President's Cancer Panel Meeting

Meeting Minutes

Quality of Cancer Care/Quality of Life

June 2, 1998
New Haven, Connecticut

Overview

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

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

Meeting Participants

President's Cancer Panel: Harold P. Freeman, M.D., Chairman; Paul Calabresi, M.D.; Frances M. Visco, J.D.

National Cancer Institute: Otis Brawley, M.D., Assistant Director, Office of Special Populations Research, National Cancer Institute; Maureen O. Wilson, Ph.D., Assistant Director, National Cancer Institute, Executive Secretary, President's Cancer Panel

Speakers:

Dr. Tim Ahles, Program Director, Center for Psycho-Oncology Research, Dartmouth-Hitchcock Medical Center

Dr. Joan Bloom, Professor, School of Public Health, University of California, Berkeley

Dr. Grace Christ, Associate Professor, Columbia University School of Social Work

Ms. Kathy Crosson, Chief, Patient Education Branch, National Cancer Institute

Dr. Vincent T. DeVita, Director, Yale Cancer Center and Yale School of Medicine

Dr. Karen Hassey Dow, Associate Professor, School of Nursing, College of Health and Public Affairs, University of Central Florida

Dr. Frederick Flatow, Medical Director, Connecticut Hospice, Inc.

Dr. Kathleen Foley, Chief, Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center

Dr. Anna Meadows, Children's Hospital of Philadelphia, University of Pennsylvania; Office of Cancer Survivorship, Division of Cancer Control, Prevention, and Surveillance, National Cancer Institute

Dr. Leslie Schover, Staff Psychologist, The Cleveland Clinic Foundation

Opening Remarks

Dr. Harold Freeman, Chairman

In opening the meeting, Dr. Freeman stated that:

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

patients and families and to encourage shared decision making. Ultimately, the balance of quality of life and quality of care issues must be decided by the patient, since patient perceptions and tolerance of complications and the resulting health burdens are unique.

- Another challenge is to develop effective systems of surveillance and support for cancer survivors that extend beyond the five-year survival period. Preventing disease recurrence and secondary complications, the provision of physical rehabilitation and psychosocial support all affect quality of life for cancer survivors.
- Quality of life as a component of quality of care is equally important for those at risk for cancer. Therefore, we need to ask what quality of care means in relation to screening, detection, and access to care for all Americans.
- As cancer detection and treatment become increasingly effective, the population of cancer survivors, as well as those considered to be at risk for developing cancer, will continue to grow. Problems associated with long-term survival will continue to emerge. Much more is needed to define and measure quality of care. The Panel also believes that it is essential to be sensitive to the needs of all segments of the population as quality of care issues are addressed.

Welcome

Dr. David Kessler, Dean, Yale School of Medicine

Key Points

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

Dr. Otis Brawley, Assistant Director, Office of Special Oopulations Research, NCI

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

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

PRESENTATION HIGHLIGHTS

Policy Issues

Introduction

Dr. Vincent DeVita

Key Points

- Numerous organizations, such as the National Coalition for Cancer Survivorship, now represent and promote the interests of cancer survivors. These organizations have had a significant impact on cancer care throughout the country and on public perceptions of cancer and cancer survivors.
- Prior to 1971, most cancer survivors were people whose cancer could be surgically removed, since there were few, if any, treatment alternatives available.

With the advent of radiotherapy and chemotherapy, patients and the public had to adjust to the idea of treating cancer differently, including, in some cases, allowing the cancer to remain in the body and treating it by nonsurgical means.

- The most important issue to current and future survivors is to create the circumstances that will lead to more survivors. The size and strength of the survivor population will in turn surface and lead to the resolution of more cancer-related policy issues.
- Since the National Cancer Act was passed in 1971, approximately $32 billion has been spent to carry out its mandate: "To support basic research and the application of the results of basic research to reduce the incidence, morbidity, and mortality from cancer." The use of the term "application" was significant, since at that time the National Institutes of Health (NIH) was more focused on the support of basic research than on the application of research results. By incorporating the term "morbidity" into the Act, its framers anticipated that with better treatment, there would be more survivors, and that these people would have quality of life issues. The framers of the Act also anticipated the growth of technology (such as high speed computers and the molecular biology revolution currently underway) that would radically change the silhouette of the National Cancer Program itself.
- In 1984, NCI developed Year 2000 goals that set specific idealized targets for reducing cancer incidence, morbidity, and mortality-a 15 percent reduction as a result of prevention, five percent due to screening, and a ten to 26 percent reduction in cancer mortality as a result of treatment. Progress to date against these goals is impressive. Approximately five of the 15 percent reduction from prevention has been achieved, however, recent data on the effectiveness of tamoxifen for breast cancer prevention (and the even greater effectiveness of raloxifene) suggest that the reduction may be more substantial. The screening goal in breast cancer was achieved several years ago. Mortality reductions attributable to improved cancer treatment are currently estimated to be between 14 and 26 percent. Overall, cancer mortality should be reduced by approximately 25 percent by the year 2000. In the last two years, two papers have been published showing cancer incidence and mortality declines beginning in 1990.
- Between 1971 and 1980 NCI's budget increased five-fold. It then took 16 more years to double the budget. Current plans are to double NCI's budget again over the next five years.

