

**CANCER CARE IN THE UNITED STATES:  
WHAT'S RIGHT, WHAT'S WRONG?**

**ENSURING THE QUALITY OF CANCER CARE**

**Robert Hiatt, M.D., Ph.D., Deputy Director of the Division of Cancer Control and  
Population Sciences**

**National Cancer Institute  
National Institutes of Health  
Department of Health and Human Services**

**Hearing before the Senate Cancer Coalition  
September 16, 1999, 1:00 P.M.  
562 Dirksen Senate Office Building**

Good afternoon, Senator Mack, Senator Feinstein, and Members of the Senate Cancer Coalition. I am Robert Hiatt, M.D., Ph.D., Deputy Director of the Division of Cancer Control and Population Sciences at the National Cancer Institute (NCI).

I am pleased to appear before you today to discuss the value of the Institute of Medicine (IOM) report, "Ensuring Quality Cancer Care" and to describe the role that the NCI envisions that we will play in improving the quality of cancer care. An estimated 1.2 million people will be diagnosed with cancer and 8 million will receive treatment for cancer in 1999. Each person who is waging a personal war against cancer needs timely access to the diagnostic, treatment, and supportive services best able to fight his or her disease. The IOM report sets a goal of providing health care of the highest quality through a coherent national cancer care system. The report has focused attention on the quality of cancer care generally, as well as highlighted the federal government's role in ensuring quality cancer care.

In its report, the National Cancer Policy Board (NCPB) of the IOM notes that although numerous programs and research activities of the federal government relate to the quality of cancer care, the efforts lack coordination. The NCI has been at the forefront of developments in the basic and clinical sciences to uncover the underlying causes of cancer and to translate this knowledge into effective interventions. Current NCI plans include an expanded research strategy for improving the quality of cancer care that will be part of a well-integrated approach to quality cancer care within the Department of Health and Human Services (HHS). NCI will work in concert with sister HHS agencies such as the Agency for Health Care Policy and Research (AHCPR), Health Care Financing Administration (HCFA), Health Resources Services Administration (HRSA), Centers for Disease Control (CDC), and Assistant Secretary for Planning and Evaluation (ASPE).

Much work lies ahead of us. However, many projects are already underway, and several new initiatives are planned that will help us reach our goals. The overall objective of

NCI's approach is to design and foster the development of research programs, projects, and studies that enhance the state-of-the-science for defining, monitoring, and enhancing the quality of cancer care. The ultimate goal is to help lead a national effort to ensure that all Americans receive the highest quality cancer care, spanning a continuum that encompasses prevention, diagnosis, treatment, rehabilitation, survivorship, and end-of-life care. The following four-point strategy will be pursued:

1. *Develop a Core Set of Outcome Measures.*

For each major cancer disease site, we would adopt, adapt, or develop one or more outcome (endpoint) measures applicable to each stage of the care process: prevention, screening, detection/diagnosis, treatment, rehabilitation, continuing care, and end-of-life care. Measures would include functional, quality-adjusted survival, patient satisfaction (both with care and the accompanying decision making process), family burden, and overall economic impact. Significant gaps and deficiencies will be investigated, including the extent to which existing measures must be further adapted in response to cultural, racial, or other demographic factors. Quite likely, the appropriate set of endpoint measures will vary by cancer disease site. To develop these core measures, NCI will conduct several major literature reviews in parallel during FY 2000.

- A major critical evaluation of the existing outcomes literature in cancer will be sponsored by the Outcomes Research Branch of NCI's Applied Research Program within the Division of Cancer Control and Population Sciences (DCCPS). To be carried out in cooperation with AHCPR, the project will identify strengths and shortcomings in a broad range of measures currently used in studies involving the major cancer disease sites. An anticipated by-product of the project will be a new methodology, and accompanying guidelines, for evaluating and selecting among competing outcome measures.
- Comprehensive review of quality-of-life measures used to date in clinical trials will be conducted by the Cancer Treatment Evaluation Program (CTEP), in the Division of Cancer Treatment and Diagnosis, and by the Community Clinical Oncology Program (CCOP) in the Division of Cancer Prevention.

