epidemiologic evidence existed demonstrating that asbestos exposure caused cancer, 27 million American workers had already been exposed. Since then, some 8,000 asbestos-related deaths have occurred annually and can be expected to continue occurring into the next century.
- Advances in microbiology and genetics have opened new fields of research that could reduce the death toll from occupational exposures, particularly concerning the interaction of chemical agents with human genetic material.
- Too few employees are being screened for important occupational exposures. The lack of accurate and cost effective screening methods has been an obstacle to collecting the level of exposure data that will prompt the deployment of effective controls and efforts to measure whether controls have been effective in reducing exposures.
- Worker compensation systems are largely irrelevant for workers who develop cancer as a result of long-term exposures because the linkage between exposure and disease is often impossible to establish, especially without adequate screening methods. These workers are left at the mercy of the Medicaid and/or Medicare systems. Even in cases where causation is established, worker compensation benefits are often woefully inadequate, and reflect the politics of a community. Many states are moving to managed care systems for worker compensation programs, limiting quality and choice for workers, reducing or eliminating screening programs, and hampering research efforts.
- The AFL-CIO and other larger unions maintain occupational health and safety staffs, and provide funding both for the worker's health fund and to relevant research and advocacy organizations. The staffs provide guidance to elected officials and government staff at state and Federal levels, identify member concerns, and design programs to help workers negotiate work place improvements. The United Auto Workers (UAW), as part of their

active participation in the National Prostate Cancer Coalition, has launched a prostate cancer awareness program. Three occupations—welders and electroplaters working with cadmium, farm workers, and rubber and tire manufacturing workers—appear to be at particular risk for prostate cancer. New research suggests that workers exposed to mineral spirits, diesel fuel, and lubricating oils may also be at risk. The UAW gathers research data on such exposures for use in public and worker education efforts, and in efforts to encourage greater cancer research funding.

- The UAW and American Federation of Teachers (AFT) have worked to publicize breast cancer risk. A 1993 NIOSH death certificate study of 2.9 million women who died from 1979 through 1987 correlated cause of death and occupation. It showed that teachers have a higher breast cancer death rate than the general population. White teachers had a 62 percent higher rate of breast cancer death than the general population; the death rate among African American teachers was nearly double that of the general population. A follow-up study by the CDC suggested that deferred childbearing, or choosing to have no children, might be among the factors contributing to the findings.
- AFT focus groups identified several barriers to breast cancer screening among its membership: lack of knowledge about breast cancer, lack of time for screening, and viewing a breast cancer diagnosis as a death sentence. A three-year education program was developed; the pilot programs are to be evaluated and results published in the 1998-99 school year.
- A study by the Laborer's International Union found that laborers were 13 percent more likely than the general population to die of cancer. Incidence of cancers of the lung, stomach, rectum, and thyroid were all higher than those of the general population. The union has established agreements for worker education, training and research projects with two major academic health centers.
- As an individual currently being treated for cancer, Ms. Floyd emphasized the crucial value of a comprehensive medical plan and employer sick leave policies that enable patients to obtain needed care and maintain economic stability while being treated for a major illness.

Additional Research Needs and Other Recommendations

- Through well-funded, comprehensive research, we must develop better methods for identifying potential carcinogens among the four million chemical products with commercial U.S. applications, and develop more extensive and effective models for extrapolating results from animal research to the human experience.
- Research on the relationships between chemicals with human genetic susceptibility to cancer must be vigorously funded and pursued.
- Occupational safety and health research should focus on reducing or eliminating worker exposure to carcinogens. This research should encompass administrative policies (e.g., work practices, worker education, training), work place engineering (e.g., equipment design, selection of materials, work methods modification), and protective equipment and techniques (e.g., respirators, protective clothing).
- Innovations and adaptations in these three areas have been achieved through the collective bargaining process; in environments in which workers have no union voice, responsible public policy and regulation is needed to require employers to adopt best practices, and provide the best level of personal protection available.

- Exposure assessment research is essential to create convenient and low cost exposure measurement tools.
- Public policy leadership on the issue of cancer in the work place and in the community at large must come at the national level. In addition, we need more public education, a stronger public commitment to funding lifesaving research, and the political will to enforce work place standards and industry screening programs that we know will save lives.

DISCUSSION—Dr. Given and Ms. Floyd

Key Points

- Dr. Given indicated that clinical outcomes of the patients involved in the rural linkage study are now being analyzed and will be compared with outcomes in a patient population matched for age, gender, cancer site, and stage of disease. The transferability of this model of care may depend in part on variations in state rules as to how master's level nurse practitioners are permitted to practice under the direction of a physician. It should be possible to adopt or adapt the model not only in other rural areas, but in any area in which there is a vulnerable population that requires extra case management support in order to stay in screening and treatment programs.
- Workers compensation systems are primarily designed to address workplace injuries, not diseases. In addition, claims for workers compensation must be filed within specified time periods; workers who develop a disease as a result of an exposure that occurred 10 or 15 years earlier will not qualify for these benefits. The problem is complicated by a lack of recordkeeping that would enable workers to prove the link between exposure and disease.
- Experience thus far with managed care systems for workers compensation suggests that patients are faced with increased paperwork, limited choice of provider, and limited services.

CLOSING REMARKS—Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- Testimony on the impact of managed care on special populations underscores the continuing debate on the evolving health care system.
- The definition of special populations remains unclear; methodologies for studying these populations and the value of doing so remains a key question in cancer research.
- The role of advocacy in addressing special population needs in cancer research was a recurrent theme.
- The input of the presenters will be of significant value as the Panel formulates its recommendations to the President in these important areas.

QUALITY OF CANCER CARE/QUALITY OF LIFE

APRIL 23, 1998
LOS ANGELES, CA

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

N A T I O N A L C A N C E R P R O G R A M

N A T I O N A L C A N C E R I N S T I T U T E

CHAIRMAN
HAROLD P. FREEMAN, M.D.
HARLEM HOSPITAL CENTER

MEMBER
FRANCES M. VISCO, J.D.
NATIONAL BREAST
CANCER COALITION

MEMBER
PAUL CALABRESI, M.D.
BROWN-TUFTS CANCER CENTER
RHODE ISLAND HOSPITAL
NEW ENGLAND MEDICAL CENTER

EXECUTIVE SECRETARY
MAUREEN O. WILSON, Ph.D.
ASSISTANT DIRECTOR
NATIONAL CANCER INSTITUTE

Quality of Cancer Care/Quality of Life Defining "Quality" for Cancer Care April 23, 1998, Los Angeles, California

Opening Remarks	Dr. Harold Freeman
Welcome	Dr. Judith Gasson
NCI Report	Dr. Otis Brawley
Defining Quality in Cancer Care	
Issues in Defining Quality in Relation to Cancer Care	Dr. Mark Schuster
Issues in Assuring Quality in Relation to Cancer Care	Dr. Laura Esserman
Quality Cancer Care—Humana Policy and Research Perspective	Dr. Mitzi Krockover
Quality Cancer Care—Kaiser Permanente Perspective	Dr. Diana Pettiti
Cancer Prevention	
Healthy and At-Risk Populations	Dr. Roshan Bastani
Molecular Epidemiology	Dr. Ronald Ross
Cancer Prevention in Women of Color	Dr. Antronette Yancey
Cancer Control	
Quality of Life in Breast Cancer Survivors	Dr. Patricia Ganz
Quality of Life in Prostate Cancer Survivors	Dr. Mark Litwin
Care and Survivorship	
Imperatives for Cancer Care	Ms. Susan A. Leigh
Diagnosis and Treatment	
Pathology	Dr. David Kleiner
New Technologies	Dr. Faina Shtern
Closing Remarks	Dr. Harold Freeman

Speakers List
Quality of Cancer Care/Quality of Life
Defining "Quality" for Cancer Care
April 23, 1998, Los Angeles, California

Dr. Roshan Bastani

Associate Director
Division of Cancer Prevention and Control Research
Assistant Professor, Department of Health Services
UCLA Jonsson Comprehensive Cancer Center
School of Public Health

Dr. Otis Brawley

Office of Special Populations Research
National Cancer Institute

Dr. Laura Esserman

UCSF Mount Zion Medical Center
Department of Surgery

Dr. Patricia Ganz

Jonsson Comprehensive Cancer Center
Prevention and Control Research

Dr. Judith Gasson

Professor of Medicine and Biological Chemistry
Director, Jonsson Comprehensive Cancer Center

Dr. David Kleiner

Chief, Post Mortem Pathology
Division of Clinical Science
National Cancer Institute

Dr. Mitzi Krockover

Vice President for Woman's Health
Humana

Ms. Susan A. Leigh

National Coalition for Cancer Survivorship

Dr. Mark Litwin

UCLA Jonsson Comprehensive Cancer Center
Assistant Professor of Urology and Public Health

Dr. Diana Pettiti

Director, Research and Evaluation
Kaiser Permanente

Dr. Ronald Ross

Professor of Preventive Medicine
Associate Director, USC Norris Cancer Center

Dr. Mark Schuster

Senior Natural Scientist
The RAND Corporation

Dr. Faina Shtern

Office of the Secretary for Women's Health
U.S. Department of Health and Human Services

Dr. Antronette Yancey

Adjunct Assistant Professor
Division of Cancer Prevention and Control Research
UCLA Jonsson Comprehensive Cancer Center

QUALITY OF CANCER CARE/QUALITY OF LIFE

Defining "Quality" for Cancer Care

April 23, 1998, Los Angeles, California

OVERVIEW

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. This meeting, the first in a series of three focusing on the meaning of quality of care and quality of life, explored issues in defining quality in cancer care from prevention through palliation.

Fifteen speakers presented testimony to the Panel on defining and assuring quality of cancer care; quality-of-life issues; policy and research perspectives on quality of care; cancer prevention in healthy, at-risk, and minority populations; cancer control; cancer care and survivorship; and diagnosis and treatment. Speakers offered specific recommendations in these areas for consideration by the Panel.

OPENING REMARKS—Dr. Harold Freeman, Chairman, President's Cancer Panel

In opening the meeting, Dr. Freeman stated that:

- This is the first of three meetings to consider the meaning of quality of care and quality of life, from preventive care through palliation. This meeting is intended to explore how the Nation defines good medical care for cancer. Future meetings will examine how quality of care is intertwined with quality of life and survivorship considerations and how guidelines impact quality of care definitions.
- The President's Cancer Panel is a three-member, Presidentially appointed advisory committee charged with examining barriers and making recommendations to the President on issues affecting the National Cancer Program. Since 1991, the Panel has championed access to appropriate delivery of quality cancer care, recognizing that access to services is as critical as the caliber of services offered.
- In 1994, the Panel called for the identification of obstacles preventing access to existing cancer prevention, diagnosis, treatment, and supportive care. A cooperative effort was mounted to educate the American public regarding its options in cancer prevention and health care access.
- In 1995, recommendations to the President included strengthening the collection and sharing of data to assure that the public has complete, truthful, and understandable information about health risks; developing and implementing a national curriculum beginning in primary schools to foster health-promoting behaviors and lifestyles; and enhancing support for and participation in clinical research.
- The Panel's 1996 annual report included recommendations for developing measures to ensure that minorities, the poor, the elderly, the uninsured, and the underinsured are not excluded from access to appropriate cancer care as the health care system evolves. The Panel also recommended that participation in all phases of clinical trials be formally incorporated into the standards of care for cancer and that appropriate clinical trials participation be an integral component of care guidelines for specific malignancies.

- The American consumer expects to receive high-quality care, but quality cancer care has not been well defined. At a minimum, every person waging a personal war against cancer needs timely access to diagnosis and treatment, as well as assurance that medical knowledge and care will be applied appropriately. The difficulty lies in determining the basis upon which guidelines are established that will assure that appropriate care is delivered under appropriate circumstances and in a cost-effective manner. The American consumer desires the most economical health plans when well, but the most advanced care when ill.
- The war against cancer involves not only the quality and effectiveness of treatment, but also the quality of prevention and detection efforts. How health-related messages are delivered and how services are provided can significantly impact individual perceptions of quality. For example, it may be that delivering standard information on cancer screening and prevention is not sufficient; to achieve quality, information may need to be delivered in a culturally tailored manner.
- How we define success in preserving quality of life during and following treatment, and at the end of life when cure is not possible, must be examined. An overarching issue is how to respond to individual perceptions of quality in light of geographic, cultural, ethnic, and socioeconomic concerns. Rapid evolution of the Nation's health care delivery system to for-profit managed care also raises issues in defining quality of care, and cost may be used as a measure of quality.
- Whether access to clinical trials should be included in the definition of quality cancer care is a critical question. From a research perspective, clinical trials must be supported and conducted for new therapies to be tested and for the overall quality of cancer care to continue to improve. Access to state-of-the-art or optimal cancer care has been equated with access to clinical trials. Therefore, any discussion of quality of care must recognize that care options encompass both investigational clinical trials as well as noninvestigational standard care.
- Cancer encompasses a continuum of care that must include screening and disease detection, treatment, symptom and side effect management, surveillance of recurrent disease, psychosocial and behavioral support, palliation, and end-of-life care, including bereavement counseling. The issue of access to care is central to any discussion of quality. Depending upon economic status, considerations range from access to any type of care, ability to obtain standard care, and ability to access clinical trials or state-of-the-art care. These fundamental needs, as well as the appropriateness of medical interventions, timeliness of delivery, consistency of medical decision making, and the ability to communicate to the consumer the basis on which medical decisions are made, must be considered in developing quality measures for cancer care.

WELCOME—Dr. Judith Gasson, Director, Jonsson Comprehensive Cancer Center

Background

The University of California, Los Angeles (UCLA), and the Jonsson Comprehensive Cancer Center have developed partnerships with a number of oncology practices extending north into the Bakersfield area, to the east in Las Vegas, and to the south into Orange County. These partnerships provide state-of-the-art care in the communities they serve and provide access to available clinical trials for individuals for whom there is no standard therapy.

Key Points

- For the 50 percent of cancers that are not curable, research is focused on finding new technologies for treatment, better methods of detection, and, ultimately, strategies to prevent them. Cancer care must be available to all members of our society regardless of their socioeconomic status, geographic location, or educational level.
- As technology improves, treatment efficacy must be judged both in terms of extended survival and quality of life.

NCI REPORT—Dr. Otis Brawley, Assistant Director, Office of Special Populations Research, NCI

Representing Dr. Richard Klausner, Director, NCI, Dr. Brawley indicated that:

- This year's NCI budget has increased and will likely continue to rise along with the overall budget at the National Institutes of Health (NIH). Declining cancer mortality and the aging of the American population are contributing to a dramatic increase in the number of cancer survivors for whom quality-of-life issues are essential. Interest in cancer screening and prevention, and the recent findings related specifically to breast cancer prevention are bringing quality-of-life issues to the forefront for the entire population.
- NCI will establish an Office for Diffusion Research in the Division of Cancer Control and Population Science (DCCPS) to examine methods related to the diffusion of treatment-related findings and issues to the public.
- Recent declines in cancer mortality rates were not experienced uniformly across ethnic groups. Though African-American, Hispanic, and Native American populations experienced mortality rate declines, they were not as steep as those experienced by whites. Recent NCI research revealed different patterns of care related to socioeconomic status and perceived race. Further understanding of these disparities will be necessary if society is to progress.

PRESENTATION HIGHLIGHTS: Defining Quality in Cancer Care

ISSUES IN DEFINING QUALITY IN RELATION TO CANCER CARE—Dr. Mark Schuster

Key Points

- The Institute of Medicine defined quality in 1990 as: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Close examination of this definition reveals a number of significant implications. First, the term "degree" shows that quality of care is a continuum (i.e., better versus worse) rather than a dichotomy (i.e., good versus bad). The term "health services" emphasizes that quality refers to those elements of care that the health care system can affect, including the extended care system (e.g., rehabilitative care, hospice care). It does not include genetics or educational level. Reference to "individuals and populations" recognizes that quality care can involve delivering care to both. "Increase the likelihood of desired health outcomes" takes into account the concept of chance, i.e., evaluating the probability that a particular intervention will have a positive impact. The term "outcomes" is of paramount importance as it emphasizes achievement of the ultimate goal. The statement also makes the connection between "health services," or processes of care, and "outcomes."

- There are two basic approaches to quality assessment: implicit review and explicit review. Implicit review involves rendering professional judgment about the quality of care through review of pertinent information. It is not systematic or necessarily data driven. It is based largely on impression or "gut feeling." Current trends have moved toward explicit review, which involves the use of care standards to assess quality.
- The three basic dimensions in quality assessment include: structure, process, and outcome. Structure refers to characteristics of the health system or individuals that affect the system's ability to meet the health care needs of individuals or communities. These include health care organizational characteristics (e.g., staffing patterns, number of beds) and provider attributes (e.g., specialty mix, provider qualifications and experience). Structure can be influenced by community characteristics that affect the health system (e.g., number and types of other facilities, transportation patterns). Also influencing care quality from a structural point of view are population characteristics, such as economic status or ethnicity.
- Service volume is the most significant structural characteristic associated with quality care. The presence of critical thresholds of patients with a specific condition being treated by the same (institutional or individual) provider is directly related to the quality of care. Service accessibility is another key element in assessing structure.
- The process of care includes both the technical expertise of the provider and his or her interpersonal skills. Process assessment considers not only whether the provider makes the right choices regarding diagnosis and treatment and is sufficiently aware of alternatives, but also whether care is provided skillfully and effectively. Interpersonal measures of quality assess whether care is provided in a patient-focused, humane manner; whether patient preferences are incorporated; and whether sufficient information is provided to support informed decision making. Process measures also take into account the appropriateness of referrals.
- Outcomes represent the results of the health care delivery process, the classic outcomes being biological status including 5-year survival rates and many aspects of morbidity. In recent years, functional status (i.e., ability to participate in physical, mental, and social activities; sense of well-being; and ability to fulfill one's role in the world) has also been taken into account. Patient satisfaction (perceptions about the quality of care received) is also an essential element of quality of care.
- In measuring and assessing patient outcomes, risk adjustment is important to ensure that differences are attributable to quality rather than characteristics not under the control of the health care system. Depending on the situation, adjustment factors may include co-morbidity, patient age, and a host of other patient attributes that affect outcome.
- Process measurement includes determining whether an intervention or service is appropriate (i.e., expected benefits outweigh the risks); necessary (there is a reasonable chance of benefit to the patient and withholding care would be harmful or unethical); and whether care adheres to professional care standards.
- Process indicators can be derived through review of the research literature and professional consensus and should be associated with outcomes. Such indicators generally target a few key markers of clinical care for a condition rather than all aspects of care, the assumption being that if one performs well on the markers, it is likely that the other aspects of care are also of high caliber.

- The low incidence of particular types of cancer in a particular hospital or health plan makes quality assessment more challenging. In many types of quality-related assessments, a certain minimum volume of patients may be necessary to observe a particular effect.
- The classic paradigm of 5-year survival rates has been very useful for research, but it is not always useful for quality assessment because of the long delay associated with obtaining meaningful results. By the time results are available, the environment or facility may have undergone substantial change.
- Another challenging issue associated with quality assessment is poor documentation in the medical record, particularly related to counseling and discussion of treatment options. This problem is compounded by increasing fragmentation of care across delivery sites and providers.
- Quality assessment information is used by an extremely diverse community that includes consumers, private employers, insurers, policy makers, and researchers. It is incumbent upon clinicians to use this information to improve the quality of care they provide.

DISCUSSION—Dr. Schuster

Key Points

- Most of what is done in the health care system has not been and will not be studied because, ultimately, practices become so routine that they evolve into the standard of care. This does not mean that current approaches are the best. However, resources are limited and research is constrained by various ethical issues (e.g., withholding standard care would not always be permitted by human subjects committees, even if that care was not based on research).
- Panels established to develop quality indicators should be sufficiently diverse to incorporate multiple perspectives and ensure that the views of any single organization do not unduly dominate the discussion.
- Though much of standard cancer care has not been adopted as the result of research, the cancer field has, unlike many other areas of medicine, established a research system to attempt to prove the efficacy of care.
- A continuing dilemma exists in that expert panels are asked to assess quality, yet little evidence from controlled studies may exist to support or refute the efficacy of standard practice.

ISSUES IN ASSURING QUALITY IN RELATION TO CANCER CARE—Dr. Laura Esserman

Key Points

- Much of the information related to what consumers consider quality of care may not be available to assist in decision making. Further, what is considered an important factor in care decisions varies significantly depending upon who is making the decision. For example, many choices women make regarding their care may have less to do with mortality concerns than with other factors. Therefore, mortality rates may be either irrelevant or of marginal importance in choosing between surgical options. Small differences in survival rates may be highly significant to some patients, but not to others. Physicians may equate quality with ensuring that patients take into account the latest results from clinical trials and making sure that every possible alternative is explored for their patients.

- Finding ways to provide complex information from clinical trials at the bedside in an environment where providers are pressured to decrease time spent with patients is extremely challenging. There is a lack of good tools to assist in explaining treatment options in the office. Results of clinical trials are presented at national meetings in the most positive light possible (relative reduction) which leads to confusion about absolute benefits to patients and an overestimate of the value of intervention.
- Quality of care is interpreted from a variety of perspectives. The purchaser/employer may care about the cost of care, the associated mortality rates, and policy implications, rather than what the patient is most concerned about. The health care plan may be more focused on low variation in patterns of care, adherence to standards, and few requests for second opinions. Plans also want ways to contain costs, and therefore develop standard, predictable ways to measure the cost impact of decision making by patients or physicians—none of which measure the true quality from the patient's perspective.
- Certain process elements may be highly correlated with high-quality care but, in fact, may be difficult or perhaps impossible to measure. Many process-related events, however, may be easy to measure but are less relevant to the quality of care.
- The range of outcomes is broad, and may include morbidity, complication rates, unnecessary procedures, mortality, and patient satisfaction. Outcomes are often related to process, the quality of the procedures performed (surgery, cytology), and the skill of the operator. For example, the use of good-quality fine needle aspiration (FNA) can eliminate surgical biopsy. It has been shown that the higher the volume of FNAs performed, the better the quality of the FNA itself. If an FNA is not done well, however, the patient is better served by an open biopsy.
- A new framework is needed to enable us to capture and systematically use data routinely collected in medical charts to document patterns of care. In the absence of such meaningful data, quality of care cannot be measured or improved. Significant issues exist as to who should finance the data collection infrastructure. Among the possibilities are the health plans, purchasers, physicians, consumers, or some combination of these.
- Currently, proposed quality measures are related primarily to what data are available, such as breast-conserving surgery rates. These rates, which vary widely from 20 to 80 percent nationwide, are highly influenced by both physicians and consumers; therefore, measuring the rates themselves may paint an incomplete picture of quality when patients were offered a choice, and capture of the reasons for that choice are critical to understanding variation.
- NCI has an initiative to try to create uniform data standards; these standards will provide the foundation for better data collection, comparisons, and analyses.
- Only about 3 percent of adult patients with cancer are on clinical trials. Among the many reasons for this is that the system is cumbersome. For example, there is a great deal of additional paperwork and forms to fill out and there are hundreds of different data standards for clinical trial eligibility; such variation and extra work is unnecessary.
- In addition to adjusting provider outcomes based on severity of illness, risk adjustment should also take patient preferences into account. Some patients do not want standard therapies, while others may find the benefits of chemotherapy insufficient to endure its toxicities, and still others may prefer alternative care. These patterns of preference may tell the physician a great deal about the quality of care he or she is providing.
- Effective methods for presenting clinical information to patients are currently under study at UCSF. Videodisc programs have been created to support shared decision making for

many different diseases. A good example is one regarding surgical intervention for prostatic hypertrophy. In examining factors that influenced patients' decision making, five significant questions were found to define patients' perspectives regarding their willingness to live with the side effects of surgery (e.g., sexual dysfunction, sleep interruptions due to more frequent urination). Responses to these questions were key determinants of the choices patients made among treatment options.

- Physicians must be provided with the tools to access data, identify different ways to present it to patients, and help understand the patient's hierarchy of values.
- We cannot pretend that the cost of care is unimportant; it is what currently drives the system. Health plans may care whether patients are satisfied with the plan if they can align wellness with benefits.
- Physicians are data driven, and providing data on quality, costs, and patient satisfaction is likely to influence them. Physicians would like to know and understand their morbidity rates. Having systems that help improve patient satisfaction or give physicians more time with their patients would make a difference.
- Empowering consumers by giving them information would change the system and influence quality of care. People care about details and how they will affect their daily lives. They also care about how information is presented. In addition, advisory groups, regulatory bodies, and advocates can have enormous influence on how care is delivered.
- Patient-centered care is essential. The goal is not to treat the disease but the patients who have it and to make their lives better, not worse.

Additional Research Needs and Other Recommendations

- To make a significant impact on quality, the stakes and major issues of concern to health care payers must be taken into account. The best system can be developed in a vacuum, but it will not necessarily influence medical practice. Market power and strategic analysis must be taken into account in implementing change. However, the most important element in the system is the patient and his or her perception of quality. Purchasers would be most interested in how quality affects people's wellness, their productivity, their disability, and the costs of their care. We need to better understand the quality measures used by purchasers to determine how to influence their decisions in favor of quality care. Thinking about who in the market has the power to affect change is critical. The food chain is not fixed. Hopefully, those now at the bottom—the patients—can become much stronger and have greater influence over the health care system.
- NCI's current efforts to re-engineer the clinical trials process should be supported. This effort may result in an increase in public-private partnerships and the development of systems for point-of-service data capture and tracking. Creating systems that decrease daily provider tasks will provide incentives for data reporting that in turn will facilitate efforts to monitor quality. Systems must be implemented to enable data tracking as part of the routine care process.
- Facilitating data capture from mission-critical processes and outcomes is very important.
- The hard questions are: Who will pay? Who will care? How much can we afford to pay? What fraction of the health care dollar can go to measurement and to extra services that contribute to better outcomes? Who are we going to allow to decide?

QUALITY CANCER CARE: KAISER PERMANENTE PERSPECTIVE—Dr. Diana Petitti

Background

Kaiser Permanente is a group-model HMO located in California. It consists of two major entities—the Kaiser Foundation Health Plan and Hospitals, and the Permanente Medical Groups. The Kaiser Foundation Health Plan and Hospitals are a not-for-profit HMO that sells insurance products. The Permanente Medical Groups contract exclusively with the Health Plan and hospitals to provide physician services to Kaiser Foundation Health Plan members. Kaiser has 9.1 million members, of whom 5.5 million are located in California. According to 1997 figures, 6.6 million (or 73 percent) were located either in California or in the Northwest Divisions.

Kaiser's mission and purpose is "...to provide affordable, high-quality health care services and to improve the health of our members and the communities we serve."

Key Points

- Quality exists only in the context of a system designed to ensure the delivery of quality care. A quality health care system has structures and processes that ensure access to and receipt of quality health care. Kaiser views itself as a system of care and not simply as a deliverer of services.
- Kaiser uses a population-based approach to health care delivery. Kaiser's members experience between 22,000 and 25,000 cancers per year. Of these, 4,000 to 5,000 are breast cancers; 2,000 to 3,000 are lung cancers; 2,500 to 3,000 are colorectal cancers; and 3,000 to 4,000 are prostate cancer. There are 150 to 200 new cases of pediatric cancers annually.
- To provide a context in which to view the cancer problem as experienced by plan members, Kaiser estimates that its membership experiences approximately 10,000 acute stroke cases per year, about 8,000 new acute myocardial infarctions (MIs), and 8,000 new diagnoses of other coronary artery disease. An estimated 250,000 members have diabetes, 800,000 members smoke, and about 6,000 members have Parkinson's disease.
- Kaiser's operational definition of quality health care is "delivering the right care for the right people at the right time, in the right place, and having the best outcomes."
- Knowing the type of care to deliver stems from the use of evidence-based guidelines. In some cases, Kaiser has developed the guidelines it employs; in other cases, guidelines developed by others have been adopted. To ensure that Kaiser knows what "the right care" is, a research component is maintained to evaluate the impact of the care provided.
- The ability to identify the needs of the target population is an essential element of quality. Kaiser has invested heavily in information systems to help determine the prevalence of various diseases and behaviors (e.g., diabetes, smoking) and support efforts to target outreach, screening, and necessary followup.
- Kaiser's Breast Buddies Program provides social support by pairing women with newly diagnosed breast cancer with a breast cancer survivor to assist in decision making regarding care options. An extensive evaluation of this program was performed to assess its impact.
- In southern California, Kaiser uses a defined process for selecting areas for specifically targeted programs to improve quality of care. The clinical strategic goals list includes the following priorities: cardiovascular disease, cancer, immunizations, pregnancy outcome, and asthma. These priorities were selected because of their associated high morbidity and mortality among Kaiser's membership.

- The following elements are used to define quality of care for clinical strategic goals: use of evidence-based guidelines; attempts to implement guidelines through communication, system changes, and processes; specific performance and outcome measures related to guidelines; performance target setting; action planning to improve process and outcome; implementation of action plans; and attempts to align performance targets with incentives.
- Clinical strategic goals have been developed for breast and cervical cancer. Goals related to smoking are included in the cardiovascular area. Process and outcome measures for breast cancer include the percent of women 50 through 75 years of age having a mammogram within 2 years. A yearly satisfaction survey of members newly diagnosed with breast cancer is also conducted. Five-year survival rates are monitored, though this is a poor measure of the current quality of care. Including the time required to do the evaluation, it is not expected that outcomes will be known for women now being treated for breast cancer until 2006.
- Quality-of-care measures for cervical cancer include the percentage of women having pap smears within 3 years, and the rate of followup within 1 month of abnormal pap smears.
- Experimental treatments differ in terms of type and level. For example, old drugs may be used in new ways (e.g., Taxol for lung cancer); new treatment devices may be developed (e.g., proton-beam therapy for prostate cancer); established procedures may find new applications (e.g., high-dose chemotherapy and bone marrow transplant for ovarian cancer); and diverse new treatments may be proposed (e.g., gene therapy, crystals). If everything new were better, research would not be necessary. People are quick to see the new as better, without waiting for adequate proof.
- Access to experimental treatments should be provided in the context of efforts to determine whether the treatment works. Unless this is the case, experimental treatment should not be provided.
- Purchasers have influence on how their premium dollars are spent. Many contracts specifically exclude experimental therapies in response to market pressure to limit premiums or out-of-pocket expenses. Kaiser would like to provide access to experimental treatments when they are provided within the context of attempts to find out what works.
- Payment for experimental treatments under Phase III randomized clinical trials is facilitated because they represent either new uses of old drugs or cases in which the drug is provided free of charge either by the NCI or by the pharmaceutical company. Participation in Phase I and II studies poses greater difficulties since there are no comparison groups, and because the treatment may not be funded by any entity other than Kaiser.
- The hierarchy of clinical trials includes primary prevention, screening, initial therapy, monitoring, symptom management, and, finally, trials of last-chance experimental therapies, which receive the greatest media attention.
- Kaiser often competes with university centers to participate in primary prevention and screening trials; these trials are often relatively simple and generally do not place heavy burdens on the health care system. Kaiser's Southern California, Northern California, and Northwest Regions, as well as Group Health Cooperative, are all affiliated with specific adult and pediatric cooperative trials groups. However, Kaiser experiences many of the same difficulties in recruitment as do other institutions; further, all patients do not want to be in a study, and for some, no appropriate study is available.
- Until recently, the NCI has been relatively impervious to complaints about some of the unnecessary cost elements of clinical trials, including tests and procedures that are done as

part of the trial but are not part of routine care and may not be necessary to address the main issues of the trial.

- Until recently, little attention has been given to assessing the marginal costs of clinical trials versus conventional therapies (i.e., the issue has been largely ignored). This may account for higher enrollment of Kaiser patients in trials and/or sending patients elsewhere for trial participation.
- In Dr. Petitti's opinion, clinical trials in cardiovascular disease have provided the best model for making contributions to the knowledge base of evidence-based medicine. Clinical trials for selected aspects of cardiovascular disease have resulted in about a 10 to 15 percent difference in overall survival between patients treated with and without the new drug. One of the reasons for the success seen in cardiovascular disease trials is the simplicity of most of these trials.
- Closer partnerships could be forged with academic medical centers if a number of significant issues are addressed. One particularly troublesome example is the "bait-and-switch" phenomenon in which a patient is sent to an academic medical center to participate in a well-designed, randomized, controlled study of an apparently promising therapy and, instead, the patient is recruited for alternative regimens that may not have a strong scientific basis, may not be a randomized study, or for which there is no good plan for scientific data gathering.