<u>Additional Research Needs and Other Recommendations</u>

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

National Cancer Institute Office of Cancer Survivorship
Dr. Anna Meadows

Key Points

- Approximately 8.25 million people are living with cancer. With advances in cancer treatment, this number will continue to increase. Approximately 25 percent of those living with cancer are breast cancer survivors; for the most part, these are young people who are in the most productive years of their lives.
- The Office of Cancer Survivorship (OCS) was established by NCI Director Richard Klausner in 1996. It was designed as a focus for extramural research to expand the knowledge base needed for improved therapeutic decision making. Although it was recognized that improving the quality of survival for survivors begins at the point of diagnosis, OCS focused its research agenda on the issues of survivors who were at least two years post-treatment, because research data has been lacking for this group of patients. Little information has been available about long-term cancer survivors (five, 10, and 15-year survivors) and the types of problems they face. A goal of NCI's efforts is also to increase awareness of survivor issues among medical professionals and the general public.
- The OCS held a number of meetings to develop a research agenda. Issues identified for emphasis included the prevalence of physiological and psychological long-term effects of cancer and its treatment; the risk of second cancers and the relationship between patients' risk levels and previous exposures, treatment received, and genetic predisposition; issues related to reproductive and sexual functioning; effects of treatment on offspring of cancer survivors; the economic impact of cancer; and the evaluation of interventions to prevent long-term problems.
- OCS was also interested in comparing cancer survivors with non-cancer patients, and in examining undesirable outcomes that could be prevented, either during the course of therapy or after therapy was completed. It was determined that information about the long-term effects of therapeutic options was needed to assist consumers in making informed decisions. Other areas of interest included obtaining more information about the risk of cardiac disease in adults treated for childhood cancers and how to prevent this delayed treatment effect; the impact of cancer treatment on renal and cognitive function; treatment of premature menopause (e.g., with hormone replacement) and its effect on quality of life and the risk of recurrence.
- One of the most significant problems of cancer survivorship is the risk of second cancers associated with treatment. OCS is interested in better understanding and quantifying this risk, and determining how it can be prevented or treated. In addition, there is a need to better understand how genetic susceptibilities interact with cancer treatments to influence second cancer risk.
- OCS determined that a number of survivor groups have been overlooked in studies to date; these include patients with certain diagnoses, survivors representing various ethnic and socioeconomic groups, and the elderly. In

addition, longitudinal survivorship studies have been lacking and instrumentation has been inadequate to measure quality of life indicators over time.

- A major OCS research priority is to develop an understanding of where cancer survivors receive surveillance and follow-up care. There are myriad potential sources of care, including primary care providers, oncologists, and managed care plans. Questions concerning how to identify the most appropriate source of care and how to gain access to that care must be resolved. Factors influencing choice of care include cost, initial treatment, risk of subsequent disease, and the survivor's relationship with his or her oncologist.
- OCS is also interested in evaluating structured interventions and determining how behavior modification can lessen future problems for survivors. Although educational materials are plentiful, it is unclear how the materials lead to behavior change or changes in quality of life. Educational materials addressing the needs of the underserved are not yet readily available.
- In the last two years, the OCS has set aside $5 million to support its research agenda and is developing partnerships with private foundations to increase the level of funding available for survivorship research. Future OCS activities will involve continuing investigator-initiated research and developing cooperative agreements with clinical trials groups to develop an infrastructure that will enable lifetime follow-up of survivors.

Policy Issues for Physicians and Caregivers

Dr. Kathleen Foley

Key Points

- End of life care is a survivors' issue, as 50 to 60 percent of patients diagnosed with cancer will eventually die from their disease. The reality is that 1,400 patients die each day from cancer. How cancer patients perceive their death dramatically affects their morbidity. A "bad death," characterized by poor symptom control, physician abandonment, or inadequate closure, creates survivors' fear of their own death. Considerable data exist suggesting that how individuals face their own death is largely a function of how they have experienced the death of loved ones.
- Public attitude surveys have shown strong support for physician-assisted suicide because of patients' concerns about suffering and the dying process. These concerns were evident in research conducted at the University of Wisconsin in which 69 percent of cancer patients indicated that they would consider suicide if their pain was not controlled adequately.
- End of life care is a quality of cancer care issue; extensive data demonstrate that health care professionals lack competency in end of life care and that a variety of physician, patient, and institutional barriers exist to providing such care. The American Society of Clinical Oncology's (ASCO) Task Force on end of life care has recently proposed a series of recommendations that will require extensive changes in health care policy and in provider education if implemented. Although there is evidence suggesting that the public is demanding improved end of life

care, our culture does not want to discuss death. This barrier to publicly address such a private topic poses considerable challenges to the NCI or to any major effort related to end of life care.

- End of life care is a quality of life issue. Research has demonstrated that one-third of cancer patients in active therapy and two-thirds of patients with advanced disease have significant pain that requires analgesic drug therapy. Numerous studies have demonstrated that pain scores greater than five interfere with patients' quality of life, their ability to perform activities of daily living, and many other aspects of their lives.
- A recent series of studies suggests that advanced cancer patients have seven major symptoms that affect their quality of life. Up to 25 percent of these patients report major depression. Recent studies have also demonstrated that depression in patients with advanced cancer in palliative care units is closely correlated with patient requests for assistance in death. At present, a wide range of therapies are available to treat these major physical and psychological symptoms, but there is an enormous need for more research to better define how these therapies affect patients' decisions, and particularly decisions relating to end of life care.
- Surveyed oncologists have reported their lack of competence in assessing and managing depression, their lack of knowledge and professional education in pain management, and a lack of resources for providing palliative care to patients with cancer.
- A recent Institute of Medicine report outlined current health care system limitations to providing compassionate, humane care for patients at the end of life. The report emphasizes that cancer patients need continuity of care from prevention to diagnosis to curative therapies and palliative care. In addition, the report supports recommendations from the World Health Organization (WHO) that a system for delivering palliative care should be established before governments consider physician-assisted suicide legislation.
- The WHO defines palliative care as the total care of patients with an incurable disease. Palliative care is family-centered; focuses on the quality of life of patients, with particular attention to managing symptoms; addresses psychological and spiritual needs; and respects cultural differences.
- End of life care is an important caregiver issue. Recent studies have demonstrated that enormous burdens are placed on caregivers who have inadequate knowledge, resources, and training to care for family members at home. Caregiver burden is often associated with caregiver depression, which in turn has a significant and major negative effect on the dying process for the cancer patient. The degree of caregiver burden is directly related to inadequate symptom control, lack of appropriate economic resources, and lack of social supports.
- Each year, an estimated 450,000 patients die in hospice care nationwide. Approximately 80 percent of these deaths are cancer-related and 90 percent of these patients die at home. Many hospices require that there be a responsible caregiver at home as a condition of enrollment. Yet hospice, which is capitation-based, can only provide four hours of home health care each day. This level of support is often inadequate, particularly for elderly patients who often

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

- Only $2 billion per year is spent on hospice care in the United States. Hospice care reimbursement is changing with health care financing changes; capitation rates are being reduced, as is the length of time that patients may remain in hospice care. Moreover, many health care programs do not adequately pay for hospice care for patients under age 65. In addition, a number of states do not cover hospice care for Medicaid patients, forcing the poor to die in hospitals because of a lack of community-based resources to provide care at home. Recent Inspector General reports have criticized hospices because as a result of the high quality of care they provide, patients have lived longer than anticipated. Further, for many patients with advanced cancer, the cost of pain medications and other drug therapies used in palliative care is not reimbursed, and these out-of-pocket expenses can total $400 to $600 per month, expending all of the patient's Social Security income. There are cases of patients foregoing the use of necessary pain medication because the costs were prohibitive.