We note that this approach is consistent with the NCPB's Recommendation 3, which urges that the quality of cancer care be measured and monitored using a core set of quality measures.

2. *Base for Quality of Care Assessment for Cancer.*

To improve the science of quality assessment in cancer, NCI will do the following:

- Support both targeted and national-level studies of newly diagnosed cancer patients to determine whether observed patterns of care are associated with good outcomes, defined broadly to include not only survival but quality of life and patient satisfaction, and with a particular focus on vulnerable populations.
  
- Test the administrative feasibility and acceptability of employing a core set of outcome measures, within each cancer disease site, that would serve both to streamline data collection and analysis and, more importantly, promote the comparability of studies both cross-sectionally and over time.
  
- Investigate methodological innovations to improve the efficiency or reduce the cost of data collection (e.g., computerized adaptive testing, and new approaches to linking data across surveys and information systems); compensate for data problems in the field (e.g., innovative techniques for handling missing or truncated data); and account for the complex array of factors B some amenable to change and others not B that influence the observed relationships between interventions and outcomes (e.g., hierarchical statistical analysis).
  
- Building on the above, promote the development and ongoing evaluation of a national-level cancer data system that will (i) monitor whether public and private providers are providing cancer care consistent with existing evidence-based guidelines; (ii) determine whether particular population groups have inadequate access to quality cancer care and, if so, identify strategies for reducing access barriers; and (iii) allow a reassessment over time of whether existing quality benchmarks actually lead to improvements in patient-valued outcomes.

This research program, designed to strengthen the infrastructure for evaluating and monitoring the quality of cancer care cross-sectionally and over time, is consistent with the recommendations of the National Cancer Policy Board, in its IOM report, and also the President's Cancer Panel in its most recent report. In particular, the NCI research program will directly support several major initiatives advocated by the NCPB: to use systematically developed guidelines across the continuum of care (Recommendation 2); to develop a cancer data system that provides quality benchmarks for use by systems of providers (Recommendation

7); to support national studies of newly diagnosed cancer patients using data sufficiently detailed to assess patterns of care and their relationship to valued outcomes (Recommendation 8); and to investigate why specific segments of the population (e.g., racial minorities, ethnic group, the elderly) are not receiving quality cancer care and to explore ways of removing access barriers (Recommendation 10).

In shaping and implementing this research program, NCI would expect to benefit from, and contribute to, the deliberations of several Departmental quality initiative work groups, including those focused on Research that Improves Quality and Strengthening Value-Based Purchasing.

To launch this initiative, NCI proposes to issue an RFA that would create cooperative agreements with a consortium of investigator teams, with each team comprising one or more academic institutions, other research organizations, professional associations, comprehensive cancer centers, cooperative groups, and/or cancer registries. Each team would be provided with core support to carry out innovative, in depth analyses consistent with the research objectives above.

While a wide range of investigators will be encouraged to participate, this is a prime opportunity to draw upon the strengths and experiences of a number of organizations deeply concerned about the quality of cancer care B including the National Comprehensive Cancer Network, the American College of Surgeons, the American Society of Clinical Oncology, the American College of Radiology, the American Cancer Society, the National Coalition for Cancer Survivorship, the National Breast Cancer Coalition, the HMO Cancer Research Network and other managed care organizations that are now actively benchmarking the quality of care, as well as the SEER (Surveillance, Epidemiology, and End-Results) program investigators, who have been pivotal in many of NCI's quality-related studies including the Prostate Cancer Outcome Study (PCOS). We envision that teams will find it useful to partner with one or more federal or state agencies, depending on the proposed research agenda. For example, efforts to strengthen the quality of data from non-SEER tumor registries might involve liaisons with state government health agencies that manage the registries and with the Centers for Disease Control and Prevention, which helps fund them. In this regard, it is important to note that NCI and CDC have begun discussions aimed at developing a Memorandum of Understanding