Additional Research Needs and Other Recommendations

- The clinical trials enterprise within cooperative groups and in health care centers should be scrutinized more carefully. The NCI has not taken a strong lead in providing direction to the national cancer research agenda in clinical trials. Some of the questions asked are not the most important clinical questions. There are concerns about the degree to which studies compete for the same patients or that there is duplication among different trials groups. This slows the process of accrual which in turn extends the research timeframe.

DISCUSSION—Dr. Petitti

Key Points

- Kaiser's decision to participate in clinical trials is based upon a number of factors that include but are not limited to: whether it will answer important scientific questions; whether the cost is reasonable; whether the protocol is well defined; and whether Kaiser has sufficient capacity to participate.
- Kaiser is proceeding from the research phase to the implementation phase of its colon cancer screening effort. Screening for colorectal cancer is now recommended for Kaiser members, and the plan is attempting to develop strategies for increasing compliance. It is recognized that the cost savings associated with colorectal screening will not be realized for 10 years or more. Although there is concern that the savings are not immediate, the plan feels it should offer a service proven to be of benefit.
- The rise of for-profit HMOs has increased competition in the health care marketplace, resulting in cost accountability and downward premium price shifts. Though limiting cost to the consumer has always been a concern, Kaiser questions whether the level of care can be maintained if there is continued downward cost pressure. Dr. Petitti maintained that quality of care is not threatened at this point, but that Kaiser and other plans struggle to both maintain quality and ensure maximum efficiency. A central strategy for doing so involves removing from the system things that cannot be justified based on quality.

- Kaiser's southern California cancer clinical trials unit is located in San Diego. Efforts are under way to make clinical trials more accessible elsewhere. In northern California, trials are available throughout the system. Patient participation in clinical trials is less the result of a selection process than an attempt to identify potential participants and inquire about their desire to participate. Kaiser relies heavily on physicians to identify people who might be eligible for clinical trials.
- Many Phase III trials are open to Kaiser members, as are some Phase II trials. A number of Phase I and II trials for novel therapeutic agents are also anticipated in the near future. Kaiser's decision to participate in these trials will be based on the scientific value of the study and the likelihood that the novel therapy will offer benefit. It is Kaiser's strong preference to offer clinical trials within its system rather than referring patients to other facilities.
- Comprehensive cancer centers have a major role in developing clinical trials and establishing the research infrastructure to evaluate them; however, increased competition in the health care marketplace is likely to limit the number of patients available to the centers. To address this issue, the UCLA Jonsson Cancer Center has formed partnerships with high-quality community-based oncology practices. Research nurses and data managers are hired from the communities and are supervised by the Jonsson Cancer Center Clinical Research Unit. The Center subsequently works with the hospitals and practices to establish research pharmacies and to obtain Institutional Review Board (IRB) approvals.
- At present, UCLA funds the research nurses and data managers, which is very expensive. Funds obtained through philanthropic activities, such as the Revlon Run-Walk, are used to offset some costs. UCLA forwards any reimbursement associated with the trials to the physician practice. In the future, UCLA hopes that sufficient resources will accompany the trials to fund the support costs. Dr. Gasson underscored that a critical mass of resources is needed for infrastructure development. Once the infrastructure is in place, patients can accrue to clinical trials more rapidly. Thus, the first patient is the most expensive and the cost per patient decreases with subsequent accruals.
- UCLA has reached out to Kaiser and to community physicians to elicit participation in its trials of novel therapeutic agents. Kaiser participates in one UCLA trial, but accrual has not been strong. The trial is located in Woodland Hills and in Riverside, California. These sites were selected due to the interest of the specific oncologists working in those settings in participating in the trial, and the fact that Kaiser was not offering other trials in that setting. At present, UCLA accrues one or more patients per day from approximately 20 practices and 50 physicians. UCLA expects to accrue more than 1,000 patients per year through such network sites as more community practices achieve full participation.
- Dr. Calabresi questioned the disparity between the limited percent of revenues the managed care industry devotes to research compared with industries such as the pharmaceutical industry, the automobile industry, General Electric, and others that invest approximately 15 percent of revenues into research and development. Dr. Petitti suggested that an accounting of investment by managed care varies depending on how research is counted and tracked. Kaiser invests substantially in operations research, program evaluation, and information systems. Consumer pressure to contain premium costs acts as a negative incentive to invest in medical research.
- Dr. Schuster indicated that his work has shown that a black woman in the United States with a T1 or T2 breast cancer is only half as likely as a white woman with the same type of

tumor to receive treatment with curative intent. This disparity accounts for 40 to 50 percent of the mortality difference between black and white women with breast cancer. Asked if Kaiser has studied this phenomenon, Dr. Petitti indicated that data from an unpublished study of women diagnosed with breast cancer in the Kaiser system in the 1980s demonstrated no difference in 10-year survival rates according to ethnicity once adjustment for stage at diagnosis was made. Dr. Petitti acknowledged, however, that ethnic differences in survival rates by stage do persist in the Kaiser population.

- Although people tend to believe that new and expensive treatments are better, research may actually demonstrate that the less expensive approaches may be more effective.
- In response to an audience question concerning what is being done to study breast cancer among black women, Dr. Brawley indicated that a great deal of data exist. NCI studies, for example, show that equal treatment yields equal outcome, regardless of race. There is no biological difference in breast cancer in white versus black women; however, race may be a factor in whether or not one enters the system and receives equivalent treatment.

QUALITY CANCER CARE: HUMANA POLICY AND RESEARCH PERSPECTIVE—Dr. Mitzi Krockover

Background

Humana is now a managed care/health services organization that no longer owns hospitals and currently covers approximately 6.4 million lives in commercial accounts, Medicaid, Medicare, and the military health system (CHAMPUS). Humana's approach to health care and to quality is population based.

Key Points

- Women in HMOs are more likely to obtain mammograms, pap smears, and clinical breast exams (CBE) than women under fee-for-service (FFS) plans. Compared with FFS, HMOs improve access to preventive services for women with low levels of education. Cancer screening is more readily available to HMO enrollees and vulnerable groups are more likely to receive screening.
- Data from a variety of studies indicate that Medicare HMO patients are diagnosed at earlier stages than FFS patients with melanoma, breast, cervical, and colon cancers. Treatment and outcomes related to colorectal cancer are similar between HMOs and FFS plans. No significant differences between Medicare HMO and FFS patients were demonstrated in symptoms duration prior to diagnosis, training of physicians rendering diagnoses, type of primary tumor, anatomic location of the tumor, disease stage, or survival rate. Another study demonstrated that low-income prostate cancer patients in HMOs live longer than FFS patients.
- Humana's highest utilizers of health care are its sickest members. The top 10 percent of Humana's highest utilizers have two or more chronic diseases and approximately one-third have one chronic disease or one primary chronic disease. In the aggregate, most of these individuals suffer from approximately 30 conditions; identifying this cluster of conditions in this population has helped Humana to focus efforts related to quality measurement.
- A number of interventions affect quality of care: use of care guidelines; case management to provide continuity of care; member education to ensure understanding; provider education; provider profiling to compare individual practice patterns with peers; patient profiling; and risk-sharing initiatives aimed at provider behavior change, among others.
- In 1994, Humana developed a breast cancer-related program in the Chicago area that was designed to standardize and coordinate services; improve consistency in imaging report

terminology and recommendations; improve consistency in mammography image quality; and reduce the time from identification of an abnormality to problem resolution. A multidisciplinary breast care committee was convened, including internists, oncologists, radiologists, surgeons, nurses, and administrative staff. Program goals included: developing a system to improve care coordination and evaluation for women undergoing mammography; standardizing coding and mammography reporting; developing a database management system; developing a quality control system based on data from the breast care management system; and achieving American College of Radiology (ACR) accreditation.

- The breast care coordinator and the breast care team used a computerized database to track the data needed to provide outcome reports and support the delivery of quality care. The system recorded standardized mammography results and the patient and physician were notified immediately regarding a questionable finding. Patients with positive findings were tracked to ensure followup testing and treatment. Primary care physicians were notified as to patient adherence with recommended followup or treatment. Radiologic and surgical performance outcomes were monitored, and the system also generated screening reminders to primary care physicians and patients.
- Timeliness of care was measured by the mean or median time between abnormal mammogram detection and biopsy and from biopsy to surgery, if necessary. Clinical outcome measures included the percent of newly diagnosed Stage I breast cancers and results from a patient satisfaction survey.
- Radiologic quality control measures included film and equipment quality, level of mammographer certification, and ACR accreditation.
- Quality is a feedback loop between research, data, and the patient care that generates the data that educates the plan and providers. Optimal appropriation of care is achieved through the most appropriate use of both resources (cost) and quality measures.

DISCUSSION—Dr. Krockover

Key Points

- Actual cost savings associated with the Humana breast care management program have not been assessed. Since Humana is moving away from a staff-model approach to care, the program itself may not be replicated in other settings; however, certain of its components may be implemented (e.g., community partnerships) in other areas.
- Case managers at Humana are individuals assigned to a member who has been identified as needing either support, services, facilitation, or education.
- Humana uses care guidelines developed by a variety of organizations; it is recognized that these may not all be evidence based, but the plan is trying to move in that direction.
- Regarding the Humana study that concluded that low-income prostate cancer patients in HMOs live longer, Dr. Krockover indicated that the study showed that for all prostate cancer patients, over a 6-1/2 year period, lifespan was increased for patients enrolled in an HMO versus FFS plan. Such differences were observed to be greater for low-income individuals. Dr. Freeman suggested that the study period was extremely short given that prostate cancer progresses very slowly, and that these results might not apply to the low-income uninsured.

PRESENTATION HIGHLIGHTS: Cancer Prevention

HEALTHY AND AT-RISK POPULATIONS—Dr. Roshan Bastani

Key Points

- Recruitment and retention of minorities is an essential element of research planning. Similarly, incorporating all segments of the population into quality assurance planning is vital.
- Minorities must be actively recruited from the communities in which they live, work, and receive health care to ensure their participation in cancer research. This principle also applies to the provision of quality health care to minority populations.
- Research results derived from studies of the general population are not necessarily applicable to minority populations. For example, mammography rates in Los Angeles County were found to be drastically different from the statewide average for all ethnic groups; it was also discovered that physician referral for screening mammography had a major influence on target women. An intervention was planned to ensure that every eligible woman received such a referral. It is essential to conduct interventions that are theoretically driven and to tailor the interventions for target audiences. UCLA has adopted a theoretical model and related interventions to measure outcomes related to adherence and psychological distress related to abnormal mammography results.
- Local studies of knowledge levels about breast cancer risk factors and other information revealed that there were more similarities among ethnic groups than there were differences. It is incorrect, however, to assume that similarities in selected areas, such as specific knowledge and attitudes, will translate into similarities in other areas, such as receptivity to programs and educational materials. To ensure broad appeal, program elements must be tailored with respect to ethnicity, gender, income, and education. In addition, it must not be assumed that people who are not white are poor and uneducated. These concepts apply equally to research and to the delivery of quality care.

MOLECULAR EPIDEMIOLOGY—Dr. Ronald Ross

Key Points

- The medical community's acceptance of treatment side effects depends on the indication for treatment. Short- and long-term side effects of treatment for life-threatening conditions are obviously much more acceptable than when treatment is for less severe conditions. For example, for patients treated with chemotherapy for testicular cancer there is a very wide tolerance for side effects. Due to medical advances, the survival rate for germ cell testicular cancers has risen from nearly zero percent to more than 80 percent. Since testicular cancer patients are living longer, and some have survived 15 to 20 years following their treatment, some of the long-term toxic effects of their chemotherapy are now emerging. Cisplatin, one of the key drugs in the therapeutic regimen, is toxic to the kidneys, cardiovascular system, and neurologic system. The full impact of this drug is unknown. Also unknown is information about the quality of life for testicular cancer survivors (e.g., ability to secure and maintain employment, quality of reproductive experiences). But whatever the long-term effects, they are accepted because they occur in the context of treating life-threatening conditions.
- The medical community must have a much lower acceptance for medication side effects when medications are provided as elective therapies, such as estrogen replacement therapy for menopausal symptoms or analgesics for mild headaches or muscular aches and pains.

- Tolerance for major medication side effects must be absolutely minimal when used for prevention-related therapy in otherwise healthy populations.
- Tamoxifen is an excellent adjuvant therapy for breast cancer treatment and for breast cancer prevention in healthy populations. Recent clinical trials reveal that tamoxifen also substantially reduces the risk of sustaining a major osteoporotic fracture; however, there are associated small but real increases in endometrial cancer risk. This increased risk for endometrial cancer may result in caution among the scientific and lay communities in recommending tamoxifen as a breast cancer preventative for the healthy population as a whole.
- Experience to date with tamoxifen has led to increased interest in other antiestrogen drugs, referred to as Selective Estrogen Receptor Modulators (SERMs), such as raloxifene. SERMs are designed to maintain the preventive effect of tamoxifen for breast cancer, without some of the purported risks, but have not yet been tested adequately.
- Finasteride, an example of a preventive therapy for prostate cancer, selectively blocks the enzyme that activates testosterone to dihydrotestosterone, which causes prostate cells to grow and divide. A national clinical trial is under way to evaluate the impact of finasteride on prostate cancer prevention in healthy men, including identification of potential side effects. Controversy remains concerning the drug's impact; in fact, some believe that finasteride may selectively stimulate certain precancerous lesions in the prostate. The medical community must have a lower tolerance for any serious side effects when prescribing drugs to otherwise healthy populations.
- Other types of iatrogenic therapies, such as low-dose radiation, have associated risks and benefits. Though radiation is a known carcinogen, as a specific therapy, tolerance for its associated acute or chronic side effect risks is higher than if it were given for diagnostic purposes.
- Aspirin is an effective, wide-spectrum, anti-inflammatory agent. It is also a wide-spectrum analgesic, useful in treating headaches and all types of muscle aches and pains. Aspirin has been recognized as effective for preventing second heart attacks in men and women, and is a primary preventive agent for heart attacks in healthy men and, logically, in healthy women. Aspirin is now being promoted as an agent that may prevent colon cancer because it reduces the rate of division of cells in the colon lining.
- The principal outgrowth of Harvard's Physician's Health Study was the recommendation that low-dose aspirin should be used to prevent myocardial infarction. A lesser finding was that aspirin use was associated with a small increase in the risk of both fatal and nonfatal strokes. Notably, however, there was no decline in overall cardiovascular-related and noncardiovascular-related mortality. Questions remain whether aspirin is a good drug for reducing overall mortality through cardiovascular disease prevention when balanced against its risks, such as ulcers, gastrointestinal bleeding, and stroke.
- There has been less study of the possible cancer-causing properties of analgesics. Phenacetin, an active ingredient in analgesics popular in Europe and the United States in the late 1950s, '60s, and '70s, is a known Class I carcinogen that causes renal pelvis cancer. Evidence that analgesics cause cancer of the renal pelvis is not limited to phenacetin, but also includes acetaminophen (the major active ingredient of phenacetin) as well as aspirin, which is known to be toxic to the kidneys.
- Approximately 10 years ago, investigators at UCLA began a major study to determine whether or not analgesics could cause cancer in the body of the kidney, i.e., renal-cell

carcinoma or renal parenchymal cancer, as it was well established that these could cause renal pelvis cancer. Study results revealed that regular users of acetaminophen or phenacetin had twice the level of kidney cancer risk compared with nonusers; risk also increased with increased cumulative dose. Aspirin and other nonsteroidal anti-inflammatories carried slightly lower but statistically significant increases in risks. Lower doses associated with cardiovascular disease prevention (e.g., one aspirin a day or less, even for long periods) did not demonstrate increased risk, but aspirin at higher doses for 10 or more years was associated with an almost fivefold greater risk compared with nonusers. Thus, physicians should carefully instruct patients about the regular use of these drugs.

- Early studies conducted in the 1970s revealed that estrogen therapy caused endometrial cancer. This observation led to a marked drop in the use of estrogen replacement therapy among American women and to a marked reduction in the usual dose prescribed. These studies also resulted in increased use of progestin to protect the endometrium. Estrogen replacement therapy substantially reduces risks associated with hot flashes, osteoporosis and associated fractures, and heart disease. The impact of estrogen replacement therapy on breast cancer risk is unknown. Such therapy may result in a modest increase in breast cancer risk of approximately 2 percent per year. Thus, after 10 years of therapy, breast cancer risk would be increased approximately 20 percent relative to nonusers. Recent evidence also indicates that estrogen increases the risk of thrombotic events.
- There is current interest in whether or not estrogens reduce the risk of presenile dementia such as Alzheimer's disease as well as the risk of colon cancer; minimal clinical evidence currently exists.
- Risk-benefit modeling was used to calculate the impact of long-term (10 years) low-dose estrogen replacement therapy on mortality rates. The benefits of such therapy (e.g., fewer deaths from heart disease and hip fractures) appear to exceed the risks (e.g., breast and endometrial cancers). These findings do not necessarily indicate that estrogen therapy is recommended for all women. For every breast cancer death, approximately six heart disease deaths would be prevented. Despite this significant benefit, any increase in breast cancer risk might be unacceptable to some patients. Providers must be aware of the risks and benefits of alternative treatment approaches, and patients must be educated about them and play an active role in determining their course of therapy.

CANCER PREVENTION IN WOMEN OF COLOR—Dr. Antronette Yancey

Key Points

- UCLA has conducted recent research in the primary prevention of cancer and other chronic diseases through community-based, lifestyle change intervention. Early evidence suggests that voluntary changes in diet and exercise decrease circulating estrogen levels and that weight loss is associated with reduced breast cancer incidence.
- One of the largest gaps in the cancer prevention literature is how to produce and sustain lifestyle change, especially in high-risk populations such as African-American women. African-American cancer incidence and mortality rates are higher than those of other major racial and ethnic groups. African-American women are the major ethnic and gender group in the United States at highest risk for obesity, excess dietary fat, and low activity levels.
- Literature reviews conducted in the last several years revealed a lack of cancer prevention research involving interventions in physical activity and diet for populations of color.

- UCLA conducted a pilot study to assess its ability to recruit middle-income, relatively well-educated (e.g., about 15 years of formal education), African-American women into a lifestyle change study and to identify appropriate incentives. Study goals included identifying correlates of leanness and obesity in African-American women and evaluating the success of various recruitment strategies. Recruitment strategies for African-American women varied by education and level of obesity. Women with higher education levels were more likely to be recruited through print and electronic media than women with less formal education. Personal recruitment strategies (personal contacts with friends, relatives, and coworkers) were more successful in recruiting obese women. Study findings will be published in the May issue of the American Journal of Health Promotion.
- A second study involving conduct of onsite physical activity programs demonstrated that key organization-specific factors contributing to success in developing and sustaining such fitness promotion activities were pre-existing group cohesion, social support, and site leadership commitment.
- “ROCK Richmond!” a community fitness promotion effort currently under way in Richmond, Virginia, is focused on increasing community involvement in healthy eating and exercise practices. Through this project, more than 800 people receive direct service (free fitness instruction) weekly and 2,500 to 3,000 people have been involved in special events. Most project participants are overweight, female, African-American, and at high risk for chronic diseases.

DISCUSSION—Drs. Bastani, Ross, and Yancey

- What we perceive as good-quality care may not be what is valued by various populations. For example, telephone counseling is a way of providing care or information, but limited research has found that various populations tend to be more (e.g., Hispanics) or less (e.g., Asians) comfortable with this method of intervention.
- Combined efforts to improve diet and promote healthier living through exercise will be successful. Previously, most of the focus in cancer prevention, especially weight loss, has related to nutrition. Other prevention efforts have concentrated almost exclusively on increased levels of exercise. The synergy between these two approaches must be harnessed if people are going to achieve and sustain substantial weight loss. Methods to institutionalize social support have not been well established.
- It is incumbent upon public health professionals, especially cancer prevention specialists, to find ways to enable people to be more active as part of their regular routines.
- Recommendations concerning various interventions, whether preventive or related to elective therapies, should be based on the results of population studies identifying the entire gamut of associated risks and benefits of such interventions. Study results can then be applied at the individual level by taking into account specific patient characteristics.

PRESENTATION HIGHLIGHTS: Cancer Control

QUALITY OF LIFE IN BREAST CANCER SURVIVORS—Dr. Patricia Ganz

Key Points

- An implied goal of all therapies for patients with cancer is quality of life. However, quality-of-life measurement has been difficult until the last 10 to 15 years when health services researchers and social scientists have begun to systematically collect information from patients regarding their quality of life.

- Recent research at the Jonsson Comprehensive Cancer Center has focused on the impact of adjuvant therapy on the quality of life for breast cancer survivors 1 to 5 years following diagnosis. Except for differences in body image, quality of life during recovery is similar for women having either mastectomy or breast-conserving surgery. Less is known about the impact of adjuvant therapies on patients' daily lives, level of functioning (physical, emotional, and sexual), and other measures of quality of life. The study included an ethnically diverse population of women with early breast cancer (noninvasive, Stage 1 or Stage 2). Study participants completed a comprehensive survey instrument that collected detailed medical and demographic information. Use of this questionnaire enabled comparisons to be performed with women who did not have major health problems. The Centers for Epidemiologic Studies-Depression (CES-D), a standardized measure of depression, was used to compare depression levels between healthy women and breast cancer survivors. Other measures were used to assess levels of sexual functioning and body image.
- Nearly 1,100 women aged 25 to 90 years completed the survey instrument. On average, participants were nearly 3 years postdiagnosis and had recovered from treatment. At least 69 percent were either married or involved in a committed relationship. Approximately 62 percent of the women had breast-conserving surgery, approximately 22 percent had mastectomy without reconstruction, and a sizeable portion had mastectomy with reconstruction.
- Approximately 24 percent had no therapy beyond surgery or surgery with radiation as their primary treatment. These were mostly women with early-stage disease, such as Stage 0 or 1. Approximately 16 percent had chemotherapy alone and 32 percent received tamoxifen alone.
- Treatment differed somewhat by age. Women who had no adjuvant therapy were on average approximately 55 years old. Those taking tamoxifen were somewhat older (about age 63) because tamoxifen alone is a more common treatment for older postmenopausal women. Those receiving chemotherapy alone were the youngest (average 47 years), and those receiving chemotherapy and tamoxifen averaged about 53 years of age.
- Type of surgery received also differed among the study group. Those who had favorable prognoses and needed no adjuvant therapy had somewhat higher rates of breast-conserving surgery compared with others, with the lowest rates of conservative surgery occurring in women who needed chemotherapy and tamoxifen (50 percent).
- Although unexpected, differences in the time since diagnosis were observed. Women receiving chemotherapy and tamoxifen were somewhat further out from their diagnosis.
- Breast cancer survivors are virtually precluded from receiving hormone replacement therapy (HRT) because of the association of breast cancer and exogenous hormones. Of the women who did not receive any adjuvant therapy and were not receiving HRT, approximately 40 percent reported having hot flashes. Sixty percent of women receiving tamoxifen alone reported hot flashes. Of those receiving chemotherapy alone, 50 percent reported hot flashes, and women receiving chemotherapy and tamoxifen reported the highest rate of hot flashes. Thus, the likelihood of hot flashes varied significantly by treatment group; more intensive therapy was associated with a greater chance of hot flashes, although the symptom was fairly frequent even among women receiving only surgery or surgery and radiation.

- Vaginal dryness, also related to hormone deficiency, was common even in study participants who had not received adjuvant therapy. There was a significant relationship between vaginal dryness and pain during intercourse in women who received chemotherapy; thus, chemotherapy leads to late toxicity contributing to sexual dysfunction in breast cancer survivors.
- Women have a tendency to gain weight after a diagnosis of breast cancer. Previously, this was attributed to chemotherapy, and possibly to the use of steroids as an antiemetic. Self-reported weight gain in the study population, however, was not significantly different among study participants. Body image concerns were a significant issue in the study population, but were not strongly related to type of adjuvant therapy.
- Generic measures of health-related quality of life (e.g., aspects of physical functioning, social and emotional functioning, pain, energy, fatigue, and general health perceptions) did not reveal significant differences by treatment type, except that women receiving some form of adjuvant therapy had more difficulty in physical functioning than those who did not.

Additional Research Needs and Other Recommendations

- Cancer survivors must be active participants in quality-of-life research.
- Additional study is warranted to examine the impact of adjuvant therapy on physical and sexual functioning for breast cancer survivors.

QUALITY OF LIFE IN PROSTATE CANCER SURVIVORS—Dr. Mark Litwin

Key Points

- According to the Donabedian model of quality-of-care assessment, quality of care can be best assessed by looking at its three major components: the structure of care, process, and outcome. The structure of care refers, for example, to provider mix in a managed care organization, access to specialists in one health care system or another, or demographic differences in one population versus another. Process refers to what actually occurs between the clinician and patient (e.g., what tests or referrals are made or ordered, what the interaction includes, and treatments recommended). Outcome refers to what happens to the patient as a result of the care process. Common disease-oriented outcome measures include morbidity, mortality, and clinical variables such as prostate specific antigen (PSA) levels related to prostate treatment and disease recurrence. Patient-centered outcomes include satisfaction with care and health-related quality of life.
- Quality of life consists of a number of general domains including, for example, physical function, social interactions, and mental health. Cancer-specific domains include anxiety about recurrence, difficulty concentrating, weight loss, fatigue, and loss of appetite. Other quality-of-life issues related to cancer type may also emerge; with prostate cancer, these may include issues related to sexual, urinary, and bowel dysfunctions.
- In certain respects, quality-of-life research in prostate cancer is in its adolescence. One of the early lessons to emerge is that the degree of dysfunction and the degree of “bother” from that dysfunction are discrete phenomena.
- The UCLA/RAND Quality of Life Project examined quality of life in 1,000 men with early-stage, clinically localized prostate cancer from a large managed care population in southern California. Study data suggested that there were no discernable differences between the study and control populations regarding physical function, social interactions,

mental health, and pain, among other measures, regardless of whether they underwent surgery, radiation, or received no treatment at all.

- In a similar study, approximately one-third of men undergoing radical prostatectomy needed to use devices to control incontinence; approximately one-half of these men felt this posed a significant problem. Only one-third of men who were potent prior to surgery and lost potency after surgery felt that this was a major problem. Almost 40 percent indicated that they were unable to have erections, but also indicated that it was not a problem. These findings further emphasized the dissonance between function and bother in these domains—although some men experience significant urinary and sexual dysfunction after prostate cancer treatment, in general, they tend to have reasonably good overall physical and mental functioning. Despite the potential dysfunctions that can occur following prostate surgery, 64 percent indicated that they would still select surgery as their treatment of choice.
- A University of Miami study of prostate cancer patients receiving surgery versus radiotherapy produced similar results; there were no significant differences between these patient groups with respect to emotional and some physical measures.
- According to research conducted at the University of Connecticut, patients' quality of life decreased as the degree of disease advanced. Though this finding may be somewhat intuitive, it is one of the earliest studies to demonstrate the ability to predict degree of disease purely by quality-of-life measures. Dr. Ganz' work likewise indicates that patients' cancers can be staged relatively accurately without direct contact based on their performance on some quality-of-life measures.
- Significant variation exists in quality-of-life-related data, depending upon the data collection methodology used. Written, self-reported data are generally the most reliable. For example, only 4 percent of urologists performing a routine postsurgical assessment of prostate cancer patients reported that the patient was experiencing significant impairment; in contrast, 35 percent of the patients reported significant impairment.

Additional Research Needs and Other Recommendations

- Quality-of-life instruments should be cancer-specific, as certain cancers and their treatment approaches have varying impact on patients' quality of life. Self-administration of quality-of-life instruments is highly important.
- Findings from quality-of-life studies need to be presented before any prostate cancer-related treatment is undertaken and prior to making treatment decisions. There is no room for paternalism in the decision-making process. Patients must make informed decisions, taking into account their expectations concerning recovery and anticipated quality-of-life levels after treatment for prostate cancer.

DISCUSSION—Drs. Ganz and Litwin

Key Points

- Among men undergoing radical prostatectomy, younger patients tend to have better baseline quality of life and function and are more likely to return to that baseline following surgery. Younger patients, therefore, have a better chance of maintaining both general quality of life and sexual, urinary, and bowel functions. Findings from an American Cancer Society-funded study indicate that younger patients are less willing to tolerate any risk for impotence and incontinence. However, these patients, assessed immediately after treatment and 6 months after therapy, tended to adjust to potency- and continence-related dysfunction quite well.

- According to Dr. Litwin, the available evidence does not support the contention that PSA screening decreases mortality in the general population; therefore, routine PSA screening cannot be recommended from an epidemiologic perspective. Since the advent of PSA screening, there has been a substantial stage migration to earlier stages of prostate cancer that presumably are more curable. As a result, more men are undergoing radical prostatectomy. It is unclear to what extent men, particularly in poor communities, are being counseled about the possible major side effects of prostate cancer treatment. Of interest, in a randomized, controlled trial of men who were offered PSA screening with varying levels of discussion devoted to the risks and benefits of screening, patients were three to four times less interested in obtaining PSA screening as their knowledge of the associated benefits and risks increased. This tendency (intervention effect) was eliminated if the patient had personal family experience with prostate cancer.
- Since there is no evidence that population-based PSA screening in healthy men decreases population mortality from prostate cancer (though such evidence may surface in five to ten years), Dr. Litwin disagrees with the American Cancer Society and the American Urological Society's recommendation that men over age 50 should have PSA screening performed routinely. The exceptions are the particularly young patient with first-degree relatives with prostate cancer or the African-American patient, who is likely to have a higher genetic risk for prostate cancer. In the general population, however, if all cases of prostate cancer were detected through 100 percent screening, the United States would not have sufficient resources to treat them.
- Urologists' data regarding treatment outcomes is based on patient reporting, but patients often minimize their symptoms and tend to want to please their physicians. It may also be true that the survey instrument does not ask the right questions (or ask them the right way) or the physician may not be listening for the information. Regardless of the reason, the importance of conducting quality-of-life research by surveying patients directly is clear.
- It is too early to identify the impact of seed-implant radiation therapy on symptom improvement in prostate cancer patients. Only 6 or 7 years of data related to the use of modern techniques are available.
- It has been assumed that tamoxifen universally reduces the risk of osteoporosis. A recent article in the *Journal of Clinical Oncology*, however, indicated that osteoporosis actually increased in premenopausal women taking tamoxifen on a prevention trial. Studies of postmenopausal women showed that bone density was preserved with tamoxifen in postmenopausal women receiving adjuvant therapy. These studies have only recently been replicated in premenopausal women, where an attempt was made to preserve bone with the new bisphosphonates on a prevention trial. In a British prevention trial, premenopausal patients given tamoxifen for prevention experienced bone loss within the first 2 years of starting the drug. There is a bone substudy currently under way in the Breast Cancer Prevention Trial; however, data are not yet available. It is possible that premenopausal women taking tamoxifen experience an initial loss of bone that subsequently stabilizes.
- In Dr. Litwin's research, patients whose prostate cancer was being managed with watchful waiting alone had significantly higher levels of anxiety about recurrence and mental health disturbances. In every other quality-of-life domain, they were indistinguishable from patients who were never diagnosed with prostate cancer. Watchful-waiting patients and control patients were similar with respect to sexual, urinary, and bowel functions. Those who had radical prostatectomy or radiation therapy had significant problems in those areas.

- Dr. Litwin indicated that though Gleason scores were assessed, they were not used as control factors in his study. He concurred with Dr. Calabresi's statement that Gleason scores typically make a difference in determining whether patients receive treatment or watchful waiting. According to Dr. Litwin, the biggest difference between the patient populations is with respect to mortality; those with higher Gleason scores are more likely to drop out of the sample because they die from Gleason-8 prostate cancer.

Additional Research Needs and Other Recommendations

- Many women who receive adjuvant therapy for breast cancer are never told that the therapy will cause them to become prematurely menopausal, or even that premature menopause is a risk associated with the therapy. As a quality-of-care issue, it is important to communicate what life will be like after breast cancer treatment. Women will tolerate an outcome if they have been prepared for its possibility. Many physicians do not have the relevant information readily available.
- It is the responsibility of the health care system to develop alternative strategies to address these issues. Many of the women treated for breast cancer can expect to live a very long time as a result of that treatment, but they should be aware of the possible negative outcomes that may accompany it. For some women, small differences in survival benefit associated with certain treatment regimens may not be worth the everyday experience of related treatment side effects.
- To get information on treatment outcomes to patients, physicians, and policy makers, the relevant data must be systematically collected, along with descriptions of what people actually experience. This information must be translated into educational tools, and patients and providers must be instructed in their use. As new treatments and technologies are developed, it will be very important to collect these outcome data so that patients can make informed decisions about their use; the experience with autologous bone marrow transplant for breast cancer underscores this need.