Additional Research Needs and Other Recommendations

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

- Cancer centers need to develop centers of excellence in palliative care to maintain their role as leaders in professional and public education and to produce experts who will sponsor clinical trials in palliative care to advance this research.

Discussion

Drs. DeVita, Meadows, and Foley

Key Points

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

- The three major issues in end of life care are: poor physician/patient communication about end of life care issues; poor symptom control (in a major study, 50 percent of the patients who were dying in five hospitals died in pain); and the lack of advanced care planning and advanced directives.
- Oncologists are able to provide active therapy for patients, but if no therapy with curative intent is possible, patients are often triaged to other systems of care (e.g., nursing home, hospice). When this occurs, patients often feel abandoned. Moreover, one cannot be admitted to a hospital to "die"; there is no Diagnosis Related Group (DRG) for dying. This barrier to institutional care at the end of life also limits the support oncologists can provide.
- In other countries, where health care is seen as a right, palliative care is provided. Twenty countries have endorsed the WHO Cancer Control Program, which includes palliative care as one of its four major components. In this country, the only group of patients who are part of an entitlement program are Medicare beneficiaries. Patients under age 65 do not receive hospice care unless they have hospice insurance and Medicaid does not fully cover hospice care in all states.
- Issues related to death and dying are a necessary part of the Panel's discussion of quality of life because they deal with the quality of living for the dying. While most patients do not necessarily want to be seen as dying, they do want to ensure that they will receive good care through the end of life. Recent research with patients receiving care in a palliative care unit who were aware of their diagnosis revealed that this knowledge did not create hopelessness; rather, it was the reality in which they functioned.
- The reason that the disabled population opposed physician-assisted suicide was because it was viewed as a form of health status discrimination. The dying may likewise suffer from discrimination because they often do not receive potentially beneficial interventions because of their health status. What dying patients need is not high technology care (e.g., respirators, ventilators, intensive care units); it is good care for patients at home, good support for their caregivers, and good symptom control. None of these things are extraordinarily costly, but they must be institutionalized nationally.
- Some positive outcomes of the cancer survivorship experience include knowing how to live in the moment and how to appreciate each day. Having a positive outlook may positively influence quality of life.
- Medical training, which tends to be focused on acute or crisis care and short-term outcomes, may create a bias among young physicians (and nurses) that long-term cancer survivorship is uncommon. This view subsequently may negatively affect the likelihood that they will recognize the long-term follow-up needs of cancer patients in their care.
- Managed care places considerable constraints on the amount of time that physicians spend with patients, causing them to focus on the most salient and immediate problems. This leaves little, if any, time to focus on issues related to prevention or quality of life. It was Dr. DeVita's view, however, that managed care is evolving as a result of the struggles (e.g., growth, consumer concerns and resultant regulatory and legislative actions) that the industry has faced and may in fact prove to be an environment in which prevention and quality of care will

flourish. For the most part, he believes, the observed deficiencies in medical care related to prevention and quality of care reflect failures of the fee-for-service system, not the weaknesses of managed care.

- There has always been a fierce debate about the proper balance between basic and applied research. Opponents of the National Cancer Act believed that the NIH should only support basic research. Thus, the reductions achieved to date in cancer incidence and mortality are attributable to the 15 percent of research funding that was allocated to the applications program. The other 85 percent of funds used to support basic research is just beginning to bear fruit with, for example, the emergence of new cancer drugs such as the anti-angiogenesis compounds. Issues governing how research funding is allocated between basic and applied research must be addressed by the NCI. It is a delicate balance, the maintenance of which depends largely on the leadership of the Institute.

Education and Communication

"The Cancer Journey: Issues for Survivors" A Training Program for Health Professionals"

Ms. Kathy Crosson

Background

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

Key Points

- Education and communication are important parts of cancer comprehensive care. "The Cancer Journey: Issues for Survivors" responds to the needs of these health providers for a better understanding of the range and complexity of issues associated with cancer survivorship. In addition, the training program focuses on providing effective support, accurate information, and useful referral information. Through the training, health professionals are taught how to empower survivors and their families to work together effectively regarding survivorship issues.
- The video can be shown in short segments in a variety of settings including grand rounds and support groups and is particularly effective when coupled with a discussion panel of survivors or a lecture presentation by a health professional

familiar with the issues. Associated resource materials will eventually be available through the NCI web site.
- The videotape "The Cancer Journey-Issues for Survivors" was shown. Copies of the video, reference materials, and Leader's Guide for trainers can be obtained free of charge by calling 1-800-4-CANCER.

Discussion
Ms. Crosson

Key Points

- "Anniversary reactions" are an important but sometimes unrecognized issue for both patients and care givers. On or near the anniversary of their cancer diagnosis, patients tend to visit their physicians and often present with symptoms or anxiety.
- The NCI has a formal promotion plan for the training video and associated materials. NCCS and ONS are working with the NCI to promote the training package. It is intended that the video be used as part of a group training program; it is not being promoted for individual use. The NCI has received inquiries concerning use of the videotape from insurance companies, small and large businesses, and health plans. Kits will be promoted to these groups. The NCI's web page includes the Cancer Patient Database, through which such videotapes and other educational materials can be located.
- The training materials are now in their second printing; response to the materials has been overwhelmingly positive.
- Plans are under discussion with the ONS to launch a training-of-trainers to help develop a cadre of individuals to lead and promote the training.
- NCI is also interested in sponsoring outcomes research to assess the impact of health professionals training programs like "The Cancer Journey."

