

President's Cancer Panel Meeting

January 1, 1997 to December 31, 1998

***CANCER CARE ISSUES IN THE UNITED STATES:
QUALIFY OF CARE, QUALITY OF LIFE***

*National Cancer Program
National Cancer Institute*

The President
The White House
Washington, D.C.

Dear Mr. President:

Though we have yet to eliminate cancer as a threat to Americans' health and well-being, I am pleased to report that more people with cancer are living longer. I can also confidently state that this is due in large part to improved standards of cancer care. However, we have not focused adequately on how best to define and implement quality care for all populations. We now understand that beyond achieving survival, delivering high quality cancer care means addressing quality of life concerns, the cultural appropriateness of care, and the personal economic consequences of cancer.

Attempts to define and measure quality in cancer care are relatively new, but they are gaining momentum due to consumer demand for care that addresses all components of quality as well as health care cost and reimbursement issues. At this time, multiple definitions of quality exist for various aspects of cancer care. Some of these definitions, and clinical practice guidelines derived from them, are based on evidence, while others are largely subjective. Moreover, the existing evidence for the efficacy of current cancer care varies greatly in the comprehensiveness and accuracy of the data collected and the methodologies and rigor with which the data have been evaluated. The result has been a lack of professional consensus and considerable public confusion as to what quality in cancer care means and how it should be defined, implemented, and evaluated.

This situation is made more difficult by the fact that standards of care for cancer are-and should be-highly dynamic. Quality of care can only be understood relative to the evidence available at a given point in time. Driven by exploding knowledge of human genetic, molecular, cellular, and behavioral influences in cancer, the pace of change in our perceptions of quality across the cancer continuum from prevention to end of life care is accelerating dramatically. Clinical guidelines that chart paths to achieving cancer care standards must evolve as rapidly as improvements in the standards of care are demonstrated. Further, it must be recognized that guidelines do not measure all components of quality, and if used improperly, have the potential to limit access to care and stifle therapeutic innovation.

The ultimate goal of defining and measuring quality is to raise the standards of cancer care and ensure that appropriate care is provided to every American battling cancer, or at risk for cancer. To address the complex barriers to effectively describing and assessing quality cancer care, the Panel recommends immediate action to:

- Expand and standardize data collection on all components of quality in cancer care to support the definition, implementation, and evaluation of high quality care

- Establish a consistent methodology for evaluating various levels of evidence that will be acceptable to those who provide, receive, and pay for care
- Increase research on short- and long-term patient outcomes to assess the impact of current cancer care on the disease and on patients' quality of life
- Establish a centralized mechanism to systematically coordinate, update, and disseminate evolving concepts and descriptions of quality cancer care to the medical community and the public
- Ensure that descriptions of quality cancer care, especially as these may affect reimbursement policies, reflect the priority of the patient's welfare over cost.

On behalf of the President's Cancer Panel, I hereby respectfully submit our full report for 1997-1998, Cancer Care Issues in the United States: Quality of Care, Quality of Life.

Sincerely,

Harold P. Freeman
Chairman

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.

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 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](#).

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

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 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 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 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 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.

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.

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.

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

² The 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.

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.

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.

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>)

⁷ Smith, T.J., Hillner, B.E. Ensuring quality cancer care: Clinical practice guidelines, critical pathways, and care maps, 1998.

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