PRESENTATION HIGHLIGHTS: Care and Survivorship

IMPERATIVES FOR CANCER CARE—Ms. Susan Leigh

Key Points

- Well-trained oncology nurses and social workers are essential to the delivery of high-quality care for cancer patients. There is a need to protect the integrity of oncology nursing and social work, because many oncology units nationwide are closing due to the rise of managed care. Oncology patients increasingly are assimilated into the general services in hospitals, and nurses who are not trained in oncology are delivering chemotherapy.
- Once patients have been treated for one cancer, they are at risk for recurrence of their primary cancer, developing other cancers, experiencing late effects of therapy, and organ system failures. Therefore, quality-of-life issues and quality cancer care must be examined as a continuum of cancer survivorship beginning at the point of diagnosis and extending for the duration of the patient's life.
- There is no guarantee that an initial cancer will not reappear, even if the patient is cancer free for 5 years following diagnosis. Recurrence is still possible, as are second primary cancers and organ system problems resulting from cancer treatment. Rather than focusing on the 5-year mark, many survivors focus on living life as effectively and as fully as possible as soon as possible after diagnosis.

- The NCCS surveyed 300 oncology professionals, including cancer center administrators, cancer and health services researchers, health economists, patient survivor support and advocacy organization leaders, the pharmaceutical industry, and payers. The survey addressed three domains. First, it focused on defining quality cancer care by comparing and contrasting fee-for-service and managed care. Second, it attempted to define psychosocial issues and their implications for total quality care. Lastly, it sought to define long-term followup care and its implications for total quality care.
- Survey results were published by the NCCS in *Imperatives for Quality Cancer Care* in May 1996; this publication is available at no cost. It is also available on the NCI's web site. The chapters dealing with psychosocial and physiologic long-term and late effects served as the inspiration for the creation of the NCI's Office of Cancer Survivorship. The original imperatives identified by NCCS have been adapted and used by scores of cancer organizations including the American Cancer Society (ACS), the American Society of Clinical Oncology (ASCO), the Oncology Nursing Society (ONS), and the American Federation of Clinical Oncology Services (AFCOS).
- Presently, the Cancer Leadership Council, a patient-led and patient-focused forum for issues related to quality of care for people with cancer, is working to modify the imperatives. Organizations involved in the revision of the imperatives include: NCCS, Cancer Care, the Susan G. Komen Breast Cancer Foundation, the National Alliance of Breast Cancer Organizations, Y-Me National Breast Cancer Organization, Candlelighters Childhood Cancer Foundation, the North American Brain Tumor Coalition, and the US-TOO International Prostate Support Organization. Also contributing to the writing of the revised imperatives were ACS, ASCO, ONS, AFCOS, the Leukemia Society of America, and the National Breast Cancer Coalition.
- In a rapidly changing health care environment where patients are managed, costs are controlled, and relationships between patients and physicians are monitored, maintaining the quality of health care can be difficult. The Cancer Leadership Council has developed 10 principles that will help achieve its goal of ensuring that all Americans have access to quality cancer care:
 1. All obstacles to access and coverage based on pre-existing conditions, genetics, or other risk factors must be eliminated.
 2. All persons with cancer and their families must have access to complete and accurate information related to their diagnosis, treatment options, and the anticipated benefits and risks of treatment to allow them to be full partners in decision making.
 3. All people should have timely access to screening; preventive services; early detection; initial treatment; supportive therapies to manage pain, nausea, fatigue, and infection; long-term followup; psychosocial services; palliative care; hospice care; and bereavement counseling.
 4. In the presence of any indications of cancer, the patient must be referred to a cancer specialist for timely confirmation of diagnosis.
 5. All people with cancer should have access to care that is planned, coordinated, and delivered by a multidisciplinary team of oncology professionals across the full continuum of care.
 6. Payers must provide ready and continuing access to pediatric specialists, recognizing that childhood cancers are biologically distinct. Though pediatricians are doing an excellent job in following young patients into adulthood, there are no transition clinics

to support the patient when he or she leaves the pediatric specialist and obtains other sources of care. The adult survivor of pediatric cancer is different from the adult survivor of adult cancers. Pediatric specialists are seeking to define transitional care to ensure that survivors entering adulthood understand the care they need and that the adult medical community understands how to care for them. The absence of transition support is evident in the number of pediatric oncologists who continue to follow their adult cancer survivors into their thirties and forties.

7. Standards of cancer care should be driven by quality of care, not only cost, and should include participation in clinical trials with quality-of-life considerations. We must look at the best of the business and medical worlds and develop a focus on health promotion, disease prevention, rehabilitative services, and identification and treatment of the physiologic and psychosocial effects of care. There are virtually no standards of care for long-term cancer survivors. If the health care system limits access to oncologists to a restricted period of time, who will develop the cancer care-related standards for primary care physicians? Patients will need to assume responsibility for understanding and communicating care plans to their primary care physicians.
 8. People living with cancer and long-term survivors should have access to specialized followup care focused on health promotion, disease prevention, a full range of rehabilitative services, and identification and treatment of physiologic and psychosocial effects. There are few, if any, standards of care for long-term survivors.
 9. People with cancer must have access to end-of-life services, including symptom management, psychosocial services, hospice care, and bereavement counseling. Cost-effectiveness must also be examined in light of the cost of suffering and its contribution in the overall health care equation.
 10. Patients with cancer, and their families, must have access to culturally sensitive cancer information, counseling, and care.
- The majority of Americans, not just historically disadvantaged populations, are now at risk of not having access to appropriate cancer care.
 - Weighing the qualitative experience of people with cancer with the critical, quantifiable evidence of what works best in cancer care is critically important. The value of patients' perceptions of their experiences must be recognized as an integral measure of the quality of their care. In the coming months, NCCS will work closely with others who share this agenda, including the Institute of Medicine's National Cancer Policy Board, the President's Commission on Quality Health Care, the Health Care Quality Alliance, the Measurement Advisory Panel of the National Committee on Quality Assurance, the Robert Wood Johnson Foundation's National Advisory Commission of Care at the End of Life, the Foundation for Accountability, and the Progressive Foundation.
 - NCCS efforts to develop standardized care guidelines and quality measures will focus on the following domains: provider accreditation, health plan initiatives, use of practice guidelines, outcome measures, and accountability.

Additional Research Needs and Other Recommendations

- Continued care for adult cancer survivors could be modeled after the long-term followup available in pediatric oncology.
- The movement toward accountability in health care is very important. Quality report cards should be developed that can be easily understood by consumers and should contain useful

outcome information. Community-based support and advocacy groups need to interpret the information and tailor it to their populations.

- The human experience must be incorporated into the quality-of-care assessment process. There is no such thing as a generic cancer patient, and we currently lack adequate ways of measuring terror, fear, anxiety, social stigma, sadness, loss, emotional distress, financial burden, and suffering. Progress will come from understanding and valuing personal experience rather than only identifying and applying systemic solutions.

DISCUSSION—Ms. Leigh

Key Points

- Establishment of the NCI Director's 15-member Consumer Liaison Group was a major step toward collaboration between the advocacy community and the research and medical communities regarding evidence-based medicine and evidence-based decision making. The National Breast Cancer Coalition's Project Lead has been highly successful in teaching advocates and activists about relevant scientific issues so that they can participate effectively in such discussions.
- Ms. Visco suggested that the advocacy community might be particularly effective in shaping public policy as it relates to managed care and third-party payer systems. She noted that observations related to quality of care (particularly criticism) are perhaps more an outgrowth of health care system changes, such as limited access, and may have nothing to do with evidenced-based medicine. Advocates and their constituencies must become more educated about the importance of evidence-based care.
- In June 1998, the President's Cancer Panel will hold a special meeting at Yale University focusing on cancer survivorship.
- Effective methods do not exist for following cancer survivors for second tumors. More studies should be performed to determine the cancer prevention needs of survivors compared with those of the general population. Further, rehabilitation for cancer has lagged far behind rehabilitation for other types of disease. For example, patients who have heart attacks are immediately enrolled in some type of rehabilitation program, yet these patients frequently do not live as long as cancer survivors.
- It has been observed that the best model for rehabilitation in oncology has been hospice. However, there are now more than 4 million cancer survivors who have survived for more than 5 years. Survivors want to know how to be healthy after their disease. Researchers need to be encouraged to develop research protocols to examine survivorship issues, including issues of long-term survivorship.
- Research is needed to identify protective agents that in combination with chemotherapy may reduce the long-range risk of heart disease, pulmonary disease, or neurological disease. The NIH and the Food and Drug Administration should more vigorously pursue research in these areas.
- Ms. Leigh observed that standards are often developed based on cost rather than quality. This is distressing to many who believe that quality of care must be part of the equation. It is disturbing to see business people making decisions that should be made by patients and their physicians or by the medical community in conjunction with advocates. This situation is unlikely to change until the country is united in expressing concern about who is making health care decisions.

PRESENTATION HIGHLIGHTS: Diagnosis and Treatment

PATHOLOGY—Dr. David Kleiner

Key Points

- The goal of pathology is to provide an accurate and complete professional assessment of the patient's specimen so that appropriate care can be given. The challenge inherent in pathology, particularly anatomic pathology, is that patient samples are unique and irreplaceable. Therefore, pathologists are under a very serious obligation to do the best they can, even in the absence of adequate or complete information.
- Pathology includes surgical pathology, cytopathology, cytogenetics, flow cytometry, and autopsy pathology services. Pathologists must also depend upon the excellence of work performed by technicians in the histology and immunohistology laboratories, and those who perform electron microscopy, cell culturing, in situ hybridization, and other molecular techniques.
- Quality assurance for pathology is divided into two broad categories: technical quality and professional quality. Technical quality is formally regulated under the Clinical Laboratory Improvements Amendments Act of 1988 (CLIA) and compliance with the Act is monitored by independent inspection of the laboratory by either agents of the Federal Government, usually acting for the Health Care Financing Administration (HCFA), or by other CLIA-approved agencies. These agencies may include State inspectors for States with approved inspection programs, and an array of professional organizations such as the Joint Commission on the Accreditation of Health Care Organizations (JCAHCO); the College of American Pathologists (CAP); the Commission on Office Laboratory Accreditation (COLA), which inspects laboratories; the American Association of Blood Banks (AABB), which inspects blood banks; and others. Technical quality inspections are performed to document technical competence, which includes assessing staff capabilities, validating methodologies employed, assuring reliability of results, determining the availability of written procedures for all techniques; and ensuring the presence of safe work practices.
- Professional quality assessment is performed through peer review to determine how well the pathologist performs his/her activities, particularly with respect to diagnoses. Accuracy of diagnoses, completeness, and timeliness of results are all evaluated. Quality assurance is performed as part of the routine process of care. For example, prior and current specimen materials are compared and diagnoses are routinely reviewed by two pathologists either internally or externally.
- Systematic internal quality assurance review might, for example, involve examining all of the breast cancer diagnoses in the most recent year; with intraoperative evaluation (i.e., the frozen section diagnosis is compared with final diagnosis).
- Secondary review by referral centers is also common. Patients receive their treatment elsewhere, but then come to the NCI or other referral center for experimental therapy. Work performed by the outside pathologist is reviewed as part of this process.
- Another part of the pathology-related quality assurance process is the correlation of pathology with clinical diagnoses, which includes open communication with the referring physician. Pathologists present pathology information to tumor boards, where patient care is planned, and also participate in tissue committee reviews, where specimens are reviewed for adequacy.

- Professional quality assurance poses several challenges. Legitimate differences in professional interpretation can occur; not everyone views the same lesion in the same way. In some cases of borderline malignancy, diagnosis can be very difficult to ascertain. In addition, universal reporting standards are lacking; issues in this regard include the data that should be included routinely and questions about the reporting of new tumor markers and other measures such as vessel or mitotic counts. Currently, the Association of Directors of Anatomic and Surgical Pathology are developing standards for the different cancer types; these standards will specify the information to be reported and how it should be presented.
- Pathology diagnoses are often used as the gold standard for assessing diagnostic accuracy and for determining patients' eligibility for entering clinical research protocols. Autopsy is used as a final assessment of patient care; in fact, about 10 to 15 percent of autopsy cases show major, unexpected findings at autopsy that reveal the inadequacy of diagnosis prior to death.
- The NCI's patient population is very mobile, and these patients are generally searching for new therapies. All of the institutions involved in the care process must have complete and timely access to pathology reports to determine the accuracy of diagnosis and to compare the diagnosis with any subsequent tissue biopsies that may be taken.

Additional Research Needs and Other Recommendations

- Ongoing dialogue between oncologists and pathologists is essential to develop cancer-specific reporting standards, including identification of the data to be collected and how the information should be presented.

DISCUSSION—Dr. Kleiner

Key Points

- Managed care is affecting pathology in important ways. Questions have been raised regarding the essential elements of specimen evaluation and how evaluations can be performed most cost-effectively. Reduced staffing may reduce the time the pathologist has to assess any particular specimen, which may adversely affect the quality of the diagnosis. The potential for tremendous personal costs to the patient and greater health care costs is significant.
- Dr. Calabresi noted that pathologists have developed and use extensively a consult network to ensure diagnostic accuracy (i.e., difficult specimens are sent to another pathologist for a second opinion). Under a fee-for-service system, the insurance plan or laboratory is billed for the consultation. Under managed care, however, laboratories may receive capitated payments and may be responsible for paying all consultants from the capitated amount. This situation poses potentially very serious problems for the patient, since the financial incentives may be in direct conflict with a preferred standard of care.

NEW TECHNOLOGIES—Dr. Faina Shtern

Key Points

- Radiologic imaging will never prevent breast cancer. Until there are fundamental breakthroughs in breast cancer prevention and treatment, however, radiologic imaging remains at the center of breast cancer care, particularly early detection and accurate staging for treatment planning.

- Conventional mammography has been shown to reduce breast cancer mortality, particularly for women older than 50 years of age. Decreased mortality for younger women has also been demonstrated, although to a somewhat lesser degree. The presence of dense tissue renders diagnosis of breast cancer with conventional mammography problematic. This is especially significant for women in their thirties and forties, since recent data indicate that up to 60 to 70 percent of women in these age groups have dense breast tissue compared with approximately 30 percent of women over age 50 years. These findings present a powerful incentive to support novel breast-imaging technologies.
- Novel breast-imaging technologies will improve early detection, which in turn will contribute significantly to decreasing mortality rates and increasing probability of effective treatment. Better imaging will improve the accuracy of cancer staging essential for treatment planning and local disease control. The development of novel technologies will also contribute to cost-effective care for breast cancer patients by eliminating unnecessary diagnostic and therapeutic procedures. Further, digital technologies such as telemammography will bring world-class radiologic expertise to community hospitals and rural, remote, and underserved areas.
- Over the last 7-1/2 years, the Department of Health and Human Services has established numerous programs in novel breast-imaging technologies, including digital mammography, breast magnetic resonance imaging (MRI), ultrasound, nuclear medicine, and positron emission tomography for anatomic, molecular biologic, physiologic, and metabolic tissue characterization.
- The goal of the novel breast-imaging program is to facilitate the transfer of promising technologies from laboratories to routine clinical settings. To achieve these goals, collaborations have been established with multiple Government agencies, industry, and academia to facilitate all stages of technology transfer, including development, evaluation, and implementation.
- At present, digital mammography is viewed as the key research area for improved control of breast cancer in large-scale screening programs. Compared with conventional film-based studies, digital mammography is expected to improve image quality (and therefore cancer detection) at reduced radiation doses. Digital technologies can lead to image processing for improved visualization, computer-aided diagnosis for automated lesion identification, and telemammography for facilitated expert consultation.
- In 1993, the NCI established an international multidisciplinary digital mammography development group that brought together industrial and academic partners. In the absence of Government leadership, industry and academia would not have invested efforts and resources in the development of full-field digital mammography, which was considered high risk from a marketing perspective. Without both industry and academia, full-field digital mammography instrumentation would not be available today.
- Multiple-agency collaborations were also established, including the Central Intelligence Agency (CIA), National Aeronautics and Space Administration (NASA), Department of Energy (DOE), Department of Defense (DoD), and other agencies that have considerable experience in digital-imaging development, processing, display, and transmission. Cooperative efforts were also developed with the Food and Drug Administration, the Agency for Health Care Policy and Research (AHCPR), and the Health Care Financing Administration to address regulatory and reimbursement issues and facilitate the transition

of technologies to the market. As a result of these extensive collaborations, development of full-field digital mammography was facilitated by at least 5 years, conservatively estimated.

- The U.S. Public Health Service's Office on Women's Health (PHA OWH) currently supports eight major academic institutions evaluating the diagnostic value of digital mammography compared with that of conventional mammography in women who have radiodense breast tissue and are at high risk for breast cancer. The study will be completed in about 6 to 9 months.
- Other work by the digital mammography development group has shown that sophisticated computer-aided diagnosis has resulted in detection of about 50 percent of lesions missed through routine mammography screening. The telemammography research component of this group has to date transmitted more than 60,000 images without any loss of data or compromise in image quality.
- Approximately 1 year ago, the PHS OWH in the Office of the Secretary identified extensive capabilities in the Department of Energy related to high-performance computing and communications for image storage, processing, and transmission. The PHS OWH, Office of the Secretary, currently supports utilization of these capabilities to develop centralized national archives of digital-imaging libraries to assist in clinical diagnosis, research, and education.
- Traditionally, imaging technology development is viewed as industry's responsibility. Breast imaging, however, is limited by low revenues. The world market is estimated at about \$250 million per year for all companies involved in breast imaging, and only 5 to 7 percent of these revenues are devoted to research and development; therefore, there are virtually no incentives for industry to support technologic innovation in breast imaging. DHHS programs demonstrate how joint efforts and risk- and cost-sharing of Government agencies, industry, and academia can stimulate development of technology that is judged by industry as high risk from a short-term marketing perspective and by the medical community as having high potential for long-term impact on health care.
- DHHS has been traditionally supporting research programs in technology evaluation. Currently, NCI is conducting a multi-center evaluation of image-guided needle biopsy as a minimally invasive and cost-effective alternative to open breast surgery. Clinical trial results will be completed within the next several months.
- In September 1997, the NCI and the Office on Women's Health jointly funded the Multicenter Clinical Evaluation of Breast MRI to facilitate validation of this promising technology. Breast MRI is most promising for detection of early breast cancer in women with radiodense breast tissue and has been shown to detect lesions as small as 1 to 2 millimeters. The multicenter study of breast MRI is expected to answer a number of critical questions: What is the accuracy of breast MRI compared with other imaging technologies for breast cancer detection? By improving local staging accuracy, can high-resolution MRI assist in the selection of optimal treatment? And, finally, can MRI improve the cost-effectiveness of breast cancer care by eliminating unnecessary diagnostic and therapeutic procedures?
- The PHS OWH, Office of the Secretary, is also supporting a study in the development and testing of MRI-guided administration of a focused ultrasound beam, a noninvasive approach that may potentially replace breast conservation surgery.

- The traditional view has been that high technologies inflate health care costs. Clinical trials conducted with breast MRI and image-guided biopsy may demonstrate that high technologies can actually decrease health care costs.
- In summary, DHHS programs demonstrate that partnerships within and among Government agencies, industry, the academic community, and consumer organizations can bridge the gap between research and marketing of innovative technologies to improve quality, access, and cost-effectiveness in breast cancer care nationwide.

DISCUSSION—Dr. Shtern

Key Points

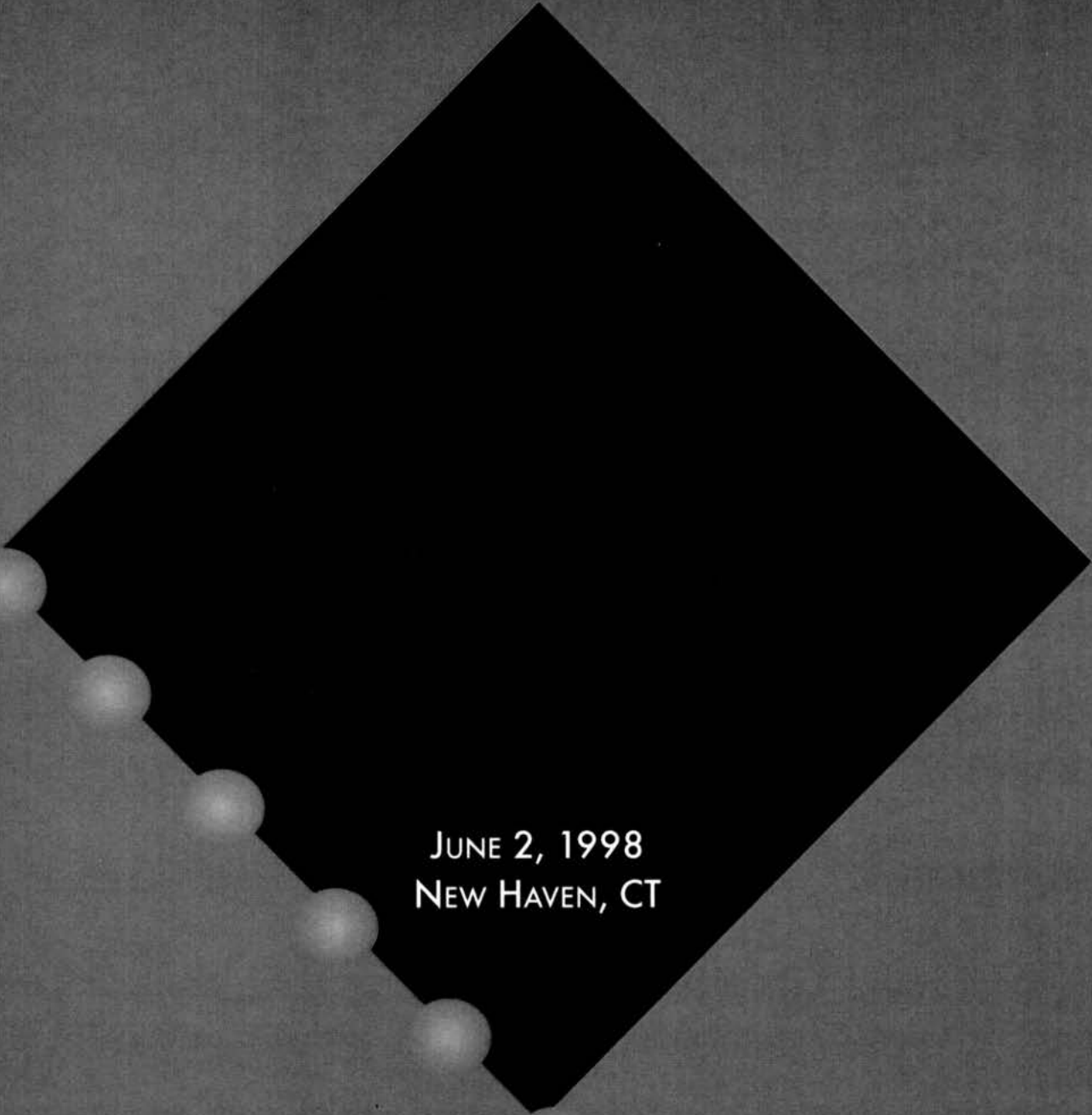
- Dr. Shtern clarified that MRI's diagnostic utility and effectiveness appear highly promising, but study results are not yet definitive. Clinical trial results will be available in approximately 2-1/2 years. Digital mammography is also still in the testing stage and until clinical results are available, these technologies, while highly promising, must still be considered experimental.
- Though MRI technology is currently very expensive, if clinical trials prove that MRI is superior to conventional mammography, industry will be more likely to develop breast-dedicated MRI units that will substantially reduce the cost of MRI breast imaging.

CLOSING REMARKS—Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- Therapies developed for breast cancer treatment must be available to all people-rich, poor, educated, and uneducated.
- Quality can be defined and evaluated from a variety of different perspectives, including those of the patient, physician, purchaser, and health plan. These perspectives must be blended in a way that will make sense to the American public. Significant issues remain regarding who will pay for the quality care we want the American public to have.
- The speakers have provided valuable input to the Panel's report to the President on these complex topics.

QUALITY OF CANCER CARE/QUALITY OF LIFE



JUNE 2, 1998
NEW HAVEN, CT

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

N A T I O N A L C A N C E R P R O G R A M

N A T I O N A L C A N C E R I N S T I T U T E

CHAIRMAN
HAROLD P. FREEMAN, M.D.
HARLEM HOSPITAL CENTER

MEMBER
FRANCES M. VISCO, J.D.
NATIONAL BREAST
CANCER COALITION

MEMBER
PAUL CALABRESI, M.D.
BROWN-TUFTS CANCER CENTER
RHODE ISLAND HOSPITAL
NEW ENGLAND MEDICAL CENTER

EXECUTIVE SECRETARY
MAUREEN O. WILSON, Ph.D.
ASSISTANT DIRECTOR
NATIONAL CANCER INSTITUTE

Quality of Cancer Care/Quality of Life Quality of Life and Survivorship June 2, 1998, New Haven, Connecticut

Opening Remarks	Dr. Harold Freeman
Welcome	Dr. David A. Kessler
NCI Report	Dr. Otis Brawley
Policy Issues	
An Introduction	Dr. Vincent T. DeVita
The National Cancer Institute Office of Cancer Survivorship	Dr. Anna Meadows
Policy Issues for Physicians and Caregivers	Dr. Kathleen Foley
Education and Communication	
The Cancer Journey: Issues for Survivors: A Training Program for Health Professionals	Ms. Kathy Crosson
Quality of Life Issues	
Long-Term Survivorship	Dr. Karen Hassey Dow
End of Life	Dr. Frederick A. Flatow
Medical Effects	
Pediatric Cancers and Medical Surveillance/Follow-Up for Second Cancers	Dr. Anna Meadows
Cognitive Effects	Dr. Tim Ahles
Psychosocial and Behavioral Issues	
Overview	Dr. Joan Bloom
Employment Issues	Dr. Joan Bloom
Sexuality	Dr. Leslie Schover
Family Issues	Dr. Grace Christ
Closing Remarks	Dr. Harold Freeman

Speakers List
Quality of Cancer Care/Quality of Life
Quality of Life and Survivorship
June 2, 1998, New Haven, Connecticut

Dr. Tim Ahles

Program Director
Center of Psycho-Oncology Research
Dartmouth-Hitchcock Medical Center

Dr. Joan Bloom

Professor
School of Public Health
University of California, Berkeley

Dr. Otis Brawley

Office of Special Populations Research
National Cancer Institute

Mr. John Carney

President, Hospice, Inc.
Chairman, National Hospice Board of Directors

Dr. Grace Christ

Associate Professor
Columbia University School of Social Work

Ms. Kathy Crosson

Chief, Patient Education Branch
National Cancer Institute

Dr. Vincent T. DeVita

Director, Yale Cancer Center
Yale University School of Medicine

Dr. Karen Hassey Dow

Associate Professor, School of Nursing
College of Health and Public Affairs
University of Central Florida

Dr. Frederick A. Flatow

Medical Director
Connecticut Hospice, Inc.

Dr. Kathleen Foley

Chief of Pain Service
Department of Neurology
Memorial Sloan-Kettering Cancer Center

Dr. David A. Kessler

Dean, Yale School of Medicine

Dr. Anna Meadows

Children's Hospital of Philadelphia
University of Pennsylvania
Office of Cancer Survivorship
Division of Cancer Control and Population Sciences,
National Cancer Institute

Dr. Leslie Schover

Staff Psychologist
The Cleveland Clinic Foundation

QUALITY OF CANCER CARE/QUALITY OF LIFE

Quality of Life and Survivorship

June 2, 1998, New Haven, Connecticut

OVERVIEW

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. This meeting, the second in a series of three, focused on the meaning of quality of cancer care, quality of life, and survivorship.

Eleven speakers presented testimony to the Panel on defining and assuring quality in cancer care; quality of life issues; policy issues for survivors, physicians and care givers; medical effects of cancer treatment; and psychosocial and behavioral impacts of cancer care and survivorship. Speakers offered specific recommendations in these areas for consideration by the Panel.

OPENING REMARKS—Dr. Harold Freeman, Chairman, President's Cancer Panel

In opening the meeting, Dr. Freeman stated that:

- This is the second of three meetings in the Panel's 1998 initiative to define the meaning of quality as it relates to cancer care. Quality of care issues are raised continually by the American public, particularly during this period of rapid change in the health care system characterized by the growth of managed care. However, a comprehensive examination of what "quality" means in the context of cancer care and the National Cancer Program has not been undertaken previously.
- The Panel believes that defining and delivering quality care is essential to achieving the National Cancer Program's goal of alleviating the burden of cancer in this country.
- In the first meeting of this series, held in April 1998, the Panel focused primarily on how quality of care with respect to cancer is defined, measured, and improved. Testimony presented at the April meeting illuminated the difficulty in achieving consensus on uniform definitions of quality. Perceptions of quality, for example, vary significantly depending upon who you are, what you have experienced, and your specific circumstances. During the April meeting, participants emphasized that cancer care is a continuum extending from prevention and control through diagnosis, treatment, palliation, and even following death, when social support and bereavement counseling for family members is needed. Quality of care must be examined in each of these areas.
- The third meeting in this series, exploring the impact of treatment guidelines in evaluating cancer care, will be held in October 1998.
- For any disease, quality of life issues must be included in discussions regarding quality of care. This is particularly true for cancer, which not only encompasses a broad spectrum of diseases with various risks and outcomes, but also has a large population of survivors (more than eight million) of all ages.
- Medical outcomes in cancer are often measured in terms of five year survival rates, which are somewhat artificial. For the person with cancer, survival begins from the date of diagnosis and continues until death.

- For cancer survivors, quality of care issues include, but are not limited to: prolonging life; maintaining function; preventing disease recurrence; and minimizing future treatment and associated complications through the remainder of life. One of the challenges for health care providers is to determine how individuals prioritize these outcomes so that the delivery of cancer care meets their needs. For example, quality of life issues may be paramount in decisions regarding cancer care when cure is not possible. If, however, significantly prolonged life or even cure is possible, the effectiveness of treatment may outweigh the immediate quality of life concerns. This underscores the need for physicians to thoroughly explain biological and functional treatment effects to patients and families and to encourage shared decision making. Ultimately, the balance of quality of life and quality of care issues must be decided by the patient, since patient perceptions and tolerance of complications and the resulting health burdens are unique.
- Another challenge is to develop effective systems of surveillance and support for cancer survivors that extend beyond the five-year survival period. Preventing disease recurrence and secondary complications, the provision of physical rehabilitation and psychosocial support all affect quality of life for cancer survivors.
- Quality of life as a component of quality of care is equally important for those at risk for cancer. Therefore, we need to ask what quality of care means in relation to screening, detection, and access to care for all Americans.
- As cancer detection and treatment become increasingly effective, the population of cancer survivors, as well as those considered to be at risk for developing cancer, will continue to grow. Problems associated with long-term survival will continue to emerge. Much more is needed to define and measure quality of care. The Panel also believes that it is essential to be sensitive to the needs of all segments of the population as quality of care issues are addressed.

WELCOME—Dr. David Kessler, Dean, Yale School of Medicine

Key Points

- Reflecting upon his tenure as Director of the Food and Drug Administration (FDA), Dr. Kessler recalled being asked at the National Cancer Advisory Board (NCAB) why the FDA did not regulate tobacco products. Since that time, the tobacco debate has expanded considerably and has reached the Senate floor for consideration. The American people are on the verge of taking an important step forward in developing comprehensive tobacco control legislation. The early inquiry from the NCAB led the FDA to consider whether nicotine in cigarettes and smokeless tobacco products should be considered a drug as statutorily defined (i.e., a substance intended to affect a structure or function of the body). It is now widely accepted that nicotine is in fact an addictive drug. Nicotine addiction and the resultant lung cancer represents a man-made epidemic and a key threat to quality of life.
- Tobacco company marketing successfully targeted women beginning in the 1920s, and the incidence of lung cancer in women has yet to plateau. Since the 1970s, tobacco companies have targeted marketing efforts at the 14-18 year old age group, knowing that 90 percent of all tobacco users begin the habit in childhood. In this sense, nicotine addiction is a pediatric disease.
- It is time to pass comprehensive tobacco legislation that does not provide the tobacco industry with special deals, settlements, or immunity from prosecution.