Quality of Life Issues

Long-Term Survivorship
Dr. Karen Hassey Dow

Key Points

- A study of long-term cancer survivors conducted by Dr. Hassey Dow in collaboration with the NCCS and co-investigators focused on: quality of life issues; the need to document quality of life after treatment; assistance in identifying high risk areas and selected problems that could be addressed through specific interventions; and the development of psychometrically sound quality of life measurement instruments.
- It is important to define quality of life as well as cancer survivorship. Quality of life is a multidimensional concept and should be measured using individual perceptions of quality of life rather than proxy measures such as the Karnofsky scale.

- Dr. Dow's study used the definition of survivorship (i.e., a fluid process that begins at the point of cancer diagnosis and continues for the balance of life) written by the NCCS. The study included a survey containing two standard quality of life instruments that were mailed to 1,200 NCCS individual members. The first instrument, Quality of Life for Cancer Survivors, was developed more than ten years ago, and is a 41- item rating scale. The second instrument, the Fact-G, contains a 33-item ordinal scale. Demographic information on study participants was collected along with several qualitative measures related to quality of life.
- Study results are based on a response rate of 57 percent. Approximately 80 percent of the respondents were females of moderate to high socioeconomic status. Mean respondent age was 49 years. Although respondents represented a variety of cancer diagnoses, 43 percent of the respondents had breast cancer. Study participants were treated with a number of different modalities and had survived approximately 80 months (or 6.7 years) post cancer diagnosis.
- Among the most salient issues identified in the study were concerns related to fatigue and pain, menopausal symptoms, and reproductive and fertility concerns. Two other key issues emerged: the first related to fear of recurrence and what to do if there is a recurrence; the other concerned immobility after treatment
- Some of the positive outcomes of cancer survivorship cited were positive effects on marital and intimate relationships and on relationships with family and children. Respondents also cited feelings of usefulness and happiness, being able to help others with cancer, and becoming a part of life and living. Some of the negative impacts included changes in body image and sexuality. Caregiver concerns, out-of-pocket costs, concerns related to testing and cancer surveillance, and loss of insurance were also noted. Other emotional issues related to cancer survivorship included emotional distress, anxiety and depression, loneliness and isolation, and feelings of loss of control.
- Survivors identified a number of interventions that they used to enhance their quality of life. Among the interventions were: patient and family education, long-term coping skills management, support groups, use of alternative or complementary therapies, and advocacy and activism. The value of support groups was cited repeatedly, yet the current insurance climate provides limited coverage for this aspect of cancer care.
- Spiritual quality of life was also cited as being very important. This included focusing on the importance of family and friends, finding hope (even in advanced disease), finding meaning in illness, and having a renewed spiritual strength. Negative concerns included uncertainty about the future and fears of dying, though not of death itself.
- Interdisciplinary research partnerships, particularly involving advocacy groups, are highly valuable. These partnerships were particularly useful in examining the study results and in identifying how the results could be used in the future.
- It is also important to target special populations for quality of life studies, especially minority populations.
- Additional Research Needs and Other Recommendations

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

End of Life Issues

Dr. Frederick Flatow

Background

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

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

The Connecticut Hospice, Inc. was the first hospice in the United States and was established as a home care hospice. In 1979, the first freestanding hospice was built in Branford as a companion to the home-based program. With 52 beds, the freestanding hospice serves 1,200 patients per year. An equal number of patients are served in the home care program; approximately 250 patients per day receive care through the home-based program, representing 80 percent of total patient days.

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

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

Key Points

- Although studies of end of life care have been performed (such as the Institute of Medicine's study "Approaching Death and Improving Care at the End of Life") and a growing number of foundations are involved providing palliative care, there still is a great deal to be accomplished.
- In 1984, hospice care was added to the list of covered Medicare benefits; under the benefit, a physician must certify that the patient suffers from a terminal illness and has a life expectancy of six months or less. Addition of the hospice benefit eased the financial burden of end of life care for many Medicare patients over 65 years old; this population represents approximately two-thirds of patients at the Connecticut Hospice. Many patients under 65 years, however, lack insurance coverage for hospice care and resources available through the Medicaid program are constrained.
- Late referrals for hospice care pose persistent problems. In the inpatient unit at Connecticut Hospice, 22 percent of patients do not survive more than three days following admission. In such cases, the patient and family are deprived of valuable care and support.
- The skills used in the hospice care of cancer patients are applicable to the care of patients with other chronic illnesses and end-stage diseases, and the clinical profile of hospice populations is changing. Cancer-related hospice admissions in Connecticut have remained constant, but their percentage relative to total hospice admissions has declined from 90 percent to approximately 70 percent as admissions of patients with other illnesses have steadily increased.
- As a result of shortened acute hospital stays, patients and families often do not have adequate time to learn about the cancer diagnosis, prognosis, and the anticipated course of the illness. They are also deprived of time to contemplate the illness and begin to prepare for what lies ahead. Many patients, therefore, arrive at hospice care requiring a great deal of support and teaching, and they are often in a state of transition and denial.
- To better address patients' needs in the current health care environment, an intermediate level of hospice care should be developed. Patients are currently accepted into hospice care while they are receiving peritoneal dialysis, ventilator support, intravenous therapies with fluids and antibiotics, and total parenteral nutrition. With teaching and emotional and spiritual support in the face of terminal illness, patients and families usually realize the futility of such measures. These therapies are gradually terminated and good symptom control can be achieved.
- Of the approximately 2.4 million deaths in the United States each year, approximately 60 percent die in the hospital, often in intensive care units; 17 percent die in nursing homes and other chronic care facilities, some with limited staff and family support. Most of the remainder die at home and approximately 20 percent of these patients have hospice contact; this represents only 14 or 15 percent of total deaths. Although this percentage is growing, it remains inadequate.

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

majority of medical problems fall between these extremes, requiring an approach that includes the multiple goals of medicine: health restoration, life preservation, rehabilitation, prevention, comfort, and caring.

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

Discussion

Drs. Dow and Flatow

Key Points

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

Medical Effects

Pediatric Cancers and Medical Surveillance/Follow-Up for Second Cancers

Dr. Anna Meadows

Key Points

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

produces late coronary artery disease and may result in premature death. Anthracycline chemotherapy produces a similar result. High dose stem cell or marrow transplant, and some of the newer drug combinations, have also been shown to cause cardiac problems. Studies are underway to determine if exercise benefits asymptomatic patients and to assess how best to use cardioprotectants in conjunction with anthracyclines to avoid later heart problems.

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

age five require cranial irradiation. Cure rates for children not receiving radiotherapy have not declined.

- In an international study of 1,400 young adolescents and children with Hodgkin's disease, the risk of second cancer was approximately seven percent overall; leukemia risk was less than four percent, but the actuarial breast cancer risk was 35 percent at 30 years.. All of these girls received more than 30Gy to their chests and they received it in their periadolescent period when their breasts were developing. As a result of this research, treatment approaches for Hodgkin's disease in adolescents now include lower doses of radiation. It may be possible in the future to cure the disease without any radiation. Similar research is underway to reduce or eliminate the radiotherapy-related risk of second cancers in children treated for retinoblastoma.
- Much remains unknown about the relationship between cancer treatment and genetic polymorphisms or population differences. For example, cardiac disease following anthracycline treatment may reflect a different genetic mechanism for metabolizing anthracyclines among affected patients. Further study of this phenomenon may affect how cancer patients are treated in the future.
- In addition to treatment modifications and the development of guidelines for follow-up of childhood cancer survivors, research has also led to interventions such as modified educational techniques for children who have received cranial irradiation; replacement of growth, thyroid, and gonadal hormones; reproductive counseling for young men about to undergo certain therapies and for young women who are going to experience premature menopause; and health behavior education.
- We are now poised to learn more about the long-term effects of treatment for both childhood and adult cancers. Findings from these studies will enable us to provide better information and better alternatives to consumers and medical caregivers.

Cognitive Effects

Dr. Tim Ahles

Key Points

- Cancer survivors have recognized that the cognitive impact of cancer treatment is an important issue requiring further study. Certain cognitive rehabilitation approaches may be effective, and medications are under study in non-cancer populations that may improve concentration and memory functioning in cancer survivors. Through further study, treatment protocols may be modified to minimize negative cognitive effects while maintaining treatment efficacy. Patients need to know about this potential side effect to make informed treatment decisions.
- Radiation therapy has been shown to affect brain tissue. There are early effects, like cerebral edema, early delayed reactions such as demyelinization, and late effects, the most dramatic of which is radiation necrosis. Radiation effects have been studied primarily in patients with primary brain tumors and as related to the prevention of central nervous system metastases. In the treatment of brain tumors,

it is often difficult to separate the impact of treatment from the impact of the disease itself. These tumors are also fairly uncommon and therefore, it is difficult to identify enough cases for comparison studies.

- With respect to prophylactic cranial irradiation for the prevention of brain metastases, most of the research has been conducted in patients with small cell lung cancer (SCLC) in whom cognitive deficits have been demonstrated consistently. These deficits can be measured on standard neuropsychological tests and through brain MRI. Results of a recently published study of patients with SCLC treated with a Cancer and Leukemia Group B (CALG-B) protocol indicated that cognitive deficits may be observable within one or two months following completion of central nervous system irradiation. Since many SCLC patients are treated with both systemic therapy and radiation, however, it is difficult to determine how much of the cognitive deficits observed are attributable to the irradiation versus the chemotherapy.
- Increasing evidence suggests that cognitive deficits such as loss of memory and concentration may be associated with systemic chemotherapies. Some of these deficits may be subtle, but may substantially affect a survivor's ability to work in certain environments within their profession. For the survivor, such changes may have a major impact on quality of life.
- Surveys conducted to date suggest that as many as half of patients treated with systemic therapies experience memory and concentration problems. Most questionnaires, however, contain only one or two items related to this effect and appropriate control groups are generally lacking to support meaningful comparisons. Further, as survivors age, problems with memory loss and concentration become more evident. This is as true for the general population as for cancer survivors, and complicates attempts to assess treatment-related cognitive deficits.
- A variety of studies have been conducted to assess cognitive deficits in patients receiving high dose chemotherapy and bone marrow transplantation, and more recently, in patients receiving standard dose chemotherapy. These studies employed a structured neuropsychological test, with appropriate controls, and have demonstrated a consistent pattern of cognitive decline in a subpopulation of treated patients. Another study of women treated with high dose chemotherapy revealed treatment-associated white matter changes detectable with MRI.
- One of the better studies of the relationship between systemic chemotherapy and cognitive deficit was published recently in the Journal of the National Cancer Institute. The study design included women with breast cancer who were randomized to either high dose or standard dose chemotherapy and a control group of women with breast cancer who had never received systemic chemotherapy. Of those in the high dose group, 32 percent had documented cognitive problems. Seventeen percent of women in the standard dose group reported cognitive deficits, while only nine percent of patients not receiving chemotherapy experienced cognitive problems.
- A study is currently underway at Dartmouth to identify the cognitive impact of systemic chemotherapy in long-term survivors of breast cancer and lymphoma. This study is interesting because it includes a large number of survivors treated

with systemic chemotherapy as well as a fairly large number treated only with local therapies such as surgery or some type of local non-central nervous system radiation therapy. The study is a three phase effort. Phase I involves identifying survivors treated at Dartmouth and interviewing them by telephone using a standardized neurobehavioral checklist and quality of life instrument to assess cognitive functioning, particularly as it may relate to quality of life. In phase II, a random subpopulation (approximately 140 patients) will participate in a standardized battery of neuropsychological tests to examine cognitive functioning with an emphasis on memory and concentration. Anxiety, depression, and fatigue will also be examined to isolate their potential confounding effects on study results. Phase III is a pilot study studying cognitive deficits in cancer survivors using functional and quantitative structural MRI. This approach permits investigators to assess brain function and perform cognitive testing while the person is undergoing an MRI.