NCI REPORT—Dr. Otis Brawley, Assistant Director, Office of Special Populations Research, NCI

Representing Dr. Richard Klausner, Director, NCI, Dr. Brawley indicated that:

- The President's Cancer Panel is one of a number of contemplative groups to assess the National Cancer Program and to determine its future direction and approaches. Others include deliberations of the NCAB, which meets three to four times a year, and studies ongoing at the Institute of Medicine and at the National Academy of Sciences. The process used by the President's Cancer Panel is a very important one as it enables experts to present testimony, and in some instances, to teach.
- The war on cancer has been underway for considerably longer than 27 years (the period since passage of the National Cancer Act). There have been tremendous improvements and successes in cancer treatment and as a result, there are increasing numbers of cancer survivors who have become a very important constituency. Survivors have served as advocates and provided support for other survivors, for science and medicine, and for scientists. Survivors have helped to maintain a focus on the concerns of people with cancer as medical research continues. They also have enlightened the medical profession regarding quality of life and issues faced by the family of a person with cancer. A great deal has been learned about pain control and the importance of appreciating and respecting the unique needs and psychosocial environments of special populations, cultures, and ethnic groups.
- Survivorship begins not at the moment of diagnosis, but from the moment a person is aware that he or she may have cancer, or in some instances, aware that he or she is at high risk for cancer.
- The Panel meeting provides an opportunity to celebrate survivorship and the contributions that survivors have made to medical science.

PRESENTATION HIGHLIGHTS: Policy Issues

INTRODUCTION—Dr. Vincent DeVita

Key Points

- Numerous organizations, such as the National Coalition for Cancer Survivorship, now represent and promote the interests of cancer survivors. These organizations have had a significant impact on cancer care throughout the country and on public perceptions of cancer and cancer survivors.
- Prior to 1971, most cancer survivors were people whose cancer could be surgically removed, since there were few, if any, treatment alternatives available. With the advent of radiotherapy and chemotherapy, patients and the public had to adjust to the idea of treating cancer differently, including, in some cases, allowing the cancer to remain in the body and treating it by nonsurgical means.
- The most important issue to current and future survivors is to create the circumstances that will lead to more survivors. The size and strength of the survivor population will in turn surface and lead to the resolution of more cancer-related policy issues.
- Since the National Cancer Act was passed in 1971, approximately \$32 billion has been spent to carry out its mandate: "To support basic research and the application of the results of basic research to reduce the incidence, morbidity, and mortality from cancer." The use of the term "application" was significant, since at that time the National Institutes of

Health (NIH) was more focused on the support of basic research than on the application of research results. By incorporating the term "morbidity" into the Act, its framers anticipated that with better treatment, there would be more survivors, and that these people would have quality of life issues. The framers of the Act also anticipated the growth of technology (such as high speed computers and the molecular biology revolution currently underway) that would radically change the silhouette of the National Cancer Program itself.

- In 1984, NCI developed Year 2000 goals that set specific idealized targets for reducing cancer incidence, morbidity, and mortality—a 15 percent reduction as a result of prevention, five percent due to screening, and a ten to 26 percent reduction in cancer mortality as a result of treatment. Progress to date against these goals is impressive. Approximately five of the 15 percent reduction from prevention has been achieved, however, recent data on the effectiveness of tamoxifen for breast cancer prevention (and the even greater effectiveness of raloxifene) suggest that the reduction may be more substantial. The screening goal in breast cancer was achieved several years ago. Mortality reductions attributable to improved cancer treatment are currently estimated to be between 14 and 26 percent. Overall, cancer mortality should be reduced by approximately 25 percent by the year 2000. In the last two years, two papers have been published showing cancer incidence and mortality declines beginning in 1990.
- Between 1971 and 1980 NCI's budget increased five-fold. It then took 16 more years to double the budget. Current plans are to double NCI's budget again over the next five years.

Additional Research Needs and Other Recommendations

- The President and the NCI should create an environment in which there are sufficient resources to support a balanced program of both basic research and research on the application of basic science discoveries.

NATIONAL CANCER INSTITUTE OFFICE OF CANCER SURVIVORSHIP—Dr. Anna Meadows

Key Points

- Approximately 8.25 million people are living with cancer. With advances in cancer treatment, this number will continue to increase. Approximately 25 percent of those living with cancer are breast cancer survivors; for the most part, these are young people who are in the most productive years of their lives.
- The Office of Cancer Survivorship (OCS) was established by NCI Director Richard Klausner in 1996. It was designed as a focus for extramural research to expand the knowledge base needed for improved therapeutic decision making. Although it was recognized that improving the quality of survival for survivors begins at the point of diagnosis, OCS focused its research agenda on the issues of survivors who were at least two years post-treatment, because research data has been lacking for this group of patients. Little information has been available about long-term cancer survivors (five, 10, and 15-year survivors) and the types of problems they face. A goal of NCI's efforts is also to increase awareness of survivor issues among medical professionals and the general public.
- The OCS held a number of meetings to develop a research agenda. Issues identified for emphasis included the prevalence of physiological and psychological long-term effects of cancer and its treatment; the risk of second cancers and the relationship between patients' risk levels and previous exposures, treatment received, and genetic predisposition; issues related to reproductive and sexual functioning; effects of treatment on offspring of cancer

survivors; the economic impact of cancer; and the evaluation of interventions to prevent long-term problems.

- OCS was also interested in comparing cancer survivors with non-cancer patients, and in examining undesirable outcomes that could be prevented, either during the course of therapy or after therapy was completed. It was determined that information about the long-term effects of therapeutic options was needed to assist consumers in making informed decisions. Other areas of interest included obtaining more information about the risk of cardiac disease in adults treated for childhood cancers and how to prevent this delayed treatment effect; the impact of cancer treatment on renal and cognitive function; treatment of premature menopause (e.g., with hormone replacement) and its effect on quality of life and the risk of recurrence.
- One of the most significant problems of cancer survivorship is the risk of second cancers associated with treatment. OCS is interested in better understanding and quantifying this risk, and determining how it can be prevented or treated. In addition, there is a need to better understand how genetic susceptibilities interact with cancer treatments to influence second cancer risk.
- OCS determined that a number of survivor groups have been overlooked in studies to date; these include patients with certain diagnoses, survivors representing various ethnic and socioeconomic groups, and the elderly. In addition, longitudinal survivorship studies have been lacking and instrumentation has been inadequate to measure quality of life indicators over time.
- A major OCS research priority is to develop an understanding of where cancer survivors receive surveillance and follow-up care. There are myriad potential sources of care, including primary care providers, oncologists, and managed care plans. Questions concerning how to identify the most appropriate source of care and how to gain access to that care must be resolved. Factors influencing choice of care include cost, initial treatment, risk of subsequent disease, and the survivor's relationship with his or her oncologist.
- OCS is also interested in evaluating structured interventions and determining how behavior modification can lessen future problems for survivors. Although educational materials are plentiful, it is unclear how the materials lead to behavior change or changes in quality of life. Educational materials addressing the needs of the underserved are not yet readily available.
- In the last two years, the OCS has set aside \$5 million to support its research agenda and is developing partnerships with private foundations to increase the level of funding available for survivorship research. Future OCS activities will involve continuing investigator-initiated research and developing cooperative agreements with clinical trials groups to develop an infrastructure that will enable lifetime follow-up of survivors.

POLICY ISSUES FOR PHYSICIANS AND CAREGIVERS—Dr. Kathleen Foley

Key Points

- End of life care is a survivors' issue, as 50 to 60 percent of patients diagnosed with cancer will eventually die from their disease. The reality is that 1,400 patients die each day from cancer. How cancer patients perceive their death dramatically affects their morbidity. A "bad death," characterized by poor symptom control, physician abandonment, or inadequate closure, creates survivors' fear of their own death. Considerable data exist

suggesting that how individuals face their own death is largely a function of how they have experienced the death of loved ones.

- Public attitude surveys have shown strong support for physician-assisted suicide because of patients' concerns about suffering and the dying process. These concerns were evident in research conducted at the University of Wisconsin in which 69 percent of cancer patients indicated that they would consider suicide if their pain was not controlled adequately.
- End of life care is a quality of cancer care issue; extensive data demonstrate that health care professionals lack competency in end of life care and that a variety of physician, patient, and institutional barriers exist to providing such care. The American Society of Clinical Oncology's (ASCO) Task Force on end of life care has recently proposed a series of recommendations that will require extensive changes in health care policy and in provider education if implemented. Although there is evidence suggesting that the public is demanding improved end of life care, our culture does not want to discuss death. This barrier to publicly address such a private topic poses considerable challenges to the NCI or to any major effort related to end of life care.
- End of life care is a quality of life issue. Research has demonstrated that one-third of cancer patients in active therapy and two-thirds of patients with advanced disease have significant pain that requires analgesic drug therapy. Numerous studies have demonstrated that pain scores greater than five interfere with patients' quality of life, their ability to perform activities of daily living, and many other aspects of their lives.
- A recent series of studies suggests that advanced cancer patients have seven major symptoms that affect their quality of life. Up to 25 percent of these patients report major depression. Recent studies have also demonstrated that depression in patients with advanced cancer in palliative care units is closely correlated with patient requests for assistance in death. At present, a wide range of therapies are available to treat these major physical and psychological symptoms, but there is an enormous need for more research to better define how these therapies affect patients' decisions, and particularly decisions relating to end of life care.
- Surveyed oncologists have reported their lack of competence in assessing and managing depression, their lack of knowledge and professional education in pain management, and a lack of resources for providing palliative care to patients with cancer.
- A recent Institute of Medicine report outlined current health care system limitations to providing compassionate, humane care for patients at the end of life. The report emphasizes that cancer patients need continuity of care from prevention to diagnosis to curative therapies and palliative care. In addition, the report supports recommendations from the World Health Organization (WHO) that a system for delivering palliative care should be established before governments consider physician-assisted suicide legislation.
- The WHO defines palliative care as the total care of patients with an incurable disease. Palliative care is family-centered; focuses on the quality of life of patients, with particular attention to managing symptoms; addresses psychological and spiritual needs; and respects cultural differences.
- End of life care is an important caregiver issue. Recent studies have demonstrated that enormous burdens are placed on caregivers who have inadequate knowledge, resources, and training to care for family members at home. Caregiver burden is often associated with caregiver depression, which in turn has a significant and major negative effect on the dying

process for the cancer patient. The degree of caregiver burden is directly related to inadequate symptom control, lack of appropriate economic resources, and lack of social supports.

- Each year, an estimated 450,000 patients die in hospice care nationwide. Approximately 80 percent of these deaths are cancer-related and 90 percent of these patients die at home. Many hospices require that there be a responsible caregiver at home as a condition of enrollment. Yet hospice, which is capitation-based, can only provide four hours of home health care each day. This level of support is often inadequate, particularly for elderly patients who often subsequently require hospitalization for end of life care, even though they prefer to die at home.
- Only \$2 billion per year is spent on hospice care in the United States. Hospice care reimbursement is changing with health care financing changes; capitation rates are being reduced, as is the length of time that patients may remain in hospice care. Moreover, many health care programs do not adequately pay for hospice care for patients under age 65. In addition, a number of states do not cover hospice care for Medicaid patients, forcing the poor to die in hospitals because of a lack of community-based resources to provide care at home. Recent Inspector General reports have criticized hospices because as a result of the high quality of care they provide, patients have lived longer than anticipated. Further, for many patients with advanced cancer, the cost of pain medications and other drug therapies used in palliative care is not reimbursed, and these out-of-pocket expenses can total \$400 to \$600 per month, expending all of the patient's Social Security income. There are cases of patients foregoing the use of necessary pain medication because the costs were prohibitive.

Additional Research Needs and Other Recommendations

- There is a need to address the financing of hospice care with respect to the six-month limit on such care and a need to expand the availability of palliative care approaches from hospice programs to cancer centers.
- An appropriate system of care should be developed to provide humane and compassionate care at the end of life. To do this, a better understanding of the dying experience for patients and families is essential as is a better understanding of the barriers to providing such care.
- There must be support for broader public discussion of death and death-related issues. This will encourage a more honest discussion about the failures of our therapies and the potential options in end of life care. Literature developed by the NCI and the President's Cancer Panel should present a balanced discussion about death and dying.
- Undergraduate and graduate palliative care programs should be developed to meet health care professional education needs.
- A reimbursement system for end of life care needs to be addressed and better defined. Medicare reimbursement restrictions concerning hospice care must be removed as well as reimbursement limits for pain medications provided to terminally ill patients who are not enrolled in a hospice program.
- Cancer survivorship as defined by the Office of Survivorship is someone who has survived two years. There is need for a nomenclature for cancer survivors who do not live more than two years, for the survivors who did not survive.

- A task force on end of life care for cancer patients should be established to address the associated educational, economic, and ethical issues.
- Palliative care should be included as an option in every clinical trial offered to patients, particularly in Phase I studies. This provides patients with a choice of whether or not to participate in active therapy protocols or to receive excellent palliative care.
- Cancer centers need to develop centers of excellence in palliative care to maintain their role as leaders in professional and public education and to produce experts who will sponsor clinical trials in palliative care to advance this research.

DISCUSSION—Drs. Devita, Meadows, and Foley

Key Points

- The current \$5 million OCS research budget is extremely low relative to interest and demand, but represents a first step. It is anticipated that additional funds will be provided. In fact, prior to the establishment of the OCS, no more than \$5 million was spent on this type of research over the past 20 years at the NCI. It has been difficult to identify the total level of prior survivorship research funding because grants were dispersed throughout the NIH and were not concentrated in the NCI research portfolio. It is estimated, however, that survivorship research funding was less than \$1 million per year prior to establishment of the OCS. Information concerning the extent to which other Federal agencies are funding outcomes and health services research is similarly difficult to identify. Such information might be available through the National Cancer Policy Board.
- The OCS is promoting the need for rehabilitation research related to cancer. Most of the earlier survivorship research concerned rehabilitation of head and neck cancer survivors and survivors who experienced orthopedic problems as a result of cancer. Very little long-term research was performed related to quality of life and physiologic function in long-term survivors.
- Advocates have attended all OCS meetings and have provided input into research agenda development. At OCS's last meeting in March 1998, 25 percent of the more than 200 attendees were individual advocates or advocacy group representatives. Research proposals submitted by 79 scientists in response to an OCS RFA were reviewed and rated by a study section consisting of 20 scientists and 12 advocates. The review process was extremely well received and was effective in identifying the most promising proposals.
- The majority of public discussion concerning cancer focuses on morbidity-related issues and tends to ignore the reality that death is a very real outcome of the disease and therefore, the needs of dying patients and their caregivers must be addressed. There is also a tendency to use euphemisms when referring to death. Similarly, the majority of NCI materials deal only with morbidity. Professional education textbooks also lack information about the dying process. A balanced discussion of morbidity and mortality is essential and demonstrates a respect for the needs of those who are dealing with death-related issues.
- Major symptoms common to dying patients (whether from cancer or other diseases) are: pain, nausea and vomiting, shortness of breath, and confusion. Further study of these symptoms forms a robust research agenda. There is no focal point in the NCI program and NIH system for obtaining funding for this type of research.
- The three major issues in end of life care are: poor physician/patient communication about end of life care issues; poor symptom control (in a major study, 50 percent of the patients

who were dying in five hospitals died in pain); and the lack of advanced care planning and advanced directives.

- Oncologists are able to provide active therapy for patients, but if no therapy with curative intent is possible, patients are often triaged to other systems of care (e.g., nursing home, hospice). When this occurs, patients often feel abandoned. Moreover, one cannot be admitted to a hospital to "die"; there is no Diagnosis Related Group (DRG) for dying. This barrier to institutional care at the end of life also limits the support oncologists can provide.
- In other countries, where health care is seen as a right, palliative care is provided. Twenty countries have endorsed the WHO Cancer Control Program, which includes palliative care as one of its four major components. In this country, the only group of patients who are part of an entitlement program are Medicare beneficiaries. Patients under age 65 do not receive hospice care unless they have hospice insurance and Medicaid does not fully cover hospice care in all states.
- Issues related to death and dying are a necessary part of the Panel's discussion of quality of life because they deal with the quality of living for the dying. While most patients do not necessarily want to be seen as dying, they do want to ensure that they will receive good care through the end of life. Recent research with patients receiving care in a palliative care unit who were aware of their diagnosis revealed that this knowledge did not create hopelessness; rather, it was the reality in which they functioned.
- The reason that the disabled population opposed physician-assisted suicide was because it was viewed as a form of health status discrimination. The dying may likewise suffer from discrimination because they often do not receive potentially beneficial interventions because of their health status. What dying patients need is not high technology care (e.g., respirators, ventilators, intensive care units); it is good care for patients at home, good support for their caregivers, and good symptom control. None of these things are extraordinarily costly, but they must be institutionalized nationally.
- Some positive outcomes of the cancer survivorship experience include knowing how to live in the moment and how to appreciate each day. Having a positive outlook may positively influence quality of life.
- Medical training, which tends to be focused on acute or crisis care and short-term outcomes, may create a bias among young physicians (and nurses) that long-term cancer survivorship is uncommon. This view subsequently may negatively affect the likelihood that they will recognize the long-term follow-up needs of cancer patients in their care.
- Managed care places considerable constraints on the amount of time that physicians spend with patients, causing them to focus on the most salient and immediate problems. This leaves little, if any, time to focus on issues related to prevention or quality of life. It was Dr. DeVita's view, however, that managed care is evolving as a result of the struggles (e.g., growth, consumer concerns and resultant regulatory and legislative actions) that the industry has faced and may in fact prove to be an environment in which prevention and quality of care will flourish. For the most part, he believes, the observed deficiencies in medical care related to prevention and quality of care reflect failures of the fee-for-service system, not the weaknesses of managed care.
- There has always been a fierce debate about the proper balance between basic and applied research. Opponents of the National Cancer Act believed that the NIH should only support basic research. Thus, the reductions achieved to date in cancer incidence and mortality are attributable to the 15 percent of research funding that was allocated to the applications

program. The other 85 percent of funds used to support basic research is just beginning to bear fruit with, for example, the emergence of new cancer drugs such as the anti-angiogenesis compounds. Issues governing how research funding is allocated between basic and applied research must be addressed by the NCI. It is a delicate balance, the maintenance of which depends largely on the leadership of the Institute.

PRESENTATION HIGHLIGHTS: Education and Communication

THE CANCER JOURNEY: ISSUES FOR SURVIVORS: A TRAINING PROGRAM FOR HEALTH PROFESSIONALS—Ms. Kathy Crosson

Background

Five years ago, in response to an increasing number of survivorship-related calls to the NCI's Cancer Information Service (CIS), a training program for CIS Information Specialists was developed and implemented to improve their familiarity with these issues and enable them to better respond to callers. Subsequently, a similar need for this type of information among a broader range of health professionals was identified. The original program, now entitled "The Cancer Journey: Issues for Survivors," was adapted for this expanded audience. The training kit includes a 30-minute videotape, a Reference Materials Manual, and a Leader's Guide. This effort was made possible through a grant from Ortho Biotech and was developed in close collaboration with the National Coalition for Cancer Survivorship (NCCS) and the Oncology Nursing Society (ONS).

Key Points

- Education and communication are important parts of cancer comprehensive care. "The Cancer Journey: Issues for Survivors" responds to the needs of these health providers for a better understanding of the range and complexity of issues associated with cancer survivorship. In addition, the training program focuses on providing effective support, accurate information, and useful referral information. Through the training, health professionals are taught how to empower survivors and their families to work together effectively regarding survivorship issues.
- The video can be shown in short segments in a variety of settings including grand rounds and support groups and is particularly effective when coupled with a discussion panel of survivors or a lecture presentation by a health professional familiar with the issues. Associated resource materials will eventually be available through the NCI web site.
- The videotape "The Cancer Journey: Issues for Survivors" was shown. Copies of the video, reference materials, and Leader's Guide for trainers can be obtained free of charge by calling 1-800-4-CANCER.

DISCUSSION—Ms. Crosson

Key Points

- "Anniversary reactions" are an important but sometimes unrecognized issue for both patients and care givers. On or near the anniversary of their cancer diagnosis, patients tend to visit their physicians and often present with symptoms or anxiety.
- The NCI has a formal promotion plan for the training video and associated materials. NCCS and ONS are working with the NCI to promote the training package. It is intended that the video be used as part of a group training program; it is not being promoted for individual use. The NCI has received inquiries concerning use of the videotape from insurance companies, small and large businesses, and health plans. Kits will be promoted

to these groups. The NCI's web page includes the Cancer Patient Database, through which such videotapes and other educational materials can be located.

- The training materials are now in their second printing; response to the materials has been overwhelmingly positive.
- Plans are under discussion with the ONS to launch a training-of-trainers to help develop a cadre of individuals to lead and promote the training.
- NCI is also interested in sponsoring outcomes research to assess the impact of health professionals training programs like "The Cancer Journey."

PRESENTATION HIGHLIGHTS: Quality of Life Issues

LONG-TERM SURVIVORSHIP—Dr. Karen Hassey Dow

Key Points

- A study of long-term cancer survivors conducted by Dr. Hassey Dow in collaboration with the NCCS and co-investigators focused on: quality of life issues; the need to document quality of life after treatment; assistance in identifying high risk areas and selected problems that could be addressed through specific interventions; and the development of psychometrically sound quality of life measurement instruments.
- It is important to define quality of life as well as cancer survivorship. Quality of life is a multidimensional concept and should be measured using individual perceptions of quality of life rather than proxy measures such as the Karnofsky scale.
- Dr. Dow's study used the definition of survivorship (i.e., a fluid process that begins at the point of cancer diagnosis and continues for the balance of life) written by the NCCS. The study included a survey containing two standard quality of life instruments that were mailed to 1,200 NCCS individual members. The first instrument, Quality of Life for Cancer Survivors, was developed more than ten years ago, and is a 41- item rating scale. The second instrument, the Fact-G, contains a 33-item ordinal scale. Demographic information on study participants was collected along with several qualitative measures related to quality of life.
- Study results are based on a response rate of 57 percent. Approximately 80 percent of the respondents were females of moderate to high socioeconomic status. Mean respondent age was 49 years. Although respondents represented a variety of cancer diagnoses, 43 percent of the respondents had breast cancer. Study participants were treated with a number of different modalities and had survived approximately 80 months (or 6.7 years) post cancer diagnosis.
- Among the most salient issues identified in the study were concerns related to fatigue and pain, menopausal symptoms, and reproductive and fertility concerns. Two other key issues emerged: the first related to fear of recurrence and what to do if there is a recurrence; the other concerned immobility after treatment
- Some of the positive outcomes of cancer survivorship cited were positive effects on marital and intimate relationships and on relationships with family and children. Respondents also cited feelings of usefulness and happiness, being able to help others with cancer, and becoming a part of life and living. Some of the negative impacts included changes in body image and sexuality. Caregiver concerns, out-of-pocket costs, concerns related to testing and cancer surveillance, and loss of insurance were also noted. Other emotional issues

related to cancer survivorship included emotional distress, anxiety and depression, loneliness and isolation, and feelings of loss of control.

- Survivors identified a number of interventions that they used to enhance their quality of life. Among the interventions were: patient and family education, long-term coping skills management, support groups, use of alternative or complementary therapies, and advocacy and activism. The value of support groups was cited repeatedly, yet the current insurance climate provides limited coverage for this aspect of cancer care.
- Spiritual quality of life was also cited as being very important. This included focusing on the importance of family and friends, finding hope (even in advanced disease), finding meaning in illness, and having a renewed spiritual strength. Negative concerns included uncertainty about the future and fears of dying, though not of death itself.
- Interdisciplinary research partnerships, particularly involving advocacy groups, are highly valuable. These partnerships were particularly useful in examining the study results and in identifying how the results could be used in the future.
- It is also important to target special populations for quality of life studies, especially minority populations.

Additional Research Needs and Other Recommendations

- Continued support for innovative behavioral and psychosocial research funding is needed. Psychosocial research must be expanded beyond sexuality and reproduction-related issues. Targeted research should be conducted regarding the late physiological effects of survivorship within a quality of life framework.
- Interdisciplinary research partnerships with advocacy groups should be developed. Advocacy groups must be educated about the importance of psychosocial and behavioral quality of life research.
- Minority research related to long-term survivorship and quality of life should be conducted.
- Guidelines and standards for long-term follow-up need to be developed.

END OF LIFE ISSUES—Dr. Frederick Flatow

Background

The Connecticut Hospice, Inc. located in Branford, Connecticut, is an active institution providing palliative care and end of life care to a large segment of the state's population. Palliative care seeks to prevent, relieve, reduce, or soothe the symptoms of a disease or disorder, but without curative intent. It attends to the emotional, spiritual, and practical needs and goals of patients and those close to them. It encompasses hospice care and end of life care, but is not necessarily restricted to those who are dying. Although dying is a fact of life, end of life care is inadequate in this country.

The hospice movement dates to the Middle Ages in Europe where hospices provided a place of shelter, sustenance, and care for travelers. In the 19th century, hospices served the dying, especially those with cancer. The modern hospice movement began in England in 1967 with the establishment of St. Christopher's Hospice in London by Dame Cecily Saunders.

The Connecticut Hospice, Inc. was the first hospice in the United States and was established as a home care hospice. In 1979, the first freestanding hospice was built in Branford as a companion to the home-based program. With 52 beds, the freestanding

hospice serves 1,200 patients per year. An equal number of patients are served in the home care program; approximately 250 patients per day receive care through the home-based program, representing 80 percent of total patient days.

In hospice care, the family and the patient together comprise the unit of care. As such, they are all involved in developing and implementing the care plan and in particular, in setting care-related goals. Care is provided by an interdisciplinary team that includes physicians, nurses, pastoral care, and the arts, among others. Bereavement care is provided to the family for one year following the death of the patient.

The mission of hospice is to provide care for the patient, giving comfort through relief of pain and symptom control and to provide emotional and spiritual support, it attempts neither to prolong life nor hasten death.

Key Points

- Although studies of end of life care have been performed (such as the Institute of Medicine's study "Approaching Death and Improving Care at the End of Life") and a growing number of foundations are involved providing palliative care, there still is a great deal to be accomplished.
- In 1984, hospice care was added to the list of covered Medicare benefits; under the benefit, a physician must certify that the patient suffers from a terminal illness and has a life expectancy of six months or less. Addition of the hospice benefit eased the financial burden of end of life care for many Medicare patients over 65 years old; this population represents approximately two-thirds of patients at the Connecticut Hospice. Many patients under 65 years, however, lack insurance coverage for hospice care and resources available through the Medicaid program are constrained.
- Late referrals for hospice care pose persistent problems. In the inpatient unit at Connecticut Hospice, 22 percent of patients do not survive more than three days following admission. In such cases, the patient and family are deprived of valuable care and support.
- The skills used in the hospice care of cancer patients are applicable to the care of patients with other chronic illnesses and end-stage diseases, and the clinical profile of hospice populations is changing. Cancer-related hospice admissions in Connecticut have remained constant, but their percentage relative to total hospice admissions has declined from 90 percent to approximately 70 percent as admissions of patients with other illnesses have steadily increased.
- As a result of shortened acute hospital stays, patients and families often do not have adequate time to learn about the cancer diagnosis, prognosis, and the anticipated course of the illness. They are also deprived of time to contemplate the illness and begin to prepare for what lies ahead. Many patients, therefore, arrive at hospice care requiring a great deal of support and teaching, and they are often in a state of transition and denial.
- To better address patients' needs in the current health care environment, an intermediate level of hospice care should be developed. Patients are currently accepted into hospice care while they are receiving peritoneal dialysis, ventilator support, intravenous therapies with fluids and antibiotics, and total parenteral nutrition. With teaching and emotional and spiritual support in the face of terminal illness, patients and families usually realize the futility of such measures. These therapies are gradually terminated and good symptom control can be achieved.

- Of the approximately 2.4 million deaths in the United States each year, approximately 60 percent die in the hospital, often in intensive care units; 17 percent die in nursing homes and other chronic care facilities, some with limited staff and family support. Most of the remainder die at home and approximately 20 percent of these patients have hospice contact; this represents only 14 or 15 percent of total deaths. Although this percentage is growing, it remains inadequate.
- Most patients who die without hospice care experience poor pain control because their health care providers have limited knowledge of opiate pharmacology and poor pain assessment skills; further, communication with patients about pain tends to be inadequate. Many providers fear governmental oversight and restrictions related to prescribing controlled substances.
- According to findings from the Study to Understand Prognoses and Preferences for Treatment (SUPPORT) trial, funded by the Robert Wood Johnson Foundation and reported in the Journal of the American Medical Association, attempts to improve communication and information flow between physicians, patients, and families through the use of skilled nurse facilitators had little effect on major outcomes. Outcomes assessed included do-not-resuscitate (DNR) orders, days spent in the intensive care unit in futile states, pain control (approximately 50 percent of the patients were not comfortable), and poor use of hospital resources. Study results demonstrated that improved communication was inadequate to change established medical practice.
- End of life care is inadequately addressed in medical education. In 1994, only five of 126 medical schools provided a separate course on the care of the dying and only 25 percent of residency programs included courses on the medical and legal aspects of end of life care. Only 17 percent of training programs offered a hospice rotation, and many of these were elective.
- Physicians have a great deal of difficulty communicating bad news to patients and families. As a result, they may not always be the patient's advocate when the futility of active therapy becomes obvious. Sometimes physicians believe that a little more treatment will offer a little more hope and allay fear, but often the patient suspects otherwise. At this point, treatment goals should be refocused to include good supportive care, good symptom control, maintenance of independence for as long as possible, control of financial burdens to the extent possible, and reassurance that the patient will not be abandoned by the physician. Providers must never say that nothing more can be done for a patient. Although treatment with curative intent may be futile, a great deal can be done to make the patient more comfortable in the dying process.
- It is also true that the pursuit of active care in a futile situation can be a result of patient and family demands. Given the constant barrage of media coverage regarding medical successes and technologic advances, the public has an unrealistic view of what caregivers can accomplish. This is a major problem for our society.
- It is difficult to practice palliative medicine and acute care medicine simultaneously. In its purest form, the curative model concentrates on the goal of cure; clinical problems are approached as puzzles to be solved. The objective of the analysis is to identify and ameliorate the disease process itself and symptoms are treated as clues to the diagnosis. Multiple laboratory tests and imaging studies are primary, and subjective experiences become secondary. By contrast, in the palliative model, symptoms are phenomena and in their own right are worthy of treatment. The goal under this model is symptom control and

the relief of suffering for the patient. Cure is admirable and the curative model is wholly appropriate when medicine is capable of restoring health completely. But the majority of medical problems fall between these extremes, requiring an approach that includes the multiple goals of medicine: health restoration, life preservation, rehabilitation, prevention, comfort, and caring.

- Medical education today overemphasizes the curative model; we need to regain a more compassionate and humanistic approach to care. The SUPPORT trial results suggest that the major efforts to change this balance should come early in the educational process. In this way, future physicians may be better skilled in both curative care and palliation, and be able to apply both models within a continuum of care.
- Connecticut Hospice staff participate in seminars for senior medical students at Yale University. They work with first and second year medical students to introduce hospice care early in these students' studies. An elective two to four week clerkship at the hospice is available to Yale and University of Connecticut medical students, involving direct patient care, family involvement, and sessions with nursing, social work, and pastoral care hospice staff. More formal programs and curricula of this type are essential. Other interdisciplinary departments at hospices also have teaching programs in nursing, advanced practice nursing, social work, and pastoral care. In addition, hundreds of volunteers are taught to assist in patient care.
- Connecticut Hospice also conducts lectures on palliative care at other hospitals and works with Blue Cross and Blue Shield as part of a program titled "Can Support." This program allows hospice nurses into the homes early in a patient's illness to help patients cope with frightening diagnoses and new information, and provide control of symptoms related to treatment and the disease itself. In addition, a hospice staff member working with other members of the Yale faculty has helped to establish a special reference section in the Yale Medical Library devoted to palliative care.

DISCUSSION—Drs. Dow and Flatow

Key Points

- To persuade the Congress to maintain and increase its funding, the NCI has emphasized curative care in its presentations to the Congress and its messages to the public. One by-product of this understandable approach is that many patients are unwilling to hear that further treatment with curative intent is pointless, and simply change physicians in search of a miracle. The NCI should communicate clearly to physicians and the American people that after appropriate expert evaluation determines that it is time to cease aggressive care, hospice care should be encouraged.
- The NCI should include information and programs on death and dying within its overall mission of public education and outreach. This type of information, including counseling and referral to hospice, should be available through NCI's 1-800-4-CANCER telephone line and through other educational programs and materials.