- There is also new research involving biological response modifiers showing a dose-related relationship between treatment and cognitive problems such as disorientation, impaired memory, and psychomotor slowing. For most patients, these problems resolve when therapy is discontinued, but new evidence suggests that for a subpopulation of patients, these deficits persist well after therapy is completed.

Additional Research Needs and Other Recommendations

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

Discussion
Drs. Meadows and Ahles

Key Points

- Patients often attribute cognitive problems they experience to a psychological source; as they continue to experience problems with memory and concentration, they tend to question their coping skills and erroneously conclude that they suffer from depression. Patients are typically relieved to learn that their cognitive problems may be physically based. This point is based on clinical experience. More research in this area is needed.
- It is important to keep in mind that while the medical effects of cancer therapies are extremely important and require further study, most cancers are fatal if untreated. For many patients, the risk of side effects pales when compared to the benefit of a lifesaving therapy.
- As new therapies emerge, it is essential to incorporate adequate follow-up to identify the long-term effects of treatment and their impact on patients' quality of life. At present, the research community is focused principally on how long patients live with these new therapies, but we now recognize that cure is not enough. Long-term quality of life assessments must be built into trials of new therapies so that we will be able to answer consumers' questions about the risks and benefits of these treatments.
- Although some of the cognitive effects discussed may be attributed to cancer therapies, it is also possible that these effects have another physical or psychological component that is not being addressed by the physician. Physicians should be careful not to oversimplify patients' complaints about cognitive problems by attributing them solely to treatment effects.
- A five-year survivor of non-Hodgkin's lymphoma expressed great concern about the long-term effects of his treatment. Due to anxiety and depression he is unable to return to work and is troubled by the lack of certainty regarding the impact of treatment on his future. Dr. Calabresi emphasized that such feelings are understandable, since having cancer and undergoing cancer treatment is no less a major trauma than experiencing war or other major catastrophes. He encouraged the speaker to recognize that he has overcome a great challenge and has a reasonable expectation of a long and healthy future. He further encouraged the speaker to continue follow-up care to confirm the health of major organ systems and ensure that all is being done to prevent future problems.
- Until recently, we have, in many cases, had little choice in the kinds of treatments we have had to use in order for patients to achieve survival. As better treatments are developed, however, the medical community must stop telling patients to just be grateful to be alive and start examining what more can be done with respect to rehabilitation and promoting better quality of life.
- Little research has been conducted on hormonal treatments and their impact on cognitive functioning, particularly in the male population. Research has been done on women who have gone through menopause and experienced cognitive problems. These problems have been improved with estrogen replacement or

other hormonal interventions. Anecdotal evidence suggests that women taking tamoxifen may experience memory problems.

Psychosocial and Behavioral Issues

Overview of Psychosocial and Behavioral Issues

Dr. Joan Bloom

Key Points

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

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

Employment Issues

Dr. Joan Bloom

Key Points

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

survivors felt this way. Among supervisors surveyed, 31 percent felt that the employee needed to be replaced; only 14 percent of the survivors expressed this feeling. These discrepancies call into question the effectiveness of the ADA in protecting survivors, most of whom do return to work. A similar current study of breast cancer survivors under age 50 years is yielding similar results.
- Some of the stigmatization of cancer survivors in the workplace is self-imposed by survivors; the remainder consists of real limitations imposed by the workplace.

Additional Research Needs and Other Recommendations

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

Sexuality

Dr. Leslie Schover

Key Points

- Sexuality encompasses more than erections or orgasms. It includes relational sex (the ability to feel attractive and lovable), recreational sex (feeling free to enjoy touch and caressing), having functional sexual activity, and reproductive sex (being able to have children if desired). Unfortunately, cancer treatments can damage all of these aspects of sexuality.
- Current social research surveys in the general population indicate that married couples are most happy with their sex lives, and throughout middle age, most of these married couples spend an average of approximately 30 minutes a week having sex. Approximately 20 percent of American adults are not sexually active and a large proportion of these adults are older women who have been widowed or divorced and therefore lack a partner. Research suggests that sexuality is an important component of well being, and although not necessarily causal, those who report being the happiest are people who have had one sexual partner in the past year, have sex fairly frequently (two to three times a week), and for women, routinely experience orgasms as part of their sexuality. Conversely, poor health is associated with being sexually inactive and unhappy.
- Sexual problems are particularly prevalent among patients with prostate and breast cancers. Approximately half of the women with breast or gynecologic cancers have persistent sexual problems. Following prostate cancer treatment, up to 70 percent of men have significant sexual problems. Most of the sexual problems that cancer survivors experience are severe. They tend to affect all phases of sexuality including desire, arousability, and the ability to feel pleasure. These problems tend to persist following cancer treatment after other aspects of quality of life have improved.