PRESENTATION HIGHLIGHTS: Medical Effects

PEDIATRIC CANCERS AND MEDICAL SURVEILLANCE/FOLLOW-UP FOR SECOND CANCERS—

Dr. Anna Meadows

Key Points

- Pediatric cancers are different from cancers that affect adults. Although it is not well known, pediatric cancers have been shown to be more responsive than adult-onset cancers to chemotherapy and radiation. However, children cured of cancer have almost universally been treated with potentially toxic therapies; this realization prompted the NCI in 1972 to support research related to long-term survivors of childhood cancers.
- Children and adolescents comprise approximately two percent of cancer cases, but they comprise three percent of all survivors—approximately 250,000 people in the U.S. at present. Today, three out of four children treated for cancer will be cured. It is estimated that by the year 2000, one in 900 people between the ages of 16 and 44 years will be a survivor of a childhood cancer; for this reason, the long-term effects of cancer treatment are of significant concern.
- Child and adolescent cancer survivors have an average life expectancy of 60 years compared to 15 years for the average adult cancer survivor.
- In pediatrics, neoadjuvant therapy (i.e., chemotherapy used prior to surgery to reduce tumor size) or adjuvant therapy (including postsurgical chemotherapy and radiation even when there is no evidence of disease) has led to increased pediatric survival. Practitioners developed a team approach and learned to use multiple drugs to provide intermittent therapy and to provide support with antibiotics and blood products. Adult oncologists have only begun in the last dozen years to appreciate and apply these principles, which may well be reflected in recent improvements in survival from some adult cancers.
- The two most significant issues of concern related to childhood cancer therapy are: (1) the impact of treatment on growth and development, and (2) reproduction, particularly related to fertility and the health of offspring. Growth and development issues include linear growth, intellectual function, psychosocial adjustment, and sexual maturation. The medical community must be able to predict the effects of treatments on children and identify treatment methods that will not adversely affect their growth.
- Research on children treated with radiotherapy for Wilms' tumor revealed that the same cure rates could be attained by decreasing the radiation dose from 40Gy (at which the average three year old lost four inches of growth) to 10Gy, which results in only a one inch loss of height.
- It has recently been determined that children treated with anthracyclines are at risk for heart failure late in adolescence or in early adulthood, even though they are cured of their childhood cancer. Efforts are underway to prevent this from occurring.
- Mediastinal irradiation, chest irradiation to the heart and the coronary arteries, as required in the treatment of Hodgkin's disease and other diseases of the chest, produces late coronary artery disease and may result in premature death. Anthracycline chemotherapy produces a similar result. High dose stem cell or marrow transplant, and some of the newer drug combinations, have also been shown to cause cardiac problems. Studies are underway to determine if exercise benefits asymptomatic patients and to assess how best to use cardioprotectants in conjunction with anthracyclines to avoid later heart problems.

- It appears that girls are more adversely affected by anthracyclines than boys and that adverse effects are age-, and dose-related. The current practice of providing anthracyclines through a continuous infusion decreases the negative effect on the heart, and cardioprotectants are enabling physicians to provide higher doses of these drugs with fewer long-term effects.
- Second neoplasms are also a problem following treatment for childhood cancers. With respect to second neoplasms, it is important to note that new cancers can develop in individuals because of the same exposures that led to the initial cancer. For example, tobacco smoking can lead to lung cancer, but it can also lead to esophageal and bronchial tree neoplasms, pancreatic cancer, and bladder cancer. Second cancers can also occur as a result of certain underlying predisposing conditions. Persons with certain cancers or cancer syndromes (e.g., retinoblastoma, neurofibromatosis, Li-Fraumeni syndrome) are more susceptible to second or multiple cancers.
- Radiotherapy is known to increase the risk of second cancers. Certain chemotherapeutic agents (not all chemotherapies) raise the risk of secondary acute and chronic myeloid leukemia, and lymphomas. Alkylating agents are the most common offenders, but newer agents, such as the epipodophyllotoxins, also induce secondary leukemias. It also appears that the effects of radiation are potentiated by certain drugs.
- Over the past decade, we learned that although epipodophyllotoxins are important agents for curing certain leukemias, when given weekly, the incidence of secondary leukemias is as high as 12 percent. One study demonstrated, however, that when the drug was given every other week, the incidence of secondary leukemias dropped to only 1.6 percent. Now these drugs are given in such a way that the incidence is reduced to virtually zero.
- Radiation is also known to produce sarcomas in doses greater than 40Gy. Recent research indicates that carcinomas of the breast increased greatly in adolescents treated for Hodgkin's disease with doses of 30Gy. Young children treated with radiotherapy are particularly susceptible to subsequent thyroid cancers, and basal cell carcinomas are also very common following radiation therapy.
- A study of second cancers in 9,000 children following childhood leukemia revealed that the risk of second cancers was approximately 2.5 percent. Most of the second cancers were located within the radiation field. Some of the second cancers were brain tumors in children who had received cranial irradiation. It is now known that more than half of children with leukemia can be cured of their disease without any radiation and that children who need radiation can be cured with lower doses. Very young children are more susceptible to radiation risks than those over five years of age. At present, very few children with leukemia under age five require cranial irradiation. Cure rates for children not receiving radiotherapy have not declined.
- In an international study of 1,400 young adolescents and children with Hodgkin's disease, the risk of second cancer was approximately seven percent overall; leukemia risk was less than four percent, but the actuarial breast cancer risk was 35 percent at 30 years.. All of these girls received more than 30Gy to their chests and they received it in their periadolescent period when their breasts were developing. As a result of this research, treatment approaches for Hodgkin's disease in adolescents now include lower doses of radiation. It may be possible in the future to cure the disease without any radiation. Similar research is underway to reduce or eliminate the radiotherapy-related risk of second cancers in children treated for retinoblastoma.

- Much remains unknown about the relationship between cancer treatment and genetic polymorphisms or population differences. For example, cardiac disease following anthracycline treatment may reflect a different genetic mechanism for metabolizing anthracyclines among affected patients. Further study of this phenomenon may affect how cancer patients are treated in the future.
- In addition to treatment modifications and the development of guidelines for follow-up of childhood cancer survivors, research has also led to interventions such as modified educational techniques for children who have received cranial irradiation; replacement of growth, thyroid, and gonadal hormones; reproductive counseling for young men about to undergo certain therapies and for young women who are going to experience premature menopause; and health behavior education.
- We are now poised to learn more about the long-term effects of treatment for both childhood and adult cancers. Findings from these studies will enable us to provide better information and better alternatives to consumers and medical caregivers.

COGNITIVE EFFECTS—Dr. Tim Ahles

Key Points

- Cancer survivors have recognized that the cognitive impact of cancer treatment is an important issue requiring further study. Certain cognitive rehabilitation approaches may be effective, and medications are under study in non-cancer populations that may improve concentration and memory functioning in cancer survivors. Through further study, treatment protocols may be modified to minimize negative cognitive effects while maintaining treatment efficacy. Patients need to know about this potential side effect to make informed treatment decisions.
- Radiation therapy has been shown to affect brain tissue. There are early effects, like cerebral edema, early delayed reactions such as demyelination, and late effects, the most dramatic of which is radiation necrosis. Radiation effects have been studied primarily in patients with primary brain tumors and as related to the prevention of central nervous system metastases. In the treatment of brain tumors, it is often difficult to separate the impact of treatment from the impact of the disease itself. These tumors are also fairly uncommon and therefore, it is difficult to identify enough cases for comparison studies.
- With respect to prophylactic cranial irradiation for the prevention of brain metastases, most of the research has been conducted in patients with small cell lung cancer (SCLC) in whom cognitive deficits have been demonstrated consistently. These deficits can be measured on standard neuropsychological tests and through brain MRI. Results of a recently published study of patients with SCLC treated with a Cancer and Leukemia Group B (CALG-B) protocol indicated that cognitive deficits may be observable within one or two months following completion of central nervous system irradiation. Since many SCLC patients are treated with both systemic therapy and radiation, however, it is difficult to determine how much of the cognitive deficits observed are attributable to the irradiation versus the chemotherapy.
- Increasing evidence suggests that cognitive deficits such as loss of memory and concentration may be associated with systemic chemotherapies. Some of these deficits may be subtle, but may substantially affect a survivor's ability to work in certain environments within their profession. For the survivor, such changes may have a major impact on quality of life.

- Surveys conducted to date suggest that as many as half of patients treated with systemic therapies experience memory and concentration problems. Most questionnaires, however, contain only one or two items related to this effect and appropriate control groups are generally lacking to support meaningful comparisons. Further, as survivors age, problems with memory loss and concentration become more evident. This is as true for the general population as for cancer survivors, and complicates attempts to assess treatment-related cognitive deficits.
- A variety of studies have been conducted to assess cognitive deficits in patients receiving high dose chemotherapy and bone marrow transplantation, and more recently, in patients receiving standard dose chemotherapy. These studies employed a structured neuropsychological test, with appropriate controls, and have demonstrated a consistent pattern of cognitive decline in a subpopulation of treated patients. Another study of women treated with high dose chemotherapy revealed treatment-associated white matter changes detectable with MRI.
- One of the better studies of the relationship between systemic chemotherapy and cognitive deficit was published recently in the Journal of the National Cancer Institute. The study design included women with breast cancer who were randomized to either high dose or standard dose chemotherapy and a control group of women with breast cancer who had never received systemic chemotherapy. Of those in the high dose group, 32 percent had documented cognitive problems. Seventeen percent of women in the standard dose group reported cognitive deficits, while only nine percent of patients not receiving chemotherapy experienced cognitive problems.
- A study is currently underway at Dartmouth to identify the cognitive impact of systemic chemotherapy in long-term survivors of breast cancer and lymphoma. This study is interesting because it includes a large number of survivors treated with systemic chemotherapy as well as a fairly large number treated only with local therapies such as surgery or some type of local non-central nervous system radiation therapy. The study is a three phase effort. Phase I involves identifying survivors treated at Dartmouth and interviewing them by telephone using a standardized neurobehavioral checklist and quality of life instrument to assess cognitive functioning, particularly as it may relate to quality of life. In phase II, a random subpopulation (approximately 140 patients) will participate in a standardized battery of neuropsychological tests to examine cognitive functioning with an emphasis on memory and concentration. Anxiety, depression, and fatigue will also be examined to isolate their potential confounding effects on study results. Phase III is a pilot study studying cognitive deficits in cancer survivors using functional and quantitative structural MRI. This approach permits investigators to assess brain function and perform cognitive testing while the person is undergoing an MRI.
- There is also new research involving biological response modifiers showing a dose-related relationship between treatment and cognitive problems such as disorientation, impaired memory, and psychomotor slowing. For most patients, these problems resolve when therapy is discontinued, but new evidence suggests that for a subpopulation of patients, these deficits persist well after therapy is completed.

Additional Research Needs and Other Recommendations

- More longitudinal study designs are needed to assess cognitive deficits related to cancer treatment. Many studies have been cross-sectional, and only examine patients after

treatment. Assumptions made in these studies that cognitive function was normal prior to treatment may be invalid.

- We need to understand better the relationship between cognitive functioning and various other measures of functioning (e.g., work and school functioning, social and family functioning, and psychological functioning). More information is needed about the predictors of cognitive deficits; it is recognized that a consistent subgroup of patients experiences this side effect. Higher educational and IQ levels tend to be protective of cognitive functioning. A history of traumatic brain injury tends to predispose patients to greater treatment-associated cognitive difficulty. Previous cancer therapies and other biologic and genetic variables may also predispose patients to greater cognitive difficulties.
- More study of the mechanisms underlying cognitive functioning is necessary. For example, it is known that hormone function in women influences cognitive functioning, however, the impact of menopause on cognitive functioning in cancer patients is not understood. Many of the systemic chemotherapies cause premature menopause. How does early menopause interact with chemotherapy? How do hormonal treatments, such as tamoxifen, affect cognitive functioning?
- Both cognitive rehabilitation and pharmacologic interventions are needed to address treatment-related cognitive deficits.

DISCUSSION—Drs. Meadows and Ahles

Key Points

- Patients often attribute cognitive problems they experience to a psychological source; as they continue to experience problems with memory and concentration, they tend to question their coping skills and erroneously conclude that they suffer from depression. Patients are typically relieved to learn that their cognitive problems may be physically based. This point is based on clinical experience. More research in this area is needed.
- It is important to keep in mind that while the medical effects of cancer therapies are extremely important and require further study, most cancers are fatal if untreated. For many patients, the risk of side effects pales when compared to the benefit of a lifesaving therapy.
- As new therapies emerge, it is essential to incorporate adequate follow-up to identify the long-term effects of treatment and their impact on patients' quality of life. At present, the research community is focused principally on how long patients live with these new therapies, but we now recognize that cure is not enough. Long-term quality of life assessments must be built into trials of new therapies so that we will be able to answer consumers' questions about the risks and benefits of these treatments.
- Although some of the cognitive effects discussed may be attributed to cancer therapies, it is also possible that these effects have another physical or psychological component that is not being addressed by the physician. Physicians should be careful not to oversimplify patients' complaints about cognitive problems by attributing them solely to treatment effects.
- A five-year survivor of non-Hodgkin's lymphoma expressed great concern about the long-term effects of his treatment. Due to anxiety and depression he is unable to return to work and is troubled by the lack of certainty regarding the impact of treatment on his future. Dr. Calabresi emphasized that such feelings are understandable, since having cancer and undergoing cancer treatment is no less a major trauma than experiencing war or other

major catastrophes. He encouraged the speaker to recognize that he has overcome a great challenge and has a reasonable expectation of a long and healthy future. He further encouraged the speaker to continue follow-up care to confirm the health of major organ systems and ensure that all is being done to prevent future problems.

- Until recently, we have, in many cases, had little choice in the kinds of treatments we have had to use in order for patients to achieve survival. As better treatments are developed, however, the medical community must stop telling patients to just be grateful to be alive and start examining what more can be done with respect to rehabilitation and promoting better quality of life.
- Little research has been conducted on hormonal treatments and their impact on cognitive functioning, particularly in the male population. Research has been done on women who have gone through menopause and experienced cognitive problems. These problems have been improved with estrogen replacement or other hormonal interventions. Anecdotal evidence suggests that women taking tamoxifen may experience memory problems.

PRESENTATION HIGHLIGHTS: Psychosocial and Behavioral Issues

OVERVIEW OF PSYCHOSOCIAL AND BEHAVIORAL ISSUES—Dr. Joan Bloom

Key Points

- Definitions of quality of life and survival vary. For example, quality of life has been defined as the difference or gap between the hopes and expectations of the individual and that individual's personal experience at a particular point in time. Health-related quality of life refers to the individual's perceptions of emotional and physical health, including perceived effects on physical and social functioning. Three stages of survival have been defined: acute, extended, and permanent. Acute survival begins at diagnosis and continues through the end of treatment. Extended survival begins at approximately one year after diagnosis or at the conclusion of treatment and continues until the risk of recurrence has decreased; permanent survival continues thereafter.
- In the acute stage of survival, patients generally experience depression and anxiety, energy reduction, decline in physical functioning, and distress related to disease symptoms; these typically relate to treatment and are independent of cancer site. Issues specific to cancer site include, for example, body image of women who undergo mastectomy, arm problems related to breast cancer surgery, abrupt menopause, and among prostate cancer patients, sexual, urinary and bowel function issues.
- Providing some of these data and setting the methodological parameters for psychosocial research to follow are the results of the Psychological Aspects of Breast Cancer Study Group which was published in 1986. The study was conducted in 61 hospitals in 11 states and examined not only women with breast cancer, but women who did not have any surgery, women who had gallbladder surgery, and women who had a negative biopsy. Study results revealed that some of the psychological outcomes that are attributed to cancer survivors may in fact be normal consequences of any type of surgery. Although women with breast cancer may recover more slowly, by the end of a year there were no significant differences in outcomes among the patient groups. This study demonstrates the importance of having comparative data to place research findings into their proper context.
- General issues related to the extended stage of survival (one to three years) include energy reduction, sexual dysfunction, altered physical functioning (especially at older ages), body image changes, relationship issues, and work-related problems. Fertility distress

(particularly related to radiation treatment) is common among testicular cancer and Hodgkin's disease survivors. For breast cancer survivors, issues include arm problems, limited mobility, and weight gain. Communication issues may also surface during this period.

- In one study of testicular cancer and Hodgkin's disease patients, 83 percent of the testicular cancer patients experienced full return of energy by the end of three years compared with only half of Hodgkin's disease patients. Hodgkin's disease survivors also experienced greater fatigue and greater inability to work at their former pace compared with testicular cancer patients. The testicular cancer survivors had greater problems in sexual function, particularly ability to achieve orgasm.
- Among the general issues prevalent during the permanent stage of survival are energy loss, second cancers, work-related problems, and relationship issues. Disease-specific issues include heart disease and infection risk among people treated for Hodgkin's disease, and physical disabilities among childhood cancer survivors.
- Another study of Hodgkin's disease survivors followed nine years from diagnosis found that younger age at diagnosis was associated with fewer problems overall.

EMPLOYMENT ISSUES—Dr. Joan Bloom

Key Points

- Work is thought to be universally important to quality of life and self-esteem, and the ability to return to work and other routine daily activities after having cancer is an important part of the adaptation and recovery process.
- Three parameters have been identified as important in return to work after major illness: characteristics of the workplace, type of work, and extent of functional limitation. Factors positively associated with return to work include supportiveness of the workplace, ability to control work pace and schedule, skill and time discretion, limited physical demands of the job, higher job status, and higher income and educational levels. Factors that have been found to reduce the likelihood of returning to work include greater physical demands of the job (also a proxy measure of socioeconomic status), transportation problems, lack of control of job pace or schedule, lower income and education, and lower job status.
- A study of Hodgkin's disease survivors found that women were more likely to be unemployed than men, and were less likely to be working full time. An important correlate of number of hours worked was coworker support (i.e., people with more support in the workplace were likely to work more hours).
- Return to work may not be a useful measure of recovery from cancer, since some studies have shown that survivors whose energy level has not fully returned expend their energy on work activities at the expense of leisure activities.
- Since passage of the 1990 Americans With Disabilities Act (ADA), which is intended to protect people with cancer (and other disabilities) from job discrimination, studies have been conducted to assess the extent to which this legislative protection is effective. One such study of 500 cancer survivors, of whom 70 percent were women, found that 14 percent had job duties decreased and seven percent were fired. Thirty-three percent of supervisors surveyed felt that the survivors could no longer handle their jobs, whereas only 19 percent of survivors felt this way. Among supervisors surveyed, 31 percent felt that the employee needed to be replaced; only 14 percent of the survivors expressed this feeling. These discrepancies call into question the effectiveness of the ADA in protecting survivors,

most of whom do return to work. A similar current study of breast cancer survivors under age 50 years is yielding similar results.

- Some of the stigmatization of cancer survivors in the workplace is self-imposed by survivors; the remainder consists of real limitations imposed by the workplace.

Additional Research Needs and Other Recommendations

- Further research is needed on issues related to return to work (e.g., use of leave time, work ability perceptions of supervisors and coworkers), work-related problems (e.g., discrimination, self-imposed limits), measurement issues (e.g., activity patterns, work problems, differentiating between individual, work type, and work site effects), policy effects (e.g., ADA implementation), and relationships between work and quality of life.

SEXUALITY—Dr. Leslie Schover

Key Points

- Sexuality encompasses more than erections or orgasms. It includes relational sex (the ability to feel attractive and lovable), recreational sex (feeling free to enjoy touch and caressing), having functional sexual activity, and reproductive sex (being able to have children if desired). Unfortunately, cancer treatments can damage all of these aspects of sexuality.
- Current social research surveys in the general population indicate that married couples are most happy with their sex lives, and throughout middle age, most of these married couples spend an average of approximately 30 minutes a week having sex. Approximately 20 percent of American adults are not sexually active and a large proportion of these adults are older women who have been widowed or divorced and therefore lack a partner. Research suggests that sexuality is an important component of well being, and although not necessarily causal, those who report being the happiest are people who have had one sexual partner in the past year, have sex fairly frequently (two to three times a week), and for women, routinely experience orgasms as part of their sexuality. Conversely, poor health is associated with being sexually inactive and unhappy.
- Sexual problems are particularly prevalent among patients with prostate and breast cancers. Approximately half of the women with breast or gynecologic cancers have persistent sexual problems. Following prostate cancer treatment, up to 70 percent of men have significant sexual problems. Most of the sexual problems that cancer survivors experience are severe. They tend to affect all phases of sexuality including desire, arousability, and the ability to feel pleasure. These problems tend to persist following cancer treatment after other aspects of quality of life have improved.
- Among the most common problems are loss of desire for sex, erectile dysfunction in men, pain with sexual activity (particularly with penetrative, or vaginal, intercourse) among women, and to a lesser extent, trouble reaching orgasm for both men and women. Orgasm-related difficulties, however, are generally secondary to the fact that patients experience both a lack of desire and difficulty with sexual functioning.
- Among the risk factors that appear to increase the likelihood of survivor distress related to sexuality are younger age; not being involved in a committed relationship; viewing sexual attractiveness as a crucial element of self-esteem; and a history of sexuality-related concerns such as multiple sexual partners, sexual abuse or trauma, or sexual dysfunction prior to having cancer.

- Many cancer treatments can interfere physiologically with male sexual function. These include pelvic cancer surgeries (e.g., radical prostatectomy, cystectomy, colorectal surgery) that can damage the nerves that direct blood flow to the penis, and therefore, interfere directly with erection. Men who have pelvic radiation therapy often develop erection problems because the radiation damages some of the small blood vessels that are also involved in achieving erection. Although some of the newer modalities, such as conformal radiation or radioactive seeds are less destructive, they all have some associated morbidity of this nature. Men who receive hormonal therapy for metastatic prostate cancer often experience profound changes in their ability to enjoy sex, to feel sexually aroused, and to feel sexual pleasure.
- Women most apt to experience sexual problems are young women who experience premature menopause as a result of their cancer treatment. This has been observed often in women diagnosed with early stage breast cancer who receive adjuvant therapy and in those who undergo pelvic irradiation or removal of their ovaries as part of their cancer treatment. It remains unclear whether breast cancer survivors may safely take exogenous estrogens, which would quickly reverse some of the problems they experience.
- Women who have pelvic radiation therapy for cervical cancer and women who have graft versus host (GVH) disease following bone marrow transplant may undergo physical changes to their vagina and the vaginal mucosa that may make intercourse painful or impossible.
- Both men and women may undergo treatments that change their body image. For women, these may include mastectomy, removal of the vulva, vagina, or other organs involved in sexual activity. Some men may have to undergo partial or total penectomy. Other treatments that affect body image include a variety of ostomies, physical scarring from radiation, amputations, the mutilating affects of head and neck cancer, and some of the transient effects of chemotherapy such as loss of hair and pallor. Some of the weight gain experienced as a side effect of chemotherapy is permanent and may also adversely affect women's perceptions of their attractiveness.
- Most couples experience some period of celibacy when one partner is undergoing cancer treatment and are faced with the task of resuming sexual activity after the treatment is completed. Although most people in this culture expect sex to be romantic and spontaneous, patients undergoing cancer treatment have to coordinate sexual activity with their medication regimen to minimize the impact of cancer treatment effects such as fatigue or nausea. In addition, they have to cope with changing perceptions of their own physical attractiveness, new sexual dysfunctions, and the stress that cancer may place on the relationship. Younger patients may also need to confront possible infertility and changes in their decisions about childbearing.
- Loss of desire is the most difficult and complex sexual problem to treat. In women, androgen replacement may occasionally be a solution, but we lack a good delivery system for giving women testosterone. Moreover, the safety of testosterone for breast cancer survivors has not been determined. Men who are receiving hormonal therapy for prostate cancer experience a loss of desire due to a reduction in their circulating androgen levels. No viable options currently exist to restore their desire. Sexual counseling with both partners can help increase sexual frequency and pleasure, but cannot directly affect how often partners desire sex.

- A number of approaches are available for treating erection problems. Although newly available Viagra may be an excellent drug, it is not a panacea; it does not cure 80 percent of men's erection problems. It provides improvement in about 80 percent of men who have the most mild form of erection problems, such as those due to anxiety or to very mild physical impairment. Among men who have had radical prostatectomy, Viagra manufacturer Pfizer's clinical trial data suggest that only 43 percent experienced improvement by taking Viagra. This does not mean that 43% achieved erections sufficiently functional to allow penile/vaginal intercourse.
- Following cancer treatment, many men will remain dependent upon other treatments to restore erections, such as injecting medication into the penis to have intercourse, using a vacuum pump device, or undergoing surgery to implant a penile prosthesis. Patient satisfaction with these treatments is variable and there is a high drop-out rate with all except surgery. There has also been very little emphasis on including a man's partner in the process of selecting among various treatment options or in follow-up to assess satisfaction with the option selected.
- More effective treatments are needed for the vaginal pain that women experience as a result of cancer treatment. To minimize vaginal changes resulting from radiation therapy, women should be encouraged to use vaginal dilators (and be instructed in their use) or have intercourse more frequently during and after radiation therapy.
- Breast cancer survivors often receive conflicting information about whether to take replacement estrogens. Even women who are not breast cancer survivors may have difficulty reaching a decision about estrogen replacement therapy because they fear that it causes cancer and are unaware of its benefits. Women should be aware of newer vaginal lubricants and vaginal, slow-release forms of estrogen.
- Cost-effective sexual counseling is essential and must be provided to a wide range of populations, including minorities and the underserved. Many members of ethnic minorities in the United States hold conservative views about sexuality and may have more anxiety and difficulty discussing these issues with their physicians and medical team. Counseling techniques must be integrated into cancer care and must be sufficiently broad and flexible to accommodate the needs and perceptions of various components of the population.

Additional Research Needs And Other Recommendations

- Information about the potential effects of cancer treatments on sexual activity and fertility and available treatment options for these problems must be integrated into the cancer care continuum. Questions concerning sexuality and infertility must be included routinely in patient assessments initially and at followup intervals.
- Cancer treatment teams should include a sex expert—an oncology nurse, social worker, or counselor who is responsible for informing patients about the sexual consequences of their treatment at the time treatment is selected. The expert should also conduct follow-up discussions with patients at predetermined intervals, and triage patients to appropriate specialists (e.g., urologists, reproductive endocrinologists) who can provide treatment for complex or severe problems.
- Policy changes are needed to provide insurance coverage for cancer-related sexual problems. Many private insurers exclude this type of care from mental health reimbursement and may also exclude medical treatment for sexual problems. Typically, men and women who

experience fertility problems after cancer lack insurance coverage for expensive infertility treatments.

- Greater emphasis should be placed on providing community outreach to respond to sexual problems experienced by cancer survivors. Many survivors are followed by their primary care provider and special issues such as sexuality often are not addressed. This problem is compounded by the fact that many people do not ask for help with a sexual problem or concern; this is particularly evident in minority populations and among the elderly.
- Sexual health after cancer must be actively promoted. Information on sexuality should be integrated into site-specific support programs for survivors. Opinion leaders should be encouraged to speak out in the media about the importance of sexual problems and infertility after cancer. Information on sexuality and fertility should be included in quality of life assessments.

FAMILY ISSUES—Dr. Grace Christ

Key Points

- Research demonstrates clearly that the availability of emotional and practical support from loved ones is enormously helpful to patients' psychological well being, quality of life, and even survival. Two realities most influence the needs of families of cancer patients. The first is that cancer treatment now involves less hospitalization, more home care, and more outpatient procedures than in years past; this reality places more responsibility on the family to provide care over long periods of time. Second, there have been vast changes in recent decades in the home supports that are realistically available to many patients. Families are more mobile and fragmented. The loss of extended families due to job relocations, retirements, and generally increased mobility has resulted in a significantly diminished system of local patient support. These changes in the fabric of society require that the family-based care model be examined more closely. A third dimension relates to resource depletion and the extent to which the family's financial and emotional resources are drained in caring for the cancer patient. In addition, a fourth important dimension affecting patient support relates to the stage of development of key family members and their developmental tasks (e.g., the effect of cancer on the parenting role with young children, the ability of an older adult to care for a spouse with cancer, the impact of cancer caregiving on a middle-aged adult's career).
- The role of the family caregiver is potentially overwhelming. Families are asked to provide financial and emotional support; assume the patients' responsibilities as they lose the ability to handle these; provide direct nursing care; become a surrogate specialist or dietician; and put their own life goals and activities on hold for an extended time period. Unchecked, stress on families reduces their availability to patients and can cause family members to develop physical symptoms and disabling psychological distress, suffer social isolation, and even become alienated from the patient. Also common are economic costs such as loss of work, increased medical expenses, and reduced productivity and effectiveness in both work and family functioning. Despite the intense pressures placed on the family, psychosocial treatment tends to focus on patient needs rather than considering the needs of the family unit. The primary health care agency may feel too overwhelmed with the care of the patient to include family concerns, and may not know how to provide time limited but potentially helpful family-focused interventions.
- The challenges faced by families caring for a cancer patient span four domains. The first of these is learning to deal with chronic stress and finding ways to build family resilience.

Each stage of cancer brings new and different stresses for family members, and new ways are needed to cope with uncertainty and each new threat to the integrity of family life. Higher levels of depression and other psychiatric problems have been reported consistently among family members of cancer patients. For example, parents of pediatric cancer patients have been found to have more post-traumatic stress symptoms than their children who are patients. Similarly, high depression and anxiety levels have been observed in young adult and middle-aged well spouses facing a partner's terminal illness. An emerging conceptualization of family resilience focuses on ways to strengthen families' abilities to surmount crises and persistent stresses. Inner personal processes such as cohesion, flexibility, open communication, and problem solving have been shown to strengthen family abilities to cope. Shared beliefs about the meaning of illness and the meaning of caregiving can also foster a sense of cohesion, collaboration, confidence, and competence. Current research is attempting to identify risk and protective factors that could form the basis of family interventions.

- The second challenge to families is their expectation of resilience (versus transformation) in cancer survivors. Expecting that the cancer patient will "bounce back" to his or her original state when this is not realistic can cause significant family stress and an undue burden on the survivor. Our culture values individuals who emerge from a crisis without "missing a beat." The notion that one can pick up where he or she left off following cancer diagnosis and treatment is at odds with the experience of an overwhelming majority of survivors. Transformation requires a series of evolving adaptations and often results in lasting changes in self-concept, values, roles, and time perspectives. Surviving cancer is a transforming experience that leads most patients to re-evaluate their values and life priorities; in many cases, survivors report that the disease led them to make changes that immeasurably enriched and enhanced their lives. To reach this outcome, however, survivors need to deal with their own, and sometimes their family's unrealistic expectations of resilience (i.e., returning to their pre-diagnosis status).
- In some cases, (often young) survivors take physically punishing jobs or jobs with high levels of responsibility just to prove they are worthy of surviving or to deny their ongoing vulnerability; this sometimes leads to physical or psychological crises. Such a heavy dose of denial may be adaptive at an earlier stage of the illness, but may be distinctly less helpful at later stages. Research has shown that those who cope well with stress are those who do not deny the adversity or tragedy of the situation, and who are also able to see it as a challenge to make positive changes in their life and relationships and extract positive meaning from the situation.
- The third challenge to families involves communication under conditions of uncertainty. Families can be weakened in their ability to provide effective support by a breakdown in communication with the patient, sometimes reflecting misinformation, misunderstanding, and different coping strategies with respect to communication. These breakdowns in communication are most clearly observed at various crisis points in the illness, such as at diagnosis, at the end of treatment, and at recurrence. Communication stresses are often observed following the initial cancer diagnosis because many families try to avoid discussing the disease to keep the patient hopeful; the patient, however, may want to talk about his or her illness. Avoiding the subject may cause the patient to become increasingly worried that his or her situation is too dangerous to discuss.
- When treatment ends, although patients know intellectually that this is a time for rejoicing, many experience a sense of anxiety and emotional unease because they are no longer

engaged in actively fighting the disease. Cessation of treatment also results in loss of contact with the medical personnel upon whom they relied on a daily basis. Family members and friends who may have been very supportive during earlier stages of the illness may become less available and indulgent. They may feel that it is time for the patient to return to a normal life and to pick up where they left off prior to diagnosis. Families are often weary of caregiving tasks and the strain of worry, and are eager to be immersed in less threatening life problems. But patients may not yet feel normal. Although the challenge of staying alive and enduring treatment may have been achieved, they must face the world and live with the psychological, social, and physical consequences of surviving cancer. This often involves living with new compromises in one's life, lasting physical problems, low energy, and other significant consequences of cancer survivorship. Most patients find ways to accept the changes without great psychological cost and are grateful for having survived the disease, however, they may need time to mourn their perceived losses, whether they be with respect to altered physical capacities, lost opportunities, or losses related to self-image.

- Communication difficulties at recurrence may occur as a result of the patient's or family's decision to avoid discussing the disease with persons outside of the family. This places considerable strain on family members by depriving them of necessary support.
- The fourth major challenge to families involves reassigning family roles and responsibilities; this can cause considerable strain and requires a great deal of effort and support. Good communication can help to ease the strain of these changes and can contribute to more effective family functioning.
- Focusing on the family unit is essential in planning interventions that improve the quality of life for both the family and the patient.

DISCUSSION—Drs. Bloom, Schover, and Christ

Key Points

- In order to detect the late effects of cancer treatment, long term follow-up of individuals treated for cancer is necessary. Due to changes in how medical care is provided and the way NCI funds clinical trials, long term follow-up has become more tenuous. For example, since the early 1960s, Stanford University has been following a cohort of 2,500 people treated for Hodgkin's disease. An important result has been their identification of some of the long term effects of cancer treatment. This research model enables findings to be communicated readily to patients and to the scientific community where it can result in modification of treatments and influence the follow-up of patients. However, many patients can no longer return for yearly follow-up because patient care funds are no longer being provided to pay for the costs nor will the patient's private insurance.
- Spleen irradiation or removal places Hodgkin's disease survivors at greater risk for infections. Consequently, survivors need to recognize important warning signs of infection, such as an elevated temperature, and know what steps must be taken to address the problem.
- Although some research is underway on the psychosocial impact of cancer in the elderly, much more needs to be done. Specifically, research needs to be expanded that focuses on identifying risk factors, protective factors, and how care can be improved within the context of the family and comorbid conditions. This is a neglected area, especially the study of psychosocial aspects of the elderly within minority communities.

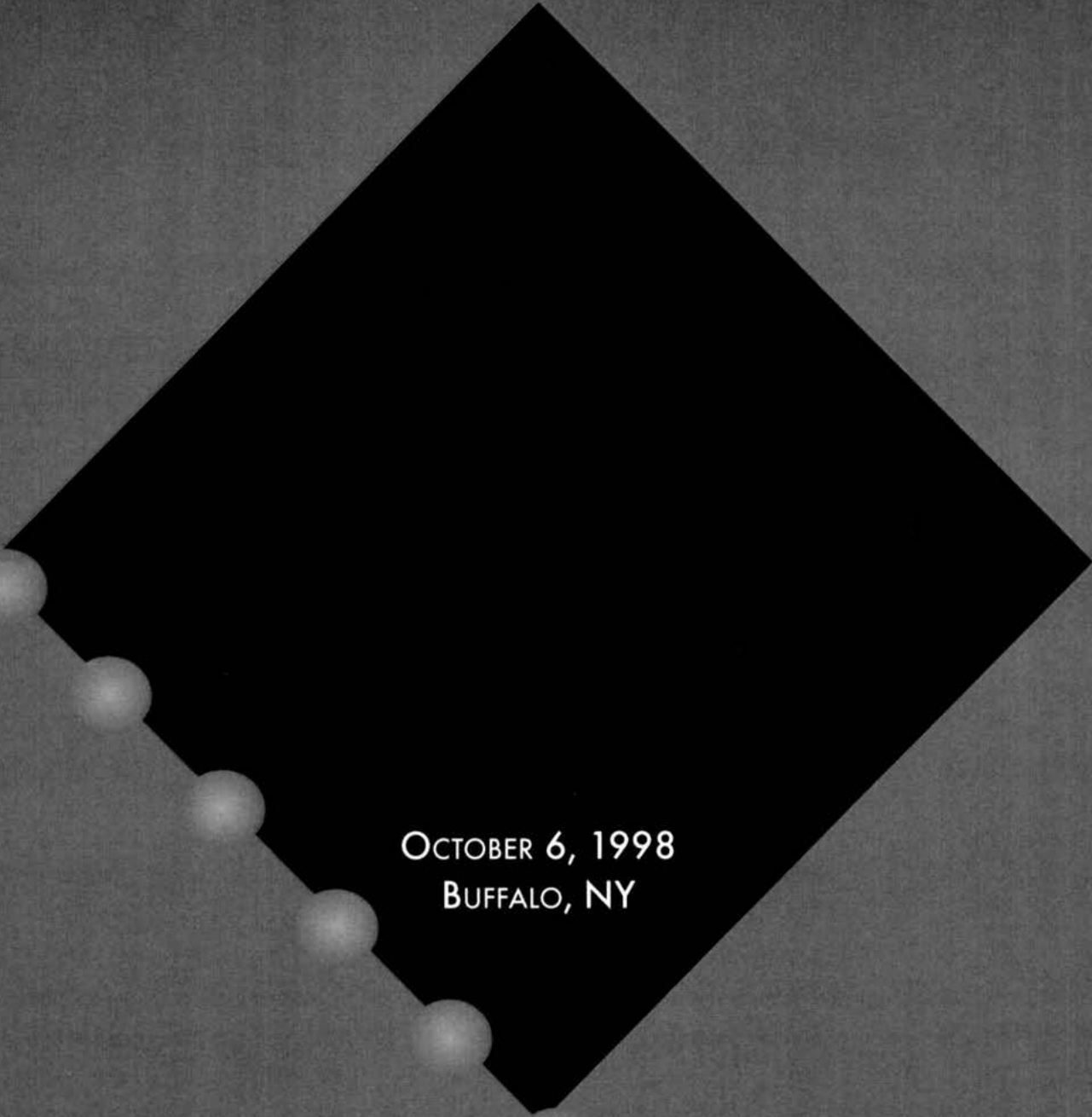
- Geographic disparities persist in the provision of quality cancer care throughout the country. In many areas of the nation, patients lack access to comprehensive or state-of-the-art care. Telemedicine provides promising opportunities for information dissemination and can improve access to experts.
- Controversy exists as to how research funds should be allocated among basic, translational, and clinical research. Dr. Freeman noted that the war against cancer focused on improving cancer research. There is, however, a gap between research and its application. Cancer treatment is not funded by the NCI nor are NCI's funds intended to be used for that purpose. Yet cancer care must be paid for, and a system is needed to ensure that all people with cancer can receive the care they need. Currently, 41 million Americans are uninsured and lack access to care.

CLOSING REMARKS—Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- We are in the midst of a new era with respect to cancer. Efforts have been focused on developing cancer treatments and improved technologies that are now beginning to work well. More emphasis must be placed on quality of life issues.
- As a result of improved treatment, there are considerably more long-term survivors of adult and pediatric cancers. One consequence of long-term survivorship is that we are beginning to see the emergence of special problems that require research.
- Meetings such as this one provide the opportunity to bring these issues to the White House and, it is hoped, stimulate greater funding for quality of life issues. The Panel will report not only on what is known in this area, but what is not known and requires research.
- The final meeting of the President's Cancer Panel on the state-of-the-art concerning quality issues will be held in October.

QUALITY OF CANCER CARE/QUALITY OF LIFE



OCTOBER 6, 1998
BUFFALO, NY

Appendix F

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

N A T I O N A L C A N C E R P R O G R A M

CHAIRMAN
HAROLD P. FREEMAN, M.D.
HARLEM HOSPITAL CENTER

MEMBER
FRANCES M. VISCO, J.D.
NATIONAL BREAST
CANCER COALITION

N A T I O N A L C A N C E R I N S T I T U T E

MEMBER
PAUL CALABRESI, M.D.
BROWN-TUFTS CANCER CENTER
RHODE ISLAND HOSPITAL
NEW ENGLAND MEDICAL CENTER

EXECUTIVE SECRETARY
MAUREEN O. WILSON, Ph.D.
ASSISTANT DIRECTOR
NATIONAL CANCER INSTITUTE

Quality of Cancer Care/Quality of Life Decision Making Based on Quality of Care Guidelines and Their Impact October 6, 1998, Buffalo, New York

Opening Remarks	Dr. Harold Freeman
NCI Director's Report.....	Dr. Otis Brawley
Roswell Park Presentation on Quality Care.....	Dr. David C. Hohn and Staff
Cost, Quality, Value, and Patient Choice in Cancer Care.....	Dr. David Asch
The Federal Role in Guidelines to Care	
Agency for Health Care Policy Research.....	Dr. Lisa A. Simpson
Health Care Financing Administration.....	Dr. Steven Clauser
Centers for Disease Control and Prevention	Dr. Dixie Snider
Professional Societies and Organizations	
National Comprehensive Cancer Network	Dr. William T. McGivney
American Medical Association: Clinical Practice Guidelines.....	Dr. Terry Hammons
ASCO Clinical Practice Guidelines: Progress, Pitfalls, and Prospects	Dr. Mark R. Somerfield
Oncology Nursing Society Position on Quality Cancer Care	Ms. Linda Krebs
American Association of Cancer Institutes.....	Drs. Max S. Wicha and Rodger Winn
Health Care and Related Organizations	
American Association of Health Plans	Dr. George J. Isham
Optimizing the Impact of Guidelines on Medical Decision-Making	Dr. James Schibanoff
Improving Care for Patients with Cancer: The Role of NCQA.....	Dr. Cary Sennett
Closing Remarks.....	Dr. Harold Freeman

Speakers List

Quality of Cancer Care/Quality of Life

Decision Making Based on Quality of Care Guidelines and Their Impact

October 6, 1998, Buffalo, New York

Dr. Cynthia Ambres

Chief Medical Officer
Blue Cross/Blue Shield

Dr. David Asch

Executive Director
Leonard Davis Institute of Health Economics
University of Pennsylvania

Dr. Otis Brawley

Office of Special Populations Research
National Cancer Institute

Dr. Gregg Broffman

Medical Director
Health Care Plan

Dr. Steven Clauser

Director
Quality Measurement & Health Assessment Group
Health Care Financing Administration

Dr. Michael Cropp

Medical Director
Independent Health Association

Dr. Stephen Edge

Director of Breast Services
Roswell Park Cancer Institute

Dr. Terry Hammons

Assistant Vice President
Quality and Managed Care Standards
American Medical Association

Dr. David C. Hohn

President and CEO
Roswell Park Cancer Institute

Dr. George J. Isham

Medical Director and Chief Health Officer
American Association of Health Plans

Ms. Linda Krebs

President
Oncology Nursing Society

Dr. William T. McGivney

Chief Executive Officer
National Comprehensive Cancer Network

Dr. James Schibanoff

Editor-in-Chief
Milliman & Robertson Healthcare Management
Guidelines
Milliman & Robertson

Dr. Cary Sennett

Executive Vice President
National Committee for Quality Assurance

Dr. Lisa A. Simpson

Deputy Administrator
Agency for Health Care Policy Research

Dr. Dixie Snider

Associate Director for Science
Centers for Disease Control

Dr. Mark R. Somerfield

Director, Health Services Research
American Society of Clinical Oncology

Dr. Max S. Wicha

President
Association of American Cancer Institutes
University of Michigan
Comprehensive Cancer Center

Dr. Rodger Winn

Chief, Section of Community Oncology
M.D. Anderson Cancer Center

QUALITY OF CANCER CARE/QUALITY OF LIFE

**Decision Making Based on Quality
of Care Guidelines and Their Impact**

October 6, 1998, Buffalo, New York

OVERVIEW

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. This meeting, the last in a series of three focusing on the meaning of quality of care and quality of life, explored issues in decision making based on quality-of-care guidelines and their impact on the delivery of cancer care.

Nineteen speakers presented testimony to the Panel on the role of Federal agencies in clinical practice guideline development, as well as the guideline-related activities of leading oncology professional societies, professional organizations, health care organizations, and health care regulators. Speakers offered specific recommendations for improving the development and implementation of cancer care guidelines in the evolving health care environment.

OPENING REMARKS—Dr. Harold Freeman, Chairman

In opening the meeting, Dr. Freeman congratulated the Roswell Park Cancer Institute on the occasion of its 100th anniversary and stated that:

- This is the last in a series of three meetings to consider the meaning of quality in the context of cancer care. The Panel believes that defining and delivering quality care is essential to achieving the goals of the National Cancer Program to alleviate the burden of cancer in this country. The first meeting of this series, held in April 1998, focused primarily on how we define, measure, and improve quality cancer care. Testimony presented at that meeting highlighted clearly the difficulty in agreeing on a uniform definition of quality cancer care. Perceptions of quality vary significantly depending on who you are and what you have experienced.
- Cancer care is a continuum, from prevention through diagnosis, treatment, and palliation, and even following death, when social support and bereavement counseling for family members are needed. We must examine the notion of quality care in each of these areas.
- The second meeting of this series, held in June 1998, focused on the special health care needs of cancer survivors, and the need to enhance research on survivorship and end of life issues. Cancer survivors, who now number more than 8 million, are rightfully demanding not merely new cancer treatments, but improved cancer care and a better quality of life following diagnosis through the end of life.
- This meeting is to examine the role that guidelines play in determining our approach to and understanding of quality cancer care. The use of guidelines in medicine is not new. Standards of care and clinical pathways for diagnosis and treatment of cancer are accepted resources for health care providers to make recommendations on the best course of cancer care for patients. However, rapid changes in our health care system, particularly the evolution of for-profit managed health care, have raised new issues regarding the development, application, and impact of guidelines. Reasonableness of cost has been

added as a measure of quality in consumer evaluations of health care delivery organizations, yet the cost and quality of care are often perceived as competing priorities. It is important to evaluate the impact of these changes and how we can best develop and apply guidelines that promote quality care in a cost-cutting environment.

- The impact of cancer care guidelines has not been well studied. Cancer, as a spectrum of chronic diseases with long-term outcomes, does not lend itself to conventional quality measurements applied to the treatment of other diseases.
- Key issues include but are not limited to: how we establish indicators of quality and of effective cancer care as applied to the general population; how we develop a process for evaluating guidelines; how we use information that is gathered about quality; and how this information will be used to refine our notions of quality cancer care. It is also important to consider how guidelines are communicated to the health professional community and to the public. New technologies, particularly the Internet, have increased access to and availability of a wide variety of research discoveries and evolving cancer care guidelines. It remains unclear how this information is affecting decision making and the delivery of care.
- Any discussion of cancer care guidelines must encompass investigational care, or clinical trials. Access to clinical trials is often equated with state-of-the-art or optimal cancer care. Guidelines incorporating cost as a measure of quality may promote quality standard care, but may in fact limit access to so-called optimal care, such as may be available in clinical trials.
- The National Cancer Institute (NCI) has worked with several organizations to ascertain the cost differentials between standard care and care in clinical trials. These analyses will be made available in the future.
- It has been asserted that every person waging a personal war against cancer needs timely access to the best therapies available to fight his or her disease, and assurance that medical knowledge and care will be applied appropriately. The difficulty is in determining on what basis we establish guidelines for care, and assuring that appropriate care is delivered under appropriate circumstances in a cost-effective manner. In the war against cancer, we must be concerned not only with the effectiveness of treatment but with its quality as perceived by patient, family, and practitioner. We must also be concerned with its appropriateness—whether more treatment was provided than necessary or at higher cost than required, or whether the treatment provided was ineffective. How we deliver health-related messages and provide services can have a significant impact on individual perceptions of quality of care. Further, technical definitions of quality must take quality of life into account, both during and after treatment, and at the end of life when cure is not possible. We cannot say that we are delivering quality care if the patient does not feel that the care is of high quality or that life is worth living.

NCI REPORT—Dr. Otis Brawley, Assistant Director, Office of Special Populations Research, NCI

Representing Dr. Richard Klausner, Director, NCI, Dr. Brawley indicated that:

- The NCI, principally through the input of expert panels from the extramural research community, has identified four areas of extraordinary opportunity in cancer research: cancer genetics, preclinical models, imaging technologies, and molecularly based detection

and diagnosis. The Institute has also been working to enhance the infrastructure for research and foster collaborations among the cancer centers throughout the country.

- NCI and other studies have shown clearly that equal treatment yields equal outcome in cancer care, and that race is not a factor in cancer outcome. Patterns-of-care studies, however, show that cancer treatment is not applied equally in the United States. Factors shown to influence outcome include socioeconomic status (SES) and comorbid conditions; many special populations in this country have both lower SES and greater numbers of comorbid conditions. Regional and racial differences in prostate cancer treatment have been demonstrated and have been used to question the efficacy of the common treatments for the disease. Within race, however, regional mortality rates are nearly identical. Disparities in quality of care have also been demonstrated among white Americans of different socioeconomic strata.
- Similar patterns have been identified in the treatment of breast cancer. One-half of the difference in the breast cancer death rates among black and white women is due to later removal of the tumor following diagnosis in black women.
- Treatment guidelines are an important vehicle for applying research findings in the population, but a key question is how to effectively disseminate the guidelines to the physicians and hospitals who treat patients.

PRESENTATION HIGHLIGHTS

ROSWELL PARK CANCER INSTITUTE—Dr. David C. Hohn

Key Points

- Cancer centers face multiple strategic challenges in the current health care environment. Necessary tactics for survival include the ability to standardize and predictably implement care not only within the institution, but within the community. Delivering care to a whole population is going to be a major challenge in cancer care, and for cancer care management, in the decade ahead. Cancer centers face difficult challenges because the care they provide is subspecialized and often more expensive; justifying the value in that added expense can be difficult, and the ability of the centers to subsidize their greater expenses from nonclinical income streams is becoming constrained.
- Increasingly, simpler cases are being treated in the community, while the more complex cases are being sent to the cancer center. Without guidelines and accompanying data defining this greater case acuity and the associated differential cost, the center will not be reimbursed by payers and will jeopardize its ability to fulfill its academic mission.
- Another strategic decision is the choice to compete or collaborate. Some cancer centers have moved to the competitive model, establishing satellite facilities throughout their service areas to capture patients and ensure the quality of care. This model is difficult to support in the Buffalo area; as a result, Roswell Park is moving toward the collaborative, or network model, bringing community physicians to the cancer center. To do so, however, it is necessary to define what care is provided through guidelines, and how it is done through clinical pathways.
- The cancer center must also maintain alignment with the area's health care systems. Guidelines and clinical pathways help the center define for these health care systems what the center does and also helps protect its academic mission. The cancer center should serve

as the hub in a hub-and-spoke relationship that supports the delivery of high-quality care to a regional population.

- Declining earned income is a continuing issue; the center is now negotiating contracts for care based more on market price than a more precise accounting of cost for the care provided. Guidelines should lead to a methodology for better cost accounting and the ability to negotiate fair, honest, value-oriented managed care contracts. Such contracts should enable the center to generate sufficient margin to support the academic mission. Revenue issues are also endangering investigators' protected time for research.
- Guidelines and pathways offer opportunities to more precisely determine clinical costs, reduce costs for inappropriate care, promote educational collaborations between physicians and other cancer care providers, develop disease-site panels to set guidelines, reduce legal risk by reducing variability in care, and measurably enhance quality of care.
- Challenges to the development and use of guidelines include difficulty in achieving physician consensus, implementing guidelines, monitoring outcomes appropriately at the level of the individual provider, influencing behavior change in physicians whose practices differ from those prescribed by the guidelines, and maintaining the confidentiality of physician-specific outcome data.
- Though guidelines have been developed for the treatment of most cancers, few have been implemented systematically. A simple, user-friendly, networked computer system is essential to support wider use of guidelines. Progress is being made toward this objective, notably by the National Comprehensive Cancer Network (NCCN), and also by the M. D. Anderson Cancer Center, which has developed an editable online disease management system that enables the physician to print out guidelines, patient education materials, and preformatted order sets and consent forms. Such approaches are needed if physicians are to embrace rather than resist the use of guidelines.
- In addition to their missions in research, education, prevention, and patient care, cancer centers need to more clearly define and actively pursue their roles in setting and maintaining the standard of cancer care in the community. The development and implementation of guidelines at the community level is the best way to accomplish this mission. Standard care guidelines must be evidence based, clearly defined, easy to use, and widely accessible to health professionals, payers, and patients. Raising the quality of care in the community will best be achieved through partnerships between cancer centers, payers, and community physicians. An informed public can help promote this revolution in the way we practice medicine and can help set the agenda for raising the quality of care.

ROSWELL PARK CANCER INSTITUTE—Dr. Stephen Edge

Background

The Roswell Park Cancer Institute, Independent Health Association (a health care payer in western New York), and a board of community physicians are engaged in a partnership to develop a breast cancer practice guideline and use the guideline to establish a regional total quality management program. The first phase of the project involves a retrospective quality review of breast cancer care in 1995 and 1996 in western New York, to be benchmarked against the NCCN breast cancer practice guidelines. The second phase is the development of a prospective quality improvement program, using prospective ongoing data collection and educational interventions using local peer experts and ongoing involvement of community physicians.

Key Points

- Breast cancer care varies widely in the United States. These variations are seen in biopsy techniques, the use of x-ray staging tests, rates of breast-conserving surgery and radiation therapy, use of adjuvant chemotherapy, and patient followup and treatment of recurrences.
- Measures of quality are difficult to develop. Cancer recurrence and survival are the ultimate measures of quality, but acquiring data on these endpoints may take many years. Single measures (e.g., mammography or breast-conserving surgery utilization rates) may serve as useful quality benchmarks, but may not get at the heart of the quality issue; in contrast, practice guidelines may provide that opportunity.
- Roswell Park conducted a retrospective analysis of its breast cancer care and compared the findings to practice guidelines developed and updated annually by the NCCN. The comparative analysis revealed a high rate of compliance with the guidelines, as well as areas of variation and areas in which guideline updating seemed indicated. Roswell Park now conducts ongoing guideline benchmarking for all breast cancer care at a monthly conference of the breast cancer staff.
- In the first phase of the Roswell Park/Independent Care/community physician project, insurer claims data will be used as the source of practice data. The advantage of using these data is that care provided in any venue is captured. Patients will be identified from procedure and diagnosis codes, and data will be collected on identified patients for all care provided in the 6 months following biopsy or a surgical procedure. It is recognized, however, that claims data have disadvantages, including the lack of cancer staging data and possible clerical coding errors. In addition, claims data by definition do not include care provided to the uninsured. Moreover, in the western New York market, most Medicare beneficiaries are not enrolled in managed care; as a result, data on care provided to the elderly population will be incomplete. Other methods will be used to obtain information on care provided to this population. Independent Health will collect the pathology and operative reports, from which cancer staging data will be obtained. Practice patterns will be reviewed and benchmarked against the NCCN guidelines. Oversight is being provided by a multidisciplinary panel of community physicians.
- Preliminary results of the claims review indicate that the process is identifying both cases and procedures with 99 percent or greater accuracy. The optimal positive rate for breast biopsy ranges from 25 to 40 percent, depending on the population being studied. A low positive rate means that many women undergo unnecessary breast biopsy without benefit and experience needlessly the anxiety that accompanies the procedure. Though surgeons who performed a high volume of excisional biopsies with needle localization (EBNLs) had a consistently higher positive rate than those who performed few such procedures, the same was not true for radiologists who placed the needles.
- For women with breast abnormalities detected by mammography, the ideal is to have only one surgical procedure performed on the breast. This reduces both cost and anxiety, and produces the best cosmetic result. Repeat surgeries (re-excisions required because of unexpected findings) should not exceed 20 to 25 percent of cases). In the Independent Health study, women who had EBNLs had far higher re-excision rates than women whose biopsies were performed by fine needle aspiration (FNA) or stereotactic core needle biopsy.
- Claims data review, in conjunction with staging data, provides detailed practice review data that may be useful for practice guideline benchmarking. The methodology developed

by Dr. Cropp and colleagues is applicable to other cancer types and other payers. Such evaluations must be provider based; i.e., they must be directed by providers and be quality-driven to promote provider acceptance and provide real quality improvement.

INDEPENDENT HEALTH ASSOCIATION—Dr. Michael Cropp

Key Points

- As a payer, Independent Health views quality of care broadly. It works with its provider partners to enhance health-promoting behaviors in the community and thereby reduce future cancer incidence among members. Cancer screening demonstrated in the literature to have a positive impact is provided to as many members as possible. Independent Health believes members need to become more aware of the early signs and symptoms of cancers. A major concern of members is the quality of the provider network available through the plan.
- The health plan strives to ensure that diagnostic care is accurate and expedient, and that treatment is effective, appropriate, coordinated, and compassionate.
- The plan's physician partners expect Independent Health to provide them with information on patients' status, including information on health maintenance and screening procedures. In addition, the plan now provides physicians with information on the status of their patient populations to encourage them to ensure that more of their patients receive recommended screenings. Information is also provided about "best practices" for both screening and treatment.
- Community physicians also want access to a network of quality institutions at which they can provide direct services or to which they can refer patients with confidence that they will receive excellent care. Independent Health looks to the Roswell Park Cancer Institute to help enhance community standards of care and to provide services either directly or through community collaborations.
- In the care of its patients with cancer, Independent Health considers population-specific measures of value, including quality of care, quality of service (e.g., timeliness, patient-friendly delivery), quality of life, and cost.

BLUE CROSS/BLE SHIELD—Dr. Cynthia Ambres

Key Points

- Unless efforts to determine how to enhance the health of the community are collaborative, such efforts are likely to fail.
- It is important that payers are participants in consensus building and guideline implementation, but also that they are facilitators rather than barriers to care. Blue Cross/Blue Shield, in collaboration with Roswell Park and other providers and physicians in the Buffalo community, hopes to be a prototype for the Nation in this regard.

HEALTH CARE PLAN—Dr. Gregg Broffman

Key Points

- Noting that "many are stubborn in pursuit of the path they have chosen; few in pursuit of the goal" (Nietzsche), Dr. Broffman cited the work of Drs. Cropp and Edge in breaking down artificial barriers to quality care in the community and advancing the common goal of improving community health. Health Care Plan welcomes the opportunity to collaborate on practice guidelines and related efforts.

COST, QUALITY, VALUE, AND PATIENT CHOICE IN CANCER CARE—Dr. David Asch

Key Points

- It is often perilous to talk directly about health care costs; even people whose job it is to reduce cost do not like to be allied explicitly with that role.
- When people talk about clinical guidelines, they usually are referring to ways to standardize clinical management. The movement toward guidelines grew out of several decades of health services research that demonstrated wide variation in clinical practices. Such variation provides an agenda for standardization, especially if health care is viewed as a commodity product and health care delivery is viewed from industrial models. A key question, however, is: What is standardization through guidelines expected to accomplish? The possible answers include: to direct patients to optimal care; to direct clinicians to provide care that provides the best value; to direct care to conform to patients' preferences; to direct patients to a concept of the most appropriate care; or to direct patients to care that will be reimbursed by insurers. The stated goals of guidelines may include one or more of the following: reduce high costs, provide high-quality care, provide cost-effective care, or provide appropriate care.
- In a choice between two screening tests, in which one test is slightly more sensitive but significantly more expensive than the other, a fully insured and fully informed patient would be expected to want the more sensitive test. It clearly offers the highest quality. Which test offers the best value, however, depends on how one values the added benefit of the more sensitive test relative to its higher cost. The clinician's selection of one test or the other may be based on a desire to provide the highest quality care, but in the current health care environment, may include other goals, such as value or cost containment. The cost perspective of the patient may depend in part on what insurers will reimburse; moreover, insurance payments can become a standard against which physicians judge their practices, and, in the extreme, may define those practices.
- Eliminating unnecessary procedures or ineffective care is good for everyone. Quality can sometimes be improved and money saved at the same time, but, often, better clinical approaches cost more. Techniques such as cost-effectiveness analysis provide a framework for understanding value, but the highest quality is still the highest quality (however quality has been defined). The real challenge facing patients, clinicians, and policymakers is deciding when cost-increasing improvements in quality are not worth their added expense.
- When we talk about seeking value in health care, we are really talking about compromise; i.e., we are saying that we are willing to accept something we believe is of lesser quality because we believe the added benefit, compared to another alternative, is not worth the additional cost. Physicians make these compromises routinely in clinical practice and have become comfortable with a notion of value (versus quality) by disguising it in one or more of several ways:
 - By thinking beyond the individual patient; i.e., considering the effects of a more expensive alternative on overall social welfare. In this case, the tension between the cost of the alternative and its benefit is overt, though displaced from a single patient to a wider field. This kind of thinking is often embedded within hospital policies and other kinds of clinical guidelines.
 - By appealing to the "standard of care," even though the standard may not represent the highest quality care. Cost does not immediately appear to be part of this argument, but the standard of care is itself often influenced by cost (i.e., if the higher quality test cost

less, the standard of care might be different). Appealing to the standard of care is one way of saying that we believe more value is more important than a certain amount of quality.

- By displacing responsibility for the decision; e.g., the health plan's formulary restricts the prescription of certain medications in certain situations. Similarly, a patient's request for a less expensive and less effective medication or treatment does not erase the provider's responsibility, since the patient may not be informed about the existence or higher quality of an alternative.
- By rationalizing making do with less than the best. This compromise involves comparing the best with the good. A shorthand assessment of quality in such cases might be: Would you recommend this approach (or this physician, or this practice) to a relative?
- By using the "best treatment" only after others fail.
- In some cases, physicians are not aware that they are making these compromises, which are embedded in practice patterns, policies, and guidelines.
- In contrast to the typical rhetoric of organized medicine, many physicians are comfortable tolerating lower quality care if it is seen as providing good value. Cost is important, understood by physicians, and recognized as meaningful in clinical decision making.
- One of the most important roles for guidelines is in setting a target for physicians, who use the strategies above to balance their sometimes conflicting goals of providing high quality and good value. Guidelines can help physicians decide whether quality or value is the goal.

DISCUSSION—Drs. Hohn, Edge, Cropp, Ambres, Broffman, and Asch

Key Points

- One of the issues we face in trying to use health care resources wisely is not only using them wisely in each individual case, but making sure that resources are distributed fairly across a population. A major problem in cancer prevention and screening is that some populations, for a variety of reasons, are not getting recommended screening tests. In general, the cost of any test can be reflected by the opportunity costs of using those resources elsewhere. One of the most efficient strategies is always to make sure that the things that work get to the people who need them. However, in the case in which a reasonably good, lower cost test has been distributed to the entire population, the decision would again arise as to the added benefit of moving to a higher quality, more expensive test. Dr. Asch noted that his comments referred principally to the health economics questions surrounding the latter point, rather than the social health questions reflected in the difficulty getting services of any quality to currently underserved populations.
- In comparing the total health care costs associated with one screening test versus another, the lifetime costs of care for patients whose cancer or other condition is missed by a less sensitive but less expensive test must be taken into account. Likewise, lost earnings and other human capital considerations should be assessed. At the same time, we cannot say that no cost is too high to save a human life, since we would then devote all of our resources to saving lives, and go bankrupt. Absent an infinite amount of money, choices must be made. These choices include whether resources saved in using a less sensitive screening test (that would result in some missed diagnoses) should be diverted to public

health improvements (e.g., better bicycle helmets, clean water for more of the population) that will impact significantly on health and quality of life.

- Currently, we lack the physician and payer data to establish and measure quality as determined by outcome. These data are crucial if we are to truly measure cost-benefit.
- Employers impose some constraints on health plans as to what treatment will be covered; however, it is up to the health plan to ensure the most appropriate distribution of the employer's health care dollar.
- Also at issue within the framework of guidelines and quality of care is the designation and responsibility of decision makers. For example, is the provider responsible for communicating choices (and related issues of quality and value) to the patient, or is the provider responsible for making the choice and providing care accordingly? How are these considerations to be incorporated into guidelines?
- In the theoretical scenario which focuses on providing a more expensive, more sensitive test to a smaller population versus applying the cost differential between that test and a less sensitive, less expensive test to provide the lesser test to a larger number of poor people (and by doing so, find more cancers and save more lives), society has decided that the lives of the undiagnosed poor people are expendable.
- Multiple tiers already exist within the health care system, though often not explicitly. Individuals at the uppermost tier(s) may, for example, choose to pay out of pocket for care not covered by their insurer. This may be more of a political issue than a medical issue. In terms of the appropriate allocation of health care dollars across a population, the issue of societal benefit versus individual benefit remains. In addition, when insurance premiums (most of which are paid by employers) rise because of increased utilization and/or utilization of more expensive care options, less money goes to wages, stockholders, widows and orphans, and others. Ultimately, therefore, when prices rise, we all pay. Dr. Asch suggested as an analogy the situation in which individuals at a restaurant tend to order more if the check is to be shared equally, but tend to order more conservatively if there will be separate checks.
- Many factors are operant in the treatment differences by race described by Dr. Brawley. In some cases, people are afraid to be treated or may have cultural reasons for not accepting treatment. Much of the difference may reflect socioeconomic issues (e.g., treatment is unaffordable, there is no source of free treatment, treatment is not offered at a time or in a place that is accessible). Disparities in receipt of radiation therapy following lumpectomy are not due to comorbidity, but are more likely due to the quality of the physicians available to poorer populations. The NCI is interested in funding more studies of these disparities.
- Health plans have a responsibility to fully disclose and educate prospective members prior to enrollment as to the treatment that will and will not be covered. Similarly, physicians and other providers must be educated concerning the plan's structure, policies, and reimbursements. Health plan members and patients should be included more fully in medical policy decision making that will govern coverage under the plan.
- Referring to the issue of using health care dollars to make screening available to populations currently not receiving it, a participant noted that some of those dollars (or additional monies) are needed for outreach and for taking the services to individuals in the community.