- Among the most common problems are loss of desire for sex, erectile dysfunction in men, pain with sexual activity (particularly with penetrative, or vaginal, intercourse) among women, and to a lesser extent, trouble reaching orgasm for both men and women. Orgasm-related difficulties, however, are generally secondary to the fact that patients experience both a lack of desire and difficulty with sexual functioning.
- Among the risk factors that appear to increase the likelihood of survivor distress related to sexuality are younger age; not being involved in a committed relationship; viewing sexual attractiveness as a crucial element of self-esteem; and a history of sexuality-related concerns such as multiple sexual partners, sexual abuse or trauma, or sexual dysfunction prior to having cancer.
- Many cancer treatments can interfere physiologically with male sexual function. These include pelvic cancer surgeries (e.g., radical prostatectomy, cystectomy, colorectal surgery) that can damage the nerves that direct blood flow to the penis, and therefore, interfere directly with erection. Men who have pelvic radiation therapy often develop erection problems because the radiation damages some of the small blood vessels that are also involved in achieving erection. Although some of the newer modalities, such as conformal radiation or radioactive seeds are less destructive, they all have some associated morbidity of this nature. Men who receive hormonal therapy for metastatic prostate cancer often experience profound changes in their ability to enjoy sex, to feel sexually aroused, and to feel sexual pleasure.
- Women most apt to experience sexual problems are young women who experience premature menopause as a result of their cancer treatment. This has been observed often in women diagnosed with early stage breast cancer who receive adjuvant therapy and in those who undergo pelvic irradiation or removal of their ovaries as part of their cancer treatment. It remains unclear whether breast cancer survivors may safely take exogenous estrogens, which would quickly reverse some of the problems they experience.
- Women who have pelvic radiation therapy for cervical cancer and women who have graft versus host (GVH) disease following bone marrow transplant may undergo physical changes to their vagina and the vaginal mucosa that may make intercourse painful or impossible.
- Both men and women may undergo treatments that change their body image. For women, these may include mastectomy, removal of the vulva, vagina, or other organs involved in sexual activity. Some men may have to undergo partial or total penectomy. Other treatments that affect body image include a variety of ostomies, physical scarring from radiation, amputations, the mutilating affects of head and neck cancer, and some of the transient effects of chemotherapy such as loss of hair and pallor. Some of the weight gain experienced as a side effect of chemotherapy is permanent and may also adversely affect women's perceptions of their attractiveness.
- Most couples experience some period of celibacy when one partner is undergoing cancer treatment and are faced with the task of resuming sexual activity after the treatment is completed. Although most people in this culture expect sex to be romantic and spontaneous, patients undergoing cancer treatment have to

coordinate sexual activity with their medication regimen to minimize the impact of cancer treatment effects such as fatigue or nausea. In addition, they have to cope with changing perceptions of their own physical attractiveness, new sexual dysfunctions, and the stress that cancer may place on the relationship. Younger patients may also need to confront possible infertility and changes in their decisions about childbearing.

- Loss of desire is the most difficult and complex sexual problem to treat. In women, androgen replacement may occasionally be a solution, but we lack a good delivery system for giving women testosterone. Moreover, the safety of testosterone for breast cancer survivors has not been determined. Men who are receiving hormonal therapy for prostate cancer experience a loss of desire due to a reduction in their circulating androgen levels. No viable options currently exist to restore their desire. Sexual counseling with both partners can help increase sexual frequency and pleasure, but cannot directly affect how often partners desire sex.
- A number of approaches are available for treating erection problems. Although newly available Viagra may be an excellent drug, it is not a panacea; it does not cure 80 percent of men's erection problems. It provides improvement in about 80 percent of men who have the most mild form of erection problems, such as those due to anxiety or to very mild physical impairment. Among men who have had radical prostatectomy, Viagra manufacturer Pfizer's clinical trial data suggest that only 43 percent experienced improvement by taking Viagra. This does not mean that 43% achieved erections sufficiently functional to allow penile/vaginal intercourse.
- Following cancer treatment, many men will remain dependent upon other treatments to restore erections, such as injecting medication into the penis to have intercourse, using a vacuum pump device, or undergoing surgery to implant a penile prosthesis. Patient satisfaction with these treatments is variable and there is a high drop-out rate with all except surgery. There has also been very little emphasis on including a man's partner in the process of selecting among various treatment options or in follow-up to assess satisfaction with the option selected.
- More effective treatments are needed for the vaginal pain that women experience as a result of cancer treatment. To minimize vaginal changes resulting from radiation therapy, women should be encouraged to use vaginal dilators (and be instructed in their use) or have intercourse more frequently during and after radiation therapy.
- Breast cancer survivors often receive conflicting information about whether to take replacement estrogens. Even women who are not breast cancer survivors may have difficulty reaching a decision about estrogen replacement therapy because they fear that it causes cancer and are unaware of its benefits. Women should be aware of newer vaginal lubricants and vaginal, slow-release forms of estrogen.
- Cost-effective sexual counseling is essential and must be provided to a wide range of populations, including minorities and the underserved. Many members of ethnic minorities in the United States hold conservative views about sexuality and may have more anxiety and difficulty discussing these issues with their physicians and medical team. Counseling techniques must be integrated into cancer care and

must be sufficiently broad and flexible to accommodate the needs and perceptions of various components of the population.

Additional Research Needs And Other Recommendations

- Information about the potential effects of cancer treatments on sexual activity and fertility and available treatment options for these problems must be integrated into the cancer care continuum. Questions concerning sexuality and infertility must be included routinely in patient assessments initially and at followup intervals.
- Cancer treatment teams should include a sex expert-an oncology nurse, social worker, or counselor who is responsible for informing patients about the sexual consequences of their treatment at the time treatment is selected. The expert should also conduct follow-up discussions with patients at predetermined intervals, and triage patients to appropriate specialists (e.g., urologists, reproductive endocrinologists) who can provide treatment for complex or severe problems.
- Policy changes are needed to provide insurance coverage for cancer-related sexual problems. Many private insurers exclude this type of care from mental health reimbursement and may also exclude medical treatment for sexual problems. Typically, men and women who experience fertility problems after cancer lack insurance coverage for expensive infertility treatments.
- Greater emphasis should be placed on providing community outreach to respond to sexual problems experienced by cancer survivors. Many survivors are followed by their primary care provider and special issues such as sexuality often are not addressed. This problem is compounded by the fact that many people do not ask for help with a sexual problem or concern; this is particularly evident in minority populations and among the elderly.
- Sexual health after cancer must be actively promoted. Information on sexuality should be integrated into site-specific support programs for survivors. Opinion leaders should be encouraged to speak out in the media about the importance of sexual problems and infertility after cancer. Information on sexuality and fertility should be included in quality of life assessments.