PRESENTATION HIGHLIGHTS: The Federal Role in Guidelines to Care

AGENCY FOR HEALTH CARE POLICY RESEARCH—Dr. Lisa Simpson

Background

The Agency for Health Care Policy Research (AHCPR) was created in 1989 from the former National Center for Health Services Research. Its mission is to enhance the quality, appropriateness, and effectiveness of health care services through a broad base of scientific research. While research is the primary product of AHCPR, it recognizes that translation and dissemination are critical to achieving its mission. The Agency has three main goals: (1) to support improved outcomes through outcomes research and the development of outcome measures and instruments; (2) to strengthen quality measurement and improvement; and (3) to improve access, foster appropriate use of services, and reduce cost. In addition to research, AHCPR also produces data sets and tools for decision makers. Its audiences are public policy decision makers at the Federal and State levels, systems policymakers, and clinical decision makers (including both clinicians and patients).

The AHCPR's initial guidelines program, which existed between 1992 and 1996, produced 19 guidelines, of which two focused on cancer-related issues (cancer pain and quality determinants in mammography). All of these guidelines were generated by multidisciplinary expert panels that included patient and consumer representatives. They used an evidence-based methodology to weigh, synthesize, and summarize the evidence. The guidelines were influential both because of their content, which was widely adapted and adopted, but also because they improved the methodologies and raised the level at which evidence-based guidelines are developed. The guidelines also were controversial (to be expected if the evidence indicates that some aspects of current practice are ineffective) and expensive, due to the labor-intensive nature of the process. In light of all of these factors, the guidelines development process was redesigned in 1997 and is now known as the Evidence-Based Practice Center Program.

Key Points

- Concerning guidelines, AHCPR sees itself as having five important roles:
 - Developing the evidence base upon which to create guidelines. This evidence base includes effectiveness research, research on cost-effectiveness analysis, and research into better methods for doing this kind of study.
 - Synthesizing all of the available evidence.
 - Conducting research to advance understanding of the use and impact of clinical practice guidelines.
 - Providing a feedback loop as to research that is still needed.
- With the establishment of the 12-center Evidence-Based Practice Center Program in 1997, AHCPR created a structure to facilitate its activities to synthesize available evidence and develop reports related to various aspects of medical practice for use in the development of guidelines. The evidence reports can also be used to develop performance measures and to inform or set priorities for quality improvement programs.
- Some of the evidence reports are intended to be used to inform coverage policies and decision making in both the public and private sectors. For example, AHCPR evidence reports are used by the Health Care Financing Administration (HCFA) in its administration

of the Medicare program. AHCPR sees the users of the evidence reports as quite varied (e.g., providers of care at both individual and system levels, researchers, purchasers of care, policymakers, consumers).

- In addition to producing evidence reports, the 12 Evidence-Based Practice Centers also will have the capacity to perform advanced analyses, conduct research, improve methodologies for evidence synthesis, and work with private-sector partners in implementing guidelines. Federal partners include the NCI, other institutes within the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Social Security Administration. Both private- and public-sector partners have been involved from the early stages of report development to ensure that the issues are defined and addressed appropriately.
- The hallmark of the evidence reports is the methodologically driven, systematic, and thorough approach to their development. Once drafted, the reports are peer reviewed. The first set of reports developed under the new process is now in review. The second set of reports has recently been commissioned; one of these will be an update of the cancer pain guideline developed in the early 1990s. It is hoped that the reports will be published and distributed within 12 to 18 months of commissioning; this represents a significant improvement over the prior program, which often took 2 to 5 years to produce a guideline.
- The evidence reports will also include an extensive bibliography and a recommended research agenda addressing identified gaps in the evidence for the area in question. Of the first 12 reports commissioned, two are cancer related (cervical cytology and testosterone suppressant treatment).
- The U.S. Preventive Services Task Force, established in 1984, is another quality-related activity of the AHCPR. The Task Force makes recommendations on clinical preventive services, including screening (including cancer screening), immunizations, counseling, and chemoprophylaxis, and like the Evidence-Based Practice Centers, uses an evidence-based and systematic methodology to review what is known about the effectiveness and cost-effectiveness of various tasks. Recommendations of the Task Force were first published in 1989; its most recent publication (1996) covers more than 200 topics. It is widely circulated and is used by many managed care organizations to guide coverage and payment decisions for clinical preventive services. The Task Force has recently been reappointed, and will receive technical support from two of the Evidence-Based Practice Centers. New or updated reviews will be made available online to expedite distribution. These products will also be linked to the Agency's dissemination and implementation agenda, entitled "Put Prevention Into Practice."
- The National Guideline Clearinghouse, now under development, will be an online service operated by AHCPR (in partnership with the American Medical Association [AMA] and the American Association of Health Plans [AAHP]) to disseminate guidelines and help clinicians and health care systems sift through the multiple guidelines in existence to identify those most appropriate for their populations and needs. It is also expected to help patients and their families make informed diagnostic and therapeutic choices. In addition to structured abstracts of the individual guidelines, tabular data will compare multiple guidelines for the same condition or aspect of care. The full text of the clinical practice guidelines will be available when possible; otherwise, hot links will be established to other sites at which the guideline or ordering information is available. Further, links will be provided to discussion groups, and to annotated bibliographies for those who wish to

access the supporting literature for a given guideline. The Clearinghouse is expected to become operational in December 1998.

- Guidelines are a tool for improving quality of care, but research has shown that simply mailing a guideline to a provider will not precipitate a change in practice. Implementation strategies are crucial; this is an area in which more research is needed to identify effective strategies that best promote behavior change. AHCPR is working in partnership with the National Committee for Quality Assurance (NCQA) to facilitate the integration of evidence-based guidelines into the quality measurement activities of NCQA.
- To better understand the impact of guidelines on the quality and outcomes of care, AHCPR is funding jointly with the American Association of Health Plans a \$7 million initiative to study the role of various features of managed care. Use of guidelines will be one of the factors studied.
- AHCPR also supports a portfolio of investigator-initiated research. Part of its agenda for the future is a continued, and possibly expanded, investment in research and demonstrations to help understand how to better translate research findings into practice. The role of guidelines and their appropriate use is an item on this research agenda.

HEALTH CARE FINANCING ADMINISTRATION—Dr. Steven Clauser

Key Points

- The Health Care Financing Administration does not itself develop practice guidelines, but relies on AHCPR and professional associations to do so. HCFA uses those guidelines to improve its programs.
- Two years ago, HCFA reorganized with the goal of becoming a value-based purchaser. The Agency has a long history of building financial considerations into its decision-making and operational processes; the reorganization was designed to also build quality considerations into these processes.
- HCFA believes performance measures should at a minimum be highly evidence based and built on the best available clinical science, but the Agency recognizes that performance measures alone are not necessarily practice guidelines. Guidelines can serve a variety of purposes, depending on the ability to measure the elements of which they are comprised.
- HCFA's goal is to use performance measurement in a data-driven strategy to serve as the benchmark for all of its quality improvement initiatives. Among the interventions now considered part of the portfolio of opportunities to improve care under Medicare and Medicaid are enforcement of the Agency's traditional regulatory responsibilities, providing technical assistance to providers, providing information and assistance to consumers, using payment and coverage to advance quality goals, and rewarding superior performance.
- As part of its traditional regulatory functions, HCFA sees itself as a protector of beneficiary health and safety. This role is carried out by setting minimum standards or conditions for provider participation in Medicare and Medicaid. With managed care providers responsible for the care of a growing number of beneficiaries, these conditions increasingly are being applied to provider contracting arrangements. In addition to traditional clinical performance and more qualitative measures, HCFA is now trying to supplement these data with process and outcome information based on performance measures derived from well-established guidelines. One of the challenges in this endeavor is to determine how to link quality improvement with HCFA's regulatory requirements.

- In its relatively new role as an extraordinarily large purchaser of care, the Agency is recognizing that regulatory strategies are only one of many possible tools to promote quality of care. It is now exploring how best to use its leverage in the marketplace to try to improve quality of care.
- Through initiatives such as the 1993 Government Performance and Results Act (GPRA) and the Vice President's National Performance Review, HCFA has been challenged to select specific, measurable improvement goals for the Medicaid and Medicare programs. To meet these goals, HCFA has worked to establish collaborative relationships with its contractors and encourage participating providers to accept some of the accountability implicit in the goals.
- HCFA's quality improvement strategies each focus on a particular program area with a focused clinical goal for a given population. For example, breast cancer screening is a national priority for the Agency; in response to the GPRA Act of 1993, HCFA has established the goal of increasing by 5 percent between 1997 and 1999 the proportion of female Medicare beneficiaries aged 65 and older who receive a screening or diagnostic mammogram in a 2-year period. To meet this and other quality improvement goals, HCFA develops measures of quality of care using comparable and accurate measures, audits the data for accuracy, and examines community variability. These data are to be fed back to providers so they can monitor their performance relative to HCFA's benchmarks; the data would also be available to beneficiaries to educate and help them make informed choices of providers and services. These steps in the quality improvement process are intended to stimulate improvement in care, provide remeasurement and evaluation, and enable the program to make changes in the delivery process and medical advances.
- It is not always clear, however, what the goal (e.g., 60 percent of female Medicare beneficiaries receive mammograms annually) of such quality improvement programs should be, or when data analyses produce conflicting results, which data should be used. Similarly, the unit of accountability for intervention may vary, or a variety of strategies may be needed. HCFA continues to research these issues, which tend to be easier to assess in the managed care setting.
- HCFA has re-engineered its peer review organization (PRO) program, which has previously been locally based, to support a more national focus on quality improvement. Six clinical priority areas have been selected for emphasis; one of these is breast cancer screening. The PROs will be held accountable for improvement in rates on a statewide basis, and HCFA will provide contracting incentives for the PROs to build voluntary partnerships between hospitals, physicians, and managed care organizations to try to achieve the desired results. In managed care, HCFA is establishing a mandatory quality improvement initiative (Quality Improvement Standards for Managed Care, QISMC) for both Medicare and Medicaid. Clinical priorities have yet to be set for this program.
- Performance measurement is still in its infancy, though it is developing rapidly. Partnership-involving the professional communities, beneficiary communities, and purchasers of care-is essential to success. Challenges include developing meaningful performance measures and encouraging scientifically based decision making at all levels.
- Many activities to promote quality improvement and partnership are under way. HCFA is, through the Vice President's Forum, involved in discussions with many large private employers. In addition, Federal agencies including HCFA, AHCPR, the Department of Defense (DoD), and the Veterans Administration have been working together through the

Secretary's Quality Improvement Interagency Council to coordinate strategies. HCFA is also involved in activities of the Joint Commission on Accreditation of Health Organizations (JCAHO), the AMA, American Hospital Association (AHA), and NCQA.

- Other HCFA quality improvement initiatives include efforts in collaboration with AHCPR to link preventive practice guidelines to coverage criteria for these services; beneficiary education efforts; and continued research on performance measures for cancer treatment, quality of life for nursing home patients (focusing particularly on pain management), and the link between specific cancer treatments and functional status.

Additional Research Needs and Other Recommendations

- Expanded collaboration is needed between the public and private sectors in the area of cancer care and quality of life.
- Efforts should be supported to translate evidence-based medicine in all aspects of cancer care into clinical quality improvement.
- Partnerships with consumers should be fostered to identify their needs, learn what they are experiencing, and provide them better choices for quality health care.

CENTERS FOR DISEASE CONTROL AND PREVENTION—Dr. Dixie Snider

Background

CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. The agency accomplishes its mission through research, public health surveillance, outbreak investigations, evaluation of interventions, public health capacity building, and national leadership.

CDC is primarily a public health agency; as such, it takes a community perspective, identifying the community as the patient, and seeking to identify community interventions to solve community health problems. CDC strongly emphasizes prevention, an area to which only 1 percent of national health care expenditures are devoted, and, in particular, primary prevention. In addition, because of the value it places on social justice, the agency takes an egalitarian view on resource allocation issues.

Issues of principal concern to the CDC include maternal and child health, chronic diseases (including breast and cervical cancer screening programs and smoking-related cancers), environmental health, occupational health, and injury prevention and control. CDC supports State and local health departments in conducting public health surveillance, including surveys for behavioral risk factors for cancer. In addition to other national surveillance efforts through the National Center for Health Statistics, CDC trains public health workers in a variety of areas, such as response to public health emergencies.

CDC's scope of responsibility has been expanding over the years. Current areas of emphasis (and guideline development) include infectious diseases associated with cancer, such as hepatitis B, hepatitis C, human papillomavirus (HPV), and others. In the United States, approximately 10 percent of cancers are estimated to be associated with preventable infections.

Key Points

- CDC maintains on its website more than 300 guidelines of various types. The agency develops guidelines because it hopes to accomplish its mission by influencing people to take actions that will reduce preventable morbidity and mortality. CDC frequently develops guidelines at the request of its State and local health delivery partners,

community organizations, and academia. Guidelines may be developed in response to an emerging health problem, the development of a new technology, the availability of new epidemiologic data, the results of research studies, or any combination of these.

- The target audiences for CDC guidelines may include State and local health department officials; other Federal, State, and local public officials; school officials; public safety officials; community-based organizations; hospital administrators and staff; laboratory personnel; physicians and other health providers; management and labor officials; and the public.
- CDC's approach to guideline development varies. For some guidelines, a standing Federal advisory committee exists that is responsible for issuing the guideline. In other cases, a guideline may be developed by an ad hoc committee, or by scientific staff at the agency. It is CDC's policy to involve in the guideline process those who will be involved in implementing the guideline. Decisions as to how a guideline will be developed may be influenced by how quickly it is needed, but generally follow the approach outlined in "CDC Guidelines: Improving the Quality." Generally, this approach includes: a statement of the problem; literature review; review of other available scientific data; ascertainment of the relevance, generalizability, and quality of the data; review of the recommendations of other groups; and consideration of practical and feasibility issues (e.g., acceptability of the recommendations to providers, community, and patients; impact of the recommendations on health care delivery systems; distributional effects in the population; other social, legal, and ethical concerns). Public meetings normally are held to solicit the views of the general public on the proposed guideline; if a topic is controversial, guidelines will be published in the Federal Register for comment.
- When the data permit, CDC guidelines are based on rules of evidence; when data are absent or inadequate, expert opinion is used without hesitation. In these cases, expert opinion may be gathered through Delphi or nominal group techniques, and meta-analyses, systematic reviews, and economic analyses are used as appropriate. In addition, since many of the guidelines must address policy as well as technical issues, formal policy analysis is encouraged.
- In establishing priorities for guideline development, CDC considers the prevalence and incidence of disease, the burden of illness, the cost of the illness, the cost of the intervention, the availability and quality of data, the availability and quality of existing guidelines, and the feasibility of implementing any recommendations.
- CDC's guideline development and dissemination process could be improved by reducing the length of time now required to develop and publish a guideline, updating guidelines more systematically, improving the process for obtaining input, and broadening dissemination.
- The extent to which CDC guidelines are followed varies. The agency assesses the impact of its guidelines by using its surveillance systems, special surveys, or other special information systems. Overall, the guidelines are believed to be influential; this is due in part to the agency's institutional culture, which values scientific integrity, openness, competence, accountability, and the involvement of constituents in the development process.
- State health departments frequently translate CDC guidelines into regulations. Similarly, many of the recommendations in CDC guidelines are consistent with managed care goals

and have been incorporated into measures such as HEDIS (Health Plan Employer Data and Information Set).

- All participants in the health care system will be challenged in the future by changes in health care providers and technology. Genetic testing and population screening for genetic predisposition to disease, including cancer, will be especially challenging to ensure that people do not experience discrimination or other adverse consequences due to loss of privacy.

DISCUSSION—Drs. Simpson, Clauser, and Snider

Key Points

- Guidelines are being developed by numerous Federal agencies and professional organizations with little coordination among these efforts, which may overlap or offer conflicting recommendations. To address this issue, CDC has established advisory committees for certain areas (e.g., immunizations) through which it attempts to “harmonize” divergent recommendations and involve all of the major participants in that aspect of care. HCFA has taken a somewhat similar approach to develop consistent measures for diabetes care. It is hoped that the National Guidelines Clearinghouse will help identify overlapping guidelines and areas in which no guidelines now exist.
- Issues related to practice guidelines are complex. Standards of care may be developed for which insurance reimbursement is available, yet physicians may know that a higher level of care is possible. Appropriate variation from a standard due to shared decision making and the tailoring of care to the patient’s circumstance can be difficult to distinguish from inadequate care when a body of evidence is being reviewed.
- The National Guidelines Clearinghouse will be an online service. To disseminate information to those without online access or with limited online resources, Clearinghouse information will be “wholesaled” to professional associations, consumer groups, and others that will reach a broad spectrum of the population. CDC relies on partnerships with community groups, churches, and others to help disseminate guideline information. Discussants agreed that no one organization can fully support the expense of information dissemination through multiple media.
- It is anticipated that guidelines from many public and private sources will be available through the National Guidelines Clearinghouse, either directly or through “hot links.” Guidelines developed by the Department of Defense, however, are unlikely to be included. It was noted that the Quality Interagency Task Force described by Dr. Clauser is considering issues of quality across programs, including the DoD, Veterans Administration, Federal employees health benefits program, and programs of the Department of Health and Human Services (DHHS) and Department of Labor (DOL).
- In addition, the DoD has recently concluded an effort to adopt a single set of breast cancer treatment guidelines to be implemented in all DoD hospitals. With the help of a consultant, 43 sets of guidelines were collected and rated on 12 key attributes, and a single set of guidelines was selected. The decision is now being reviewed at the topmost ranks. A participant suggested that implementation will be challenging, noting that adherence to the widely accepted cancer pain management guidelines is only about 39 percent.
- Though reimbursement, or lack of it, can be used to motivate providers not to do something, it is harder to motivate them to adopt new behaviors or practices. Recent summaries of available literature on motivating adherence to guidelines suggest that no

single strategy is sufficient, and that depending on the setting, population, and type of clinician, the combination of strategies required will vary.

- Tools are lacking to help the public evaluate medical evidence and practice guidelines or to determine who is to be considered the authority on various aspects of care. It is hoped that abstracting and presenting in tabular form multiple guidelines on a given topic will assist practitioners and the public in evaluating existing guidelines. In addition, tools are needed to facilitate shared decision making, since each person weighs risks (including side effects) and benefits differently. The development of such tools is challenged by the science literacy level of the public relative to the vast amounts of information available through various media.
- The dissemination and implementation of practice guidelines is also complicated by political forces that may be difficult to sway. It was observed that some people or organizations may become so invested in the path they have chosen with respect to guidelines that they may lose sight of the goal—reduced cancer incidence, morbidity, and mortality. The Nation must resolve philosophical questions as to how and by whom guidelines should be developed and managed, and the appropriate limits of public policy or Congressional mandate in these areas.
- Even when a guideline is developed by a representative group of constituents, local or regional groups tend to want to modify the guideline to accommodate cultural or other local values. This situation reflects our ambivalence about national standards of medical practice for various conditions. We want a guideline to ensure quality care, but we want the flexibility to tailor it to local needs.

PRESENTATION HIGHLIGHTS: Professional Societies and Organizations

NATIONAL COMPREHENSIVE CANCER NETWORK—Dr. William McGivney

Background

The National Comprehensive Cancer Network (NCCN) is an alliance of 17 major cancer centers across the United States. Since 1995, NCCN has supported the basic missions of these institutions to provide the highest quality of care to the greatest number of patients in need, and to advance the state of the art in cancer care through research. NCCN also was initiated to help make member institutions more competitive in the evolving health care marketplace.

Activities of the Network have been based in the guideline development process. In just under 3 years, NCCN has completed guidelines that cover over 90 percent of all cancer patients, in over 1,000 pages of algorithms and text developed predominantly by expert panels. Presently, more than 500 physician experts in various fields are involved in 38 expert panels. A decision was made 15 months ago to also involve patients in the development of NCCN guidelines. NCCN has recently reached an agreement with a major partner to begin the translation of its guidelines into patient information.

Key Points

- The trend toward outcomes-based decision making has been a major change in the health care system over the past 10 to 12 years. Accordingly, NCCN takes an evidence-based consensus approach to guideline development. The process includes outcomes data review, integration and consensus by expert panels, solicitation of input from member institutions and other constituencies in the health care community, multidisciplinary review at member

institutions, and finalization by the expert panel. The guidelines are living documents, and the entire guideline process depends on continual updating.

- The NCCN guideline process seeks to restore authority in determining appropriate practice and decision-making autonomy to practicing oncologists.
- NCCN guidelines have been published in *Oncology* and disseminated to its circulation of 32,000 individuals. The Network has encouraged and supported the efforts of other oncology centers and oncology groups to adopt and integrate the guidelines into their practices.
- The NCCN process has addressed four common deficiencies in guideline development: (1) lack of timeliness, (2) lack of specificity, (3) failure to update guidelines regularly to reflect clinical advances, and (4) poor implementation.
- Implementation is achieved by monitoring the performance of individual practitioners. To facilitate performance measurement, an oncology outcomes database is being developed by NCCN. The ultimate goal is to collect uniform, comprehensive, sociodemographic, clinical treatment, outcome, and cost data on all patients with the common cancers treated at NCCN member institutions. The database was initiated in July 1998 at five member institutions for the collection of data on breast cancer patients. By the end of 1998, another six institutions will be added. The effort will continue to be expanded over the next few years; it is anticipated that by the end of 2001, the oncology outcomes database could be collecting extensive data on patient treatment and outcome for approximately 50 percent of all cancer patients (people with breast, prostate, colorectal, or lung cancer together comprise approximately 50 percent of all cancer patients).
- The database will be used to evaluate the level of practice conformance with NCCN guidelines within member institutions, and to evaluate the clinical and relevant nonclinical (e.g., days lost from work during specified time periods following diagnosis) outcomes of treatment. It is expected that these data will provide a foundation for establishing partnerships with various constituencies in the health care community.
- A 224-element data dictionary in breast cancer was developed directly from the NCCN breast cancer guideline. It includes sociodemographic data and a focused set of outcomes. The database is multidisciplinary in approach and the information collected, and permits severity adjustment across patient populations. In addition to monitoring general conformance with the guideline, the database can be used to address controversial issues that arise in the expert panels during the discussion of guidelines, compare performance across institutions, and serve as a benchmark for practices across the country.
- NCCN is about to launch a partnership with a large managed care company to implement NCCN guidelines across its oncology network. It is expected that all centers will begin reporting to the NCCN database within 24 to 30 months.
- All of NCCN's data forms are available on the Internet. NCCN can collect and receive data, and can structure and maintain databases accessible through a data coordinating center website.

Additional Research Needs and Other Recommendations

- Practice guidelines implemented through performance measurement is the model for continuous quality improvement in cancer care.

AMERICAN MEDICAL ASSOCIATION—CLINICAL PRACTICE GUIDELINES—Dr. Terry Hammons**Background**

The American Medical Association's guideline activities center on its role as a coordinator and conveyor of information, and on setting attributes or criteria for guideline development and dissemination. AMA works with national medical specialty societies, methods experts, government, and other private-sector organizations in these efforts. As part of its activities in these areas, AMA has established a coordinating entity, the Practice Parameters Partnership and Forum. The Practice Parameters Partnership, composed of the 13 large medical specialty organizations, the American Hospital Association, AHCPR, the JCAHO, and HCFA, focuses principally on policy development. The Practice Parameters Forum includes more than 80 specialty societies and other organizations and functions as a broader source of expertise and an information dissemination mechanism.

The AMA has for 10 years published the Directory of Clinical Practice Guidelines, which includes information on approximately 2,000 guidelines from a variety of physician organizations and Government entities, including the NIH, the American Cancer Society, the American Heart Association, and others. The Directory is updated annually; the new edition will have about 100 oncology-related guidelines from approximately 20 organizations.

Key Points

- Guidelines are strategies for care and decision-making support. They define the process of care with the goal of achieving the best possible outcomes. Since guidelines typically provide the rationale for recommendations made, they also serve as summaries of knowledge and its application in clinical care. Clinical practice guidelines can also be used in continuing professional education, and as key information when adding or refining critical pathways or protocols in the care process.
- Guidelines are also useful in deciding what to measure about care or outcomes to assess whether the intended process of care is being delivered and the intended outcomes are being realized. Thus, guidelines are useful for designing measurement systems and review criteria.
- Guideline development at the American Medical Association began about 15 years ago. Early emphasis was on developing and disseminating sound guidelines. It was assumed, however, that thorough dissemination alone would yield changes in practice and better patient outcomes. AMA has since learned that dissemination is not enough to ensure implementation. It has become clear that implementing or embedding guidelines in thought and action requires motivation (not limited to financial or professional incentives) and capability to improve, measurement and feedback to enable clinicians to see improvement, and organizational support.
- The AMA is piloting a new project, the Clinical Practice Guidelines Recognition Program. Its purpose is to identify guidelines developed with a sound process and broad representation, and having recommendations based on evidence from the literature.
- AMA has emphasized that guidelines must be implemented flexibly, with respect for clinical judgement by the physician and for the patient's particular needs. Reflecting this emphasis, AMA has recently initiated the American Medical Accreditation Program (AMAP), a program to accredit physicians and engage them in measuring the care they provide and the results they achieve for their patients. This program, which will

incorporate measures for oncologic conditions, will provide feedback to physicians to support improvement. To become accredited under the program, physicians will be required to satisfy a number of standards. One such standard will initially encourage and later require participation in measurement, feedback, and care improvement related to the physician's patient population.

- AMAP will establish criteria for measurement systems and measures, for effective feedback, and for protecting patient and physician confidentiality. In addition, AMAP will develop core measure sets for 50 to 80 specific conditions and populations (including oncology populations). Physicians may initially participate in programs measuring their performance only against core measures, then progress to a more extensive measurement system.
- AMAP is leading the oversight of accreditation development and the measurement systems to support it. Individuals from national and State medical societies and methodological experts are working with AMA in advisory committees and work groups in these efforts.
- AMAP has also established the Performance Measurement Coordinating Council (PMCC) with NCQA and JCAHO. Through the PMCC, the three accrediting bodies seek to bring commonality and rationality to their measurement and feedback activities. In this way, measurement at the physician level regarding a particular condition will be consistent with what hospitals are measuring about that condition, and consistent with health plan measures through HEDIS.
- As part of its work to disseminate information on performance measurement, the AMA will this year publish the Clinical Process and Outcomes Measurement Directory, which will contain approximately 250 examples of work from varied sources. The Directory replaces the Outcomes Resource Guide, which focused only on outcomes. The new directory recognizes the need to measure both process and outcome.
- To augment measurement, feedback, and improvement efforts, AMAP will provide one-on-one support for physicians to help them understand program data and guidelines and how these relate to the individual provider's practice, as well as to share ideas for improvement.
- In addition to oncology guidelines in the AMA Directory and oncology measures included in the AMAP, the PMCC will facilitate an integrated approach to measurement across time, space, and organization. It will enable clinicians to link activities occurring in the physician's office with those occurring in the hospital, the rehabilitation facility, and in home care.
- AMA's initiatives in clinical practice guidelines and clinical performance measurement have the potential to speed the application of advances in the knowledge, diagnosis, and treatment of cancer.

ASCO CLINICAL PRACTICE GUIDELINES: PROGRESS, PITFALLS, AND PROSPECTS—

Dr. Mark R. Somerfield

Key Points

- Since 1993, when its Health Services Research Committee was formed, the American Society of Clinical Oncology (ASCO) has published four practice guidelines in its Journal of Clinical Oncology (JCO). Another 10 guidelines are in progress. The published guidelines are on: (1) use of hematopoietic colony-stimulating factors (CSF), (2) tumor markers in breast and colorectal cancer, (3) breast cancer surveillance, and (4) treatment of

unresectable non-small-cell lung cancer. Each is being updated, in some cases for the second or third time. Updates are also published in the JCO. ASCO is also developing consumer versions of the guidelines; those for breast cancer surveillance and advanced non-small-cell lung cancer are nearing completion.

- Most of the ASCO guidelines are boundary guidelines, which define the appropriate use of novel and often expensive technologies. These guidelines are distinguished from path or algorithm guidelines that describe the current standard of care for a single disease.
- In addition to practice guidelines, ASCO recently has undertaken technology assessments, defined as the establishment of a process for determining if a procedure, device, or test is appropriate for broad-based conventional usage (i.e., when it is no longer considered experimental). A technology assessment has been initiated on the use of tamoxifen and raloxifene for breast cancer prevention. The working group for this activity will complete a systematic review of the evidence and provide guidance to the clinicians who are responsible for discussing risks and benefits of these preventive agents with healthy women. It is hoped that a document will be ready to be presented to the ASCO Board in February 1999.
- A paradox of evidence-based guideline development is that guideline topics selected on the grounds of practice variation do not lend themselves to evidence-based guidelines, to the extent that practice variation is the result of limited or inconsistent evidence.
- Two of the more common criteria for selecting a guideline topic are that: (1) significant variation in the practice exists; and (2) suitable data on the practice are available. The availability of consistent randomized trial data, however, does not necessarily lead to changes in practice. In such cases, one purpose of guidelines is to put existing evidence into concrete, formal recommendation form, and thereby serve as a catalyst for translating evidence into practice. The most common scenario is one in which there is some evidence, but it is insufficient in both quantity and quality. The challenge, then, is to ensure that the guideline consumer clearly understands the strength of the evidence supporting the recommendation.
- ASCO has adopted two methods for characterizing the strength of evidence contributing to guidelines. The first method, adopted from the American College of Chest Physicians, employs a combination of levels of evidence and grades of recommendations. In this method, five levels of evidence are defined:
 - I. Evidence obtained from meta-analysis of multiple, well-designed, controlled studies; randomized trials with low false-positive and low false-negative errors (high power).
 - II. Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or false-negative errors (low power).
 - III. Evidence obtained from well-designed, quasi-experimental studies such as non-randomized, controlled single-group, pre-post, cohort, time, or matched case-control series.
 - IV. Evidence from well-designed, nonexperimental studies such as comparative and correlational descriptive and case studies.
 - V. Evidence from case reports and clinical anecdotes.

The recommendations are graded as follows, reflecting the consistency of available evidence:

- A. There is evidence of type I or consistent findings from multiple studies of types II, III, or IV.
- B. There is evidence of types II, III, or IV and findings are generally consistent.
- C. There is evidence of types II, III, or IV but findings are inconsistent.
- D. There is little or no systematic empirical evidence.

- The second method employs three categories of guidelines defined by the evidentiary support for or against a given clinical practice:

- Recommendation: Reserved for guidelines that are based on level I or level II evidence.
- Suggestion: Used for guidelines that are based on level III, IV and V evidence; this implies panel consensus on the interpretation of this evidence.
- No Guideline Possible: Used when there is insufficient evidence on which to base a guideline. This conclusion implies that: (a) little or no evidence exists on the practice in question; and (b) the panel lacks consensus on the interpretation of existing evidence.

This second categorization method was developed to address the perception that the levels of evidence and grades of recommendations under the first method were being misconstrued by the readership (e.g., every guideline seemed to carry the same amount of weight).

- It is hoped that the “No Guideline Possible” category will help ASCO’s expert panels resist the temptation to venture guidelines in instances where none are warranted. This has been referred to as the “right to refrain from making recommendations,” based on the contention that society may be better served at times by having expert groups admit that there is considerable uncertainty.
- ASCO has completed two membership surveys on the use of growth factors; key findings were that: (1) use of CSF growth factors was related to physician practice setting (physicians in fee-for-service settings were more likely to use growth factor than those in managed care or academic settings); and (2) practice across settings is in line with many of the growth factor guidelines, but not with others. The surveys do not reveal why publication of the guideline on growth factors has not led to wholesale changes in practice. The problem is believed to be due in part to limited implementation efforts beyond publication in the JCO. Some have argued that in rationing resources for clinical practice guidelines, 10 percent of the effort should be spent to develop the guidelines, with the remainder allotted to implementation. For example, implementation of a preauthorization requirement for the use of CSF resulted in a marked overall decline in use (and related cost) at one institution, but no change in use for indications described in the ASCO guideline.
- To better assess the impact of ASCO’s guidelines, the Health Services Research Committee established a working group on guideline evaluation. The working group concluded that, ideally, an evaluation would assess whether guidelines are of high quality, whether ASCO members are aware of and satisfied with the guidelines, whether payers and providers are using the guidelines, if practice is changing in accordance with the guidelines, if guidelines are changing practice, and if guidelines are leading to improved patient outcomes. The working group decided that, initially, ASCO should focus on the first four items. Efforts

are now under way to assess these parameters relative to ASCO's four published guidelines. ASCO recognizes, however, that all of the assessment items must be addressed to realize the full potential of clinical practice guidelines for improving the care of individuals with cancer.

ONS POSITION ON QUALITY CANCER CARE—Ms. Linda Krebs

Background

The Oncology Nursing Society (ONS) is the largest oncology-related health care organization in the country, with more than 27,000 members. ONS is entering its 24th year of existence, and is dedicated to making a difference in the care and well-being of people experiencing cancer. ONS has been active in guideline development for some time, particularly in the areas of chemotherapy administration and safe handling, venous access device management, and standards of oncology nursing education and practice at both the advanced and basic levels. The goal of achieving quality is the cornerstone of ONS' strategic plan and a focus of its mission to promote excellence in oncology nursing and quality cancer care.

Key Points

- Quality cancer care means timely access to specialty cancer care, insurance coverage for specialty care, a comprehensive approach to cancer care, involvement of all relevant disciplines (including social workers, nurses, pharmacists, chaplains, and others) on the treatment team, and equal and active inclusion of the patient and family on the treatment team.
- Quality cancer care is a continuum that includes prevention, early detection, treatment, supportive care, long-term followup, and end-of-life care. Prevention means helping others learn about cancer risks and lifestyle changes that can decrease the chances of developing cancer. Early detection includes screening activities that result in early detection of cancers, when they are most curable; these services should be covered by the patient's health plan. Treatment means timely access to the range of treatments best suited to treat the specific cancer affecting each patient.
- Supportive care includes timely access to resources in the community that can augment the self-care and home care abilities of the patient and family. With increasing levels of cancer treatment now being provided on an outpatient basis, families are being asked to be health care providers without the education or resources to complete those tasks safely and effectively; this is a major burden for these individuals. Thus, supportive care also includes helping patients and families learn about cancer treatment and side effects of treatment, and how to cope with them.
- Long-term followup includes rehabilitation services and followup by oncology specialists for all cancer survivors. In many communities, rehabilitation is not occurring, or it is not being provided by oncology specialists who can monitor survivors for long-term sequelae of cancer and its treatment.
- End-of-life care means access to services that preserve and assure the quality of life when long-term survival is no longer possible. This includes competent and comprehensive symptom management, emotional support of patients and families, hospice care, and bereavement counseling.
- Quality cancer care is also culturally competent, ethical, and cost-effective. Further, it is coordinated and delivered by competent cancer care providers. Many hospitals and other

agencies do not believe cancer patients require specialized nursing care. ONS believes accountability and coordination of quality cancer care is best accomplished by registered nurses (RNs) educated and certified in oncology nursing. ONS further maintains that there is a moral obligation to make decisions guided by quality, rather than by cost alone, in all health care restructuring efforts.

- To promote the ideas above, the ONS has adopted an active health policy agenda advocated at the local, State, national, and international levels. Among the specific positions being advanced by ONS are adequate pain management for cancer patients; RN workplace identification (currently denied nurses in many settings); expanded roles for nurses in genetic testing and risk assessment counseling; reasonable hospital stays for breast surgery, as determined by the woman and her physician; assurance of proper nursing credentials for those administering chemotherapy; and strategy development for decreasing the worldwide burden of tobacco use. Other positions include: care of individuals with HIV, rehabilitation of people with cancer, and ensuring safeguards (e.g., cardiopulmonary resuscitation and advanced life support capability, or "crash carts") in outpatient oncology treatment settings.
- In addition, ONS is collaborating with the Association for Oncology Social Workers on end-of-life care issues, and has recently developed a patient bill of rights.
- Future plans of the ONS include: collaborating in the development of a quality cancer care consumer brochure; conducting outcomes research to evaluate and define the role of the oncology specialty nurse in the delivery of cost-effective quality cancer care; and developing positions and forming partnerships that will promote the Society's strategic goal of quality cancer care.

AMERICAN ASSOCIATION OF CANCER INSTITUTES—Drs. Max Wicha and Rodger Winn

Background

Organized in 1959, the American Association of Cancer Institutes (AACI) is a forum for cancer organizations to exchange information on research, education, administrative, and financial policies. AACI represents the national cancer centers, both those designated by the NCI and those actively working to achieve that designation. The AACI has more than 100 members representing all regions of the country, and collaborates on cancer issues with NCI and many other organizations in the cancer community.

AACI's mission includes providing the best possible scientific base for cancer research, improving cancer prevention and education programs, promoting the highest quality of treatment and care for cancer patients from diagnosis through survivorship, taking an active role in public-policy-making issues, and cooperating with cancer and patient communities to further mutual goals.

Key Points

- Academic centers have a role in the three principal domains involved in clinical practice guidelines-development, dissemination, and implementation.
- Key attributes of a system of oncology practice guidelines include completeness (i.e., following the entire course of the disease), comprehensiveness (i.e., covering all cancers), relevance to the majority of patients with a particular cancer, formal processes for guideline development, and scheduled updates.
- Guideline development must be structured, and one of several processes are used. Informal consensus involves bringing together a group of experts who apply their opinion to the

review and assessment of the available data and develop the guideline. The formal consensus process, used by NIH, brings together a set of experts who are provided a formal set of data that they may use as they wish in developing a guideline. Evidence-based guideline development is the current gold standard; it involves a rigorous delineation of the data; however, in many cases the evidence does not exist. Explicit guideline development, the goal for the future, is a quantitative model that attempts to assess the cost, percentage, and probability of outcomes.

- One study of decision points in a set of guidelines for hematologic/lymphatic cancers concluded that high-level randomized clinical trial evidence was available to support only 24 percent of decisions. Single-arm trial evidence supported 20 percent of decision points; for the remaining decisions, no real evidence existed. These findings suggest that one role of the academic centers is to develop their expertise in interpreting the quality of high-level trials, resolving inconsistencies in data from such trials, assessing the importance of single-arm trial findings, providing rational guidance based on experience, deriving guideline logic, and assessing evidence and providing specific recommendations.
- If a guideline is to conform to the clinical decision-making process, it must be logical. Because of its complexity and heterogeneity, cancer does not always conform to the algorithms typical of path guidelines, yet appropriate models are not too complex to be practical.
- In the current managed care environment, primary care physicians and nurses will be involved in providing oncologic care. Guidelines will be very important in helping perform these tasks well.
- Reliability (reproducibility) is a problem in the use of expert opinion. Reproducibility means that given the same evidence and method of development, two separate consensus groups would produce essentially the same guideline. A comparative study of ASCO (narrative) and NCCN (algorithm) guidelines for advanced non-small-cell lung cancer found that recommended workup, treatment, and followup were highly similar or identical. The two guidelines were produced by different groups using different methods, but yielded reproducible products.
- Academic institutions can manage bias by taking a multidisciplinary, multi-institutional approach, and ensuring that the spectrum of clinical approaches is represented. It is also important to include geographic diversity on the expert panel. Multiple iterations and feedback loops are also essential for eliminating bias in guideline development.
- It is important to bear in mind that guidelines developed at academic institutions may not always be generalizable to community care, since treatment at academic centers tends to be more aggressive and focused on clinical trials. Communities may lack the technology, surgical or other expertise, and access to trials necessary to conform to such guidelines.
- Academic centers are no longer ivory towers; they are community affiliates, hospital network members, and managed care participants. Many academic centers are developing disease management systems, including guidelines-monitoring systems and quality improvement systems. Through these, they will have a broad impact on how care is delivered.
- Websites and interactive programs will be essential future keys to guideline dissemination. Effective implementation will be aided by education, the participation of respected leaders, feedback mechanisms, administrative and regulatory mechanisms, and positive and negative incentive systems.

- Guidelines are being used for quality improvement, resource utilization control, and provider profiling. They will be used as quality indicators; in oncology, it will be necessary to use process indicators rather than outcome indicators for some time. Since guidelines are process maps, adherence to a guideline that has been validated to predict for favorable outcomes should be a good measure of quality.

DISCUSSION—Drs. McGivney, Hammons, Somerfield, Wicha, and Winn, and Ms. Krebs

Key Points

- The ASCO guideline development process typically involves a methodologist; some of the panels include consumers, but primary care physicians and public health experts have not been included.
- The NCCN process did not include consumers initially. A decision was made approximately 15 months ago to include consumers in every new panel (typically composed of 8 to 12 individuals from varied disciplines). Currently, approximately half of the NCCN panels have a consumer representative.
- NCCN does not charge for its guidelines; they have been disseminated through the JCO. Totalling more than 550 pages, the most recent set of guidelines was distributed to more than 32,000 subscribers, including all U.S. oncologists and others.
- All of the guidelines and guideline-rating processes are works in progress. Guideline evaluation is an iterative process; its value will grow as guidelines are refined, and where question marks exist, trials may be done and more evidence collected. The ethical pitfalls exist principally in the areas where the evidence is unclear. The improvement process for guidelines should be continual; cyclic review and updating are important. Updating processes should include consumers.
- Though it currently conducts some activities focused on the public policy-oriented issues associated with cancer care and clinical guidelines, NCCN has decided for the near term not to engage in public policy development or specific legislative lobbying. Instead, NCCN will maintain its focus on developing comprehensive guidelines and integrating them with its database. In part, this decision stems from one of NCCN's missions—to develop programs to enhance the competitive position of member institutions in the marketplace. Voicing a personal perspective, Dr. Freeman suggested that NCCN's leadership has the opportunity and authority in the cancer community to have a substantial impact on public policy issues such as access to care and insurance coverage.
- In the guideline development process, it is necessary to balance the need for specificity with the need for flexibility in making treatment decisions for the individual patient. This is a delicate balance. When guidelines lack specificity (and when they are not based on good scientific evidence), their usability and utilization drop significantly. At the same time, the guideline algorithm must present reasonable options for physicians and patients. Dr. McGivney expressed his view that physicians in the late 1980s lost an important opportunity to have substantial input into coverage development processes at major managed care companies because of their reticence to take stands on important issues; this is an opportunity that NCCN member organizations do not want to miss again.
- Though it is possible that by freely distributing its guidelines to community oncology practices, NCCN may actually create competition for its member institutions, NCCN is working toward key partnerships and affiliations and a growing role in consultation, evaluation, and referral with community oncology groups that follow its guidelines. In

addition, it is anticipated that member institutions will hold seminars to support implementation of updated guidelines. In time, the outcomes database will also be a resource for significant education and collaboration in improving both clinical and nonclinical (e.g., days lost from work, patient satisfaction, financial impact) outcomes. This potential for interactive and constructive relationships is perceived to be of greater value than could be achieved through a more proprietary stance.

- Good guidelines should improve care at all levels; they should not just be a “vacuum cleaner” to pull care in one direction or another. The appropriate role of guidelines includes trying to provide guidance as to when particular types of care are unwarranted (i.e., avoidance of overtreatment). Unfortunately, the needed evidence to provide such guidance is woefully lacking; in many cases, we are still using response rates rather than survival or quality-of-life data to inform these recommendations.
- Guidelines must be constructed carefully, since once guidelines are set, payers, the Government, and the medical community will respond. The history of treatment advances suggests that guidelines based on clinical experience may reflect what is known at that point, but may be wrong. For example, the radical mastectomy was the established standard of care for breast cancer for decades, yet time has shown that lumpectomy plus radiation offers the same survival benefit with fewer side effects and less disfigurement. Discussants pondered whether current guidelines may pose barriers to the next generation of researchers and clinicians who question currently recommended clinical care, or if collecting and using outcome data from nonrandomized trials in guideline development will discourage the conduct of needed controlled studies. It was suggested that guidelines actually point out deficiencies in existing evidence and encourage the design and conduct of needed trials. It was also observed that because of the existence and widespread implementation in the United States of guidelines on mammography screening for women aged 40 to 49 years, it is now virtually impossible to conduct a randomized controlled study on the efficacy of screening in this age group in this country. A similar phenomenon is occurring with respect to prostate cancer screening guidelines and their implementation.
- Participants further suggested that guidelines leading to overly aggressive care (e.g., mastectomy for breast carcinoma in situ) may have a perfect outcome (e.g., the patient is a survivor), but have prescribed the wrong care. The ethic should be to question everything, and to strive continually to improve on standard care rather than allow “fossilization” around guidelines. Unless standard care is totally curative, it is never good enough. Cancer centers and academic centers should take the lead in this endeavor.
- Ad hoc investigational care is a difficult issue because it contributes nothing to the body of knowledge, even though it may satisfy the patient. It may even delay the day in which we have the answer. One strategy for discouraging ad hoc investigational care is to provide coverage for the costs of well-defined, rigorous clinical trials that will advance knowledge.
- Local tailoring of national guidelines is inevitable; recognizing this, NCCN sees its guidelines as templates and is seeking ways to make sure that adaptations remain consistent with the guidelines.
- Particularly in cancer, in which nearly half of patients (excluding basal- and squamous-cell skin cancer patients) die of their disease, the lack of explicit links in most guidelines to clinical trials is disturbing. Since standard care is clearly inadequate for many patients, this linkage to participation in trials should be explicit to prevent denial of insurance coverage.

PRESENTATION HIGHLIGHTS: Health Care and Related Organizations

AMERICAN ASSOCIATION OF HEALTH PLANS—Dr. George Isham

Background

The American Association of Health Plans represents more than 1,000 health maintenance organizations (HMOs), preferred provider organizations (PPOs), and other similar health plans. Together, member plans provide coverage for more than 140 million Americans. There is tremendous variety among these plans in terms of structure and organizational behavior. This variation has led to AAHP developing a philosophy of care that: (1) emphasizes active partnerships between patients and their physicians; (2) maintains that comprehensive health care is best provided by networks of health care professionals who are willing to be held accountable for the quality of their services and the satisfaction of their patients; and (3) is committed to high standards of quality and professional ethics, and to the principle that patients come first.

Key Points

- AAHP defines clinical practice guidelines as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances. They are designed to close gaps between current and optimal practice. Thus, clinical practice guidelines are recommendations for clinical interventions and are not designed to replace the judgment or experience of clinicians. Guidelines vary in their degree of flexibility and are broad strategies for patient management within the limits of accepted clinical practice. Narrower types of guidelines exist that are specific clinical pathways defining the specific sequence of clinical events, often linked by timeframes, specific conditions, care processes, and expected outcomes. In addition to practice guidelines, other guides or policies are used in reimbursement and accrediting decisions; these are used in concurrent or retrospective utilization management.
- AAHP has no guidelines of its own—it is neither a medical professional society nor a care delivery organization. Health plan members of AAHP formulate and disseminate derivative guidelines based on AHCP or professional society guidelines. The result of the process of developing these derivative guidelines is not necessarily different from what is seen in many professional guidelines. Most health plan guidelines, however, are based on broad population factors, resulting in a different perspective on clinical practice.
- Over a 2-year period, representatives from a number of AAHP member health plans have met to identify problems or other areas in which guideline development might be warranted. Such issues included practice variations, the availability of evidence, the frequency of occurrence in a population, cost differentials, and whether external concerns exist about the quality of care. Reflecting defined attributes of a well-developed guideline, health plans choosing to develop a guideline in response to a problem are following an evidence-based process. This process typically includes problem identification, data acquisition, multidisciplinary review of the literature with evaluation based on a criteria set similar to the U.S. Task Force for Clinical Preventive Services, two cycles of draft and comment, pilot testing, finalization, and dissemination. The guideline, which should be clinically flexible (to allow for exceptions and patient preferences) is presented in easily understood language for each of the intended audiences, and in patient versions. A committee is kept in place to be responsible for updating the guideline in response to new literature or other issues that may arise. The committee meets at least annually to

determine if updating is required. In terms of evaluation, data are collected to assess changes in practice, before/after studies are conducted, administrative systems are used to collect data, and qualitative information is gathered from clinical practice to assess the effect of the guideline.

- Key strategies for implementing clinical guidelines in managed care settings include identifying clinical and academic leaders who will champion the guidelines; sharing with practitioners the synthesis of evidence that informs the guideline; offering practitioners effective implementation tools (e.g., education, resources, support systems); employing logic, discussion, and incentives rather than exhortation; and engaging practitioners and other stakeholders in an ongoing, interactive process of improvement.
- Effectively engaging physicians in guideline implementation includes involving them in guideline development and implementation activities to ensure that the guideline fits their needs, providing information to clinicians about their practice patterns, using academic detailing to investigate and discuss reasons underlying current practices where change is suggested, and recruiting opinion leaders to promote the cause in unstructured situations.
- Educating physicians about clinical guidelines is important; it is particularly effective to provide continuing medical education (CME) credit for these educational efforts. Small-group sessions on narrow, specific topics work well.
- Tools to support decision making consistent with guidelines include flagged laboratory slips, pharmacy alerts, tags on charts, standing orders (e.g., immunization orders for nurses), and administrative policies.
- Managed care systems are in a unique position to promote clinical guidelines development and use, since they have a broad, multidisciplinary approach to health care, access to levels of empirical data necessary to create and improve guidelines, and an infrastructure for educating providers on guidelines.
- AAHP has joined AHCPR and AMA in sponsoring the National Guidelines Clearinghouse, which AAHP believes will promote better guidelines by providing an authoritative, easily accessed resource for guideline developers.

OPTIMIZING THE IMPACT OF GUIDELINES ON MEDICAL DECISION-MAKING—

Dr. James Schibanoff

Background

Milliman and Robertson is a consulting company founded more than 50 years ago. Growing out of its health care consulting practice in the late 1980s, the company has developed a set of health care management guidelines that now encompass seven volumes, with another two volumes in progress. These guidelines span a range of health issues that includes acute care, worker compensation, ambulatory surgery, home care, and primary care. Some of these guidelines (e.g., acute, subacute, and home care) are utilization management guidelines focused on quantitative issues of efficiency.

Milliman and Robertson's guidelines related to oncology are limited to diagnostic issues that face primary care physicians, and referral, hospital admission, and length of stay issues. Its guidelines on ambulatory mastectomy have earned the company a degree of notoriety. Milliman and Robertson does not develop guidelines for chemotherapy or radiation therapy, leaving these to the expertise of practitioners in those fields.

Key Points

- Guidelines have been called “the battlefield of cost and quality” (D. Eddy). It may be more accurate to say that guidelines are where issues in defining efficiency meet issues of quality. Issues of efficiency may be implicit in that a certain course of therapy is prescribed and another is not. These issues also may be explicit, such that the efficiency issue is quantitated, or specific items are not recommended.
- Issues of quality are best conceptualized as in the Institute of Medicine’s Roundtable on Health Care Quality report published in the Journal of the American Medical Association in September 1998. The report describes quality problems in three general areas: (1) underuse (i.e., failure to use a treatment or a procedure that could benefit the patient, and for which the benefit far exceeds the risk); (2) overuse (i.e., using a procedure or treatment when the risk of harm significantly exceeds benefit); and (3) misuse, which could include complications of surgical or diagnostic procedures.
- Overuse issues include questions of appropriateness; in such cases, cost and quality issues are the same. Similarly, in the area of misuse, by reducing complications, quality is improved and cost is reduced. In issues of underuse, cost and quality considerations may be synchronous (for example, the use of beta blockers after myocardial infarction), or asynchronous (e.g., cases in which certain preventive services are more costly than the outcome being prevented). Overall, however, Milliman and Robertson sees cost and quality moving in the same direction.
- The ideal guideline development process would consist of an outcomes research project on a specific issue that could be converted directly into a guideline. Current guideline processes, however, consist of the review of evidence by expert clinicians, who make judgments about the evidence and develop a guideline based on those decisions.
- Milliman and Robertson concurs with the statement that “evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett, British Medical Journal, January 1996). Its guideline efforts categorize evidence as follows: Level 1-randomized controlled trials (RCTs); Level 2-observational studies published in peer-reviewed journals; and Level 3-expert opinion (often informed by unpublished data as well as clinical experience). Published studies, especially RCTs, are relatively rare, particularly those addressing efficiency issues. In the best systems, practice innovation that improves quality and efficiency occurs continuously, but this information generally is not published. Much knowledge comes from sources other than RCTs. For example, there are multiple instances of institutions sharing best practices that lead to significant improvement in outcomes and lower cost. Such efforts are not documented in the literature because it is the institutions’ ethic to care for patients rather than to publish. The RCT may be the last step in closing the loop of evidence rather than the first.
- Milliman and Robertson uses the available literature in its guideline development process, but also uses other sources of data. These include the expertise of clinician and academic partners; specialty societies; its own healthcare management consultants and actuaries; data purchased from national, State, and private sources; chart reviews; site visits; and feedback from guideline users.
- Actuaries develop aggregate data that help make guidelines meaningful. These data are used by clinicians to write the practice guidelines. This approach reflects a move from the

consideration of one patient at a time to consideration of aggregate groups of patients, and a shift from minimally acceptable standards to benchmarking and process improvement.

- Guidelines have an important educational role in that they synthesize the evidence for the physician and present it in a form more readily usable to practitioners than individual articles in the published literature. Guidelines are not cookbooks; rather than replacing clinical judgment, they require it. Moreover, guidelines do not apply to every patient, and must be updated regularly. Local review of guidelines, now required by NCQA, is necessary so that local modifications can be made as indicated. Guidelines are best when they describe the best practice benchmark rather than an average; this is particularly true of length of stay—average length of stay does not lead to improvement, whereas benchmarking optimal length of stay gives an organization a target for a future period.
- Milliman and Robertson perceives guideline implementation as having several key components: (1) the availability of appropriate infrastructure to support implementation; (2) appropriate incentives for participants; (3) information that can be fed back to physicians to motivate change; (4) integration of all parts of the organization; and (5) involvement of the local practice community. Utilization management is critical, but should be proactive and collaborative rather than retrospective and punitive.
- Outpatient modified radical mastectomy has been controversial; however, it is possible to perform this procedure in a manner that provides control of pain and nausea, includes adequate home care, and incorporates patient choice.

IMPROVING CARE FOR PATIENTS WITH CANCER: THE ROLE OF NCQA—Dr. Cary Sennett

Background

The National Committee for Quality Assurance (NCQA), a non-Governmental, independent, not-for-profit organization, is headquartered in Washington, DC. Its mission is to improve the quality of health care service in America by providing information that changes how people choose their health care and how organizations provide it.

Key Points

- The public wants health care competition based on value; at present, most health care plans are competing based on price. To move to a market that is competitive based on value, we need information about the other elements in the value equation (e.g., quality, performance). By providing this information to those who use health care, provider organizations will be motivated to deliver high-value care, and a marketplace will be created in which competition leads to improvement.
- NCQA's approach to evaluating health plans combines a review of systems (structure and process) with a review of outcomes. These evaluations are limited by the available technologies, but NCQA is committed to using the best possible technology, and to advancing the state of the art in health plan evaluation. NCQA accreditation is the Nation's standard in health plan evaluation, and it relies on an assessment of the strength of the core systems upon which high-quality care and service depend. Beginning in 1999, performance results as measured by HEDIS will be incorporated into the accreditation program, with 25 percent of the overall score dependent on demonstrated performance (half coming from clinical performance measures and half from member satisfaction).
- HEDIS is a broad set of measures designed to assess performance in key areas important both to those who purchase health benefits and those who use them. The more than 70 HEDIS measures are precisely specified to ensure comparability and are supported by a

specialized infrastructure. HEDIS measures comprise the core of most of the health plan “report cards” and are also used by the lay media. Though they are imperfect measures, a process is in place to ensure their continuing evolution and improvement. Oversight of this evolution is the responsibility of a broadly constituted Committee on Performance Measurement (CPM). The CPM is intended to bring the public’s voice and the perspectives of all stakeholders in quality measurement and improvement into NCQA’s work.

- The process of developing HEDIS measures involves the explicit use of criteria designed to ensure that to the extent possible, measures are supported by available science. The criteria address the relevance of measures, their scientific soundness, and the feasibility of implementing them. In the last 18 months, Measurement Advisory Panels (MAPs) have been established to bring clinicians more directly into NCQA’s work; the MAPs are working with NCQA to address the gaps that still exist in the HEDIS measures.
- HEDIS was introduced in late 1993, with results first reported in 1995. Despite this limited experience, NCQA has learned that there is striking variation in the performance of health plans related to screening and treatment for a wide range of conditions (including cancer), that this variation has a real impact on the health and satisfaction of the public, and that there is demand for, and increasingly widespread use of, the HEDIS data.
- Relative specifically to the evaluation of cancer care, some screening and treatment HEDIS measures exist, and additional measures are in the testing phase. A MAP has been established to work with NCQA on cancer-related measures.
- Health plan evaluation is a work in progress that is still far from completion, but we are moving incrementally and regularly toward more numerous, better, and more robust techniques for evaluating the quality of care delivered in health plans (principally HMOs). At this point, little information is available about care delivered in PPOs, other managed care arrangements, or fee-for-service plans. Further, little or no comparative information exists on institutional performance, and institutional performance is critical to the delivery of high-quality care.
- The availability of information is restricted both by limitations in the science of medicine and in the science of measurement. In the area of measurement, some of the limitations are profound and relate to the long time lines associated with some measures. Moreover, the small denominators involved (i.e., populations in the average health plan) result in low statistical power, and the science also is limited with respect to risk adjustment. The high cost of data collection is another constraint reflecting limitations of the environment, including lack of standardization and disincentives to invest in information systems. Such investment is seen as wasteful by those whose focus is on medical loss ratio. In addition, there is a limited market for quality; until organizations are rewarded for providing higher value care, this will not change.
- Public information can stimulate and enable real improvements in health care. Though the information needed to do this is currently limited, information volume is increasing, as is the rate of information production. Overcoming the barriers to creating and using information will require concerted action and coordination among all who wish to move this agenda forward.

DISCUSSION—Drs. Isham, Schibanoff, and Sennett

Key Points

- According to Dr. Schibanoff, approximately one-half of the purchasers of Milliman and Robertson's guidelines are payers, while the remainder are primarily providers (e.g., hospitals, medical groups, and Independent Practice Associations). He also clarified that in an ideal guideline development process, outcomes data from RCTs would be the basis of the guideline.
- It remains unclear exactly how incentives should be structured, but rewards should flow to individual and organizational providers and to health care purchasers who show by their performance or decisions that they value higher quality or higher value care.
- Currently, health plans that participate in clinical research do not get higher performance scores. The MAPs have indicated that clinical trials participation is important; whether a measure in this area should be developed may be explored by NCQA.
- Regarding the guideline concerning outpatient mastectomy, Dr. Schibanoff indicated that it was implied that the patient's choice as to whether or not to undergo the procedure as an outpatient would take precedence over cost and reimbursement issues. He stated that this would be made explicit.
- There was general agreement among the discussants that the prevalent public perception that health plans are forcing mastectomy patients out of the hospital prematurely reflects the behavior of a minority of health plans. It was also noted that it is not good to keep a patient in the hospital longer than she wishes to be there. It is necessary to put the patient in control, and disconnect the economics from the achievement of a good outcome and patient satisfaction. This may become easier as we move from per diem as a payment methodology to case rates.
- Outpatient mastectomy, assuming the patient's agreement, can only be successful if the patient and family are properly educated and prepared well before the procedure. Care must be taken to ensure that the patient and family will be able to handle the postoperative care, both emotionally and in terms of skill. If they cannot, nursing home or hospital care must be provided.
- In some instances, health plans may not provide care consistent with clinical practice guidelines if the purchaser of care (public or private) restricts coverage for a particular aspect of care.

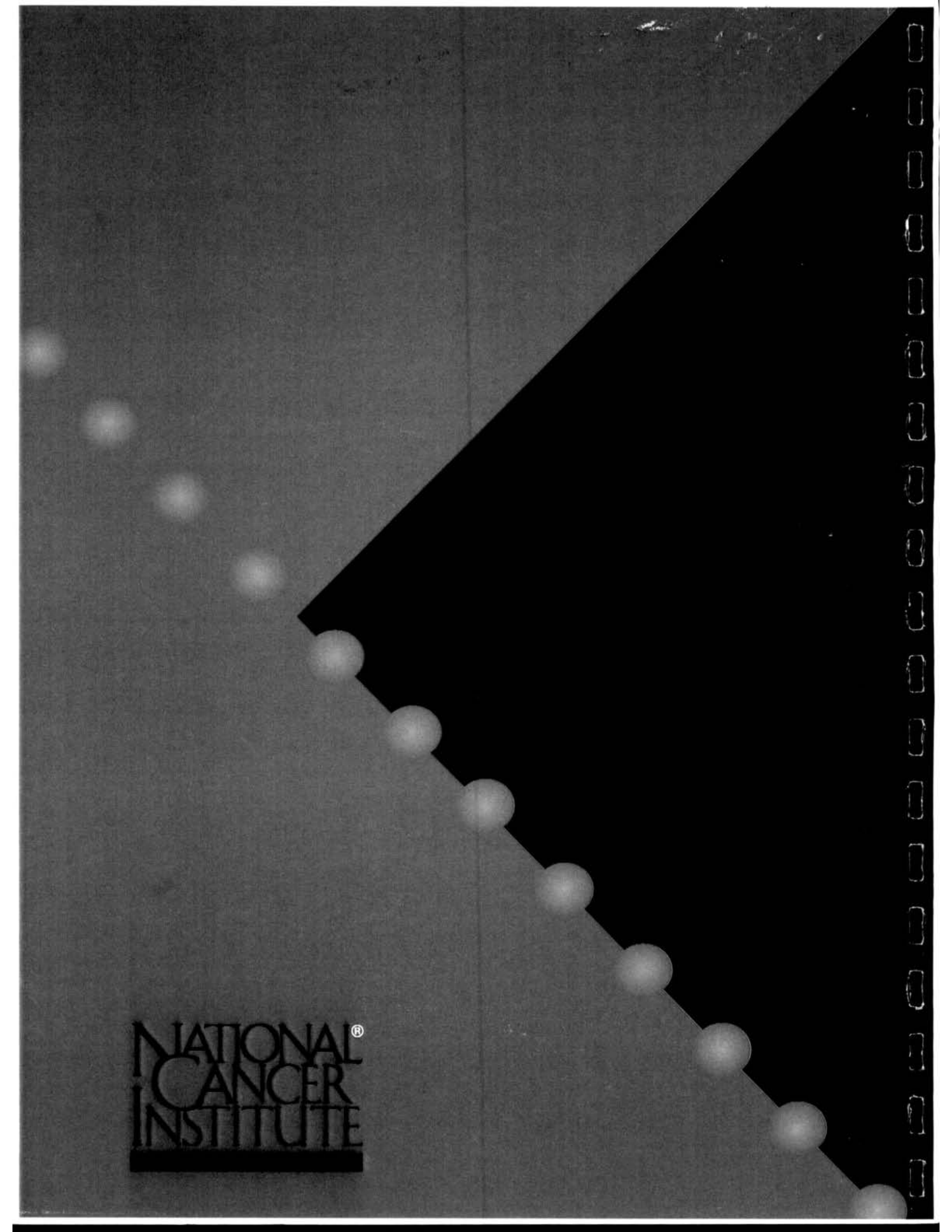
CLOSING REMARKS—Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- Our society will have to grapple with the conflict between public health considerations that may favor dispersing health care resources across a broader population, and the medical approach that seeks the best possible care for the individual patient.
- Standards of care, which tend to become the standards for payment, have the potential to stifle medical progress by denying support for experimental/investigational care.
- Issues must also be resolved as to who should have the authority to make decisions on the care provided to a patient. This has traditionally been the purview of the physician, but this

is no longer so. Some of this authority is being taken over by payers and is influenced by political decisions.

- We believe people should be treated according to the evidence, with the highest level of evidence being the clinical trial. Yet most of what is done in medicine has not been proven in clinical trials. Thus, the standard of care typically is based on lesser evidence which may never be challenged by controlled research studies.
- The Panel will need to address all of the complex issues raised today in its report to the President.

The background of the entire image is a dark, textured surface with a diagonal line running from the top right towards the bottom left. Along this diagonal line, there is a series of white, circular, pill-like shapes. On the right edge of the image, there is a vertical strip of white rectangular frames, resembling a film strip.

NATIONAL[®]
CANCER
INSTITUTE