Family Issues

Dr. Grace Christ

Key Points

- Research demonstrates clearly that the availability of emotional and practical support from loved ones is enormously helpful to patients' psychological well being, quality of life, and even survival. Two realities most influence the needs of families of cancer patients. The first is that cancer treatment now involves less hospitalization, more home care, and more outpatient procedures than in years past; this reality places more responsibility on the family to provide care over long periods of time. Second, there have been vast changes in recent decades in the home supports that are realistically available to many patients. Families are

more mobile and fragmented. The loss of extended families due to job relocations, retirements, and generally increased mobility has resulted in a significantly diminished system of local patient support. These changes in the fabric of society require that the family-based care model be examined more closely. A third dimension relates to resource depletion and the extent to which the family's financial and emotional resources are drained in caring for the cancer patient. In addition, a fourth important dimension affecting patient support relates to the stage of development of key family members and their developmental tasks (e.g., the effect of cancer on the parenting role with young children, the ability of an older adult to care for a spouse with cancer, the impact of cancer caregiving on a middle-aged adult's career).

- The role of the family caregiver is potentially overwhelming. Families are asked to provide financial and emotional support; assume the patients' responsibilities as they lose the ability to handle these; provide direct nursing care; become a surrogate specialist or dietician; and put their own life goals and activities on hold for an extended time period. Unchecked, stress on families reduces their availability to patients and can cause family members to develop physical symptoms and disabling psychological distress, suffer social isolation, and even become alienated from the patient. Also common are economic costs such as loss of work, increased medical expenses, and reduced productivity and effectiveness in both work and family functioning. Despite the intense pressures placed on the family, psychosocial treatment tends to focus on patient needs rather than considering the needs of the family unit. The primary health care agency may feel too overwhelmed with the care of the patient to include family concerns, and may not know how to provide time limited but potentially helpful family-focused interventions.
- The challenges faced by families caring for a cancer patient span four domains. The first of these is learning to deal with chronic stress and finding ways to build family resilience. Each stage of cancer brings new and different stresses for family members, and new ways are needed to cope with uncertainty and each new threat to the integrity of family life. Higher levels of depression and other psychiatric problems have been reported consistently among family members of cancer patients. For example, parents of pediatric cancer patients have been found to have more post-traumatic stress symptoms than their children who are patients. Similarly, high depression and anxiety levels have been observed in young adult and middle-aged well spouses facing a partner's terminal illness. An emerging conceptualization of family resilience focuses on ways to strengthen families' abilities to surmount crises and persistent stresses. Inner personal processes such as cohesion, flexibility, open communication, and problem solving have been shown to strengthen family abilities to cope. Shared beliefs about the meaning of illness and the meaning of caregiving can also foster a sense of cohesion, collaboration, confidence, and competence. Current research is attempting to identify risk and protective factors that could form the basis of family interventions.
- The second challenge to families is their expectation of resilience (versus transformation) in cancer survivors. Expecting that the cancer patient will

"bounce back" to his or her original state when this is not realistic can cause significant family stress and an undue burden on the survivor. Our culture values individuals who emerge from a crisis without "missing a beat." The notion that one can pick up where he or she left off following cancer diagnosis and treatment is at odds with the experience of an overwhelming majority of survivors. Transformation requires a series of evolving adaptations and often results in lasting changes in self-concept, values, roles, and time perspectives. Surviving cancer is a transforming experience that leads most patients to re-evaluate their values and life priorities; in many cases, survivors report that the disease led them to make changes that immeasurably enriched and enhanced their lives. To reach this outcome, however, survivors need to deal with their own, and sometimes their family's unrealistic expectations of resilience (i.e., returning to their pre-diagnosis status).

- In some cases, (often young) survivors take physically punishing jobs or jobs with high levels of responsibility just to prove they are worthy of surviving or to deny their ongoing vulnerability; this sometimes leads to physical or psychological crises. Such a heavy dose of denial may be adaptive at an earlier stage of the illness, but may be distinctly less helpful at later stages. Research has shown that those who cope well with stress are those who do not deny the adversity or tragedy of the situation, and who are also able to see it as a challenge to make positive changes in their life and relationships and extract positive meaning from the situation.
- The third challenge to families involves communication under conditions of uncertainty. Families can be weakened in their ability to provide effective support by a breakdown in communication with the patient, sometimes reflecting misinformation, misunderstanding, and different coping strategies with respect to communication. These breakdowns in communication are most clearly observed at various crisis points in the illness, such as at diagnosis, at the end of treatment, and at recurrence. Communication stresses are often observed following the initial cancer diagnosis because many families try to avoid discussing the disease to keep the patient hopeful; the patient, however, may want to talk about his or her illness. Avoiding the subject may cause the patient to become increasingly worried that his or her situation is too dangerous to discuss.
- When treatment ends, although patients know intellectually that this is a time for rejoicing, many experience a sense of anxiety and emotional unease because they are no longer engaged in actively fighting the disease. Cessation of treatment also results in loss of contact with the medical personnel upon whom they relied on a daily basis. Family members and friends who may have been very supportive during earlier stages of the illness may become less available and indulgent. They may feel that it is time for the patient to return to a normal life and to pick up where they left off prior to diagnosis. Families are often weary of caregiving tasks and the strain of worry, and are eager to be immersed in less threatening life problems. But patients may not yet feel normal. Although the challenge of staying alive and enduring treatment may have been achieved, they must face the world and live with the psychological, social, and physical consequences of surviving cancer. This often involves living with new compromises in one's life, lasting

physical problems, low energy, and other significant consequences of cancer survivorship. Most patients find ways to accept the changes without great psychological cost and are grateful for having survived the disease, however, they may need time to mourn their perceived losses, whether they be with respect to altered physical capacities, lost opportunities, or losses related to self-image.

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

Discussion

Drs. Bloom, Schover, and Christ

Key Points

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

- Controversy exists as to how research funds should be allocated among basic, translational, and clinical research. Dr. Freeman noted that the war against cancer focused on improving cancer research. There is, however, a gap between research and its application. Cancer treatment is not funded by the NCI nor are NCI's funds intended to be used for that purpose. Yet cancer care must be paid for, and a system is needed to ensure that all people with cancer can receive the care they need. Currently, 41 million Americans are uninsured and lack access to care.

Closing Remarks

Dr. Freeman

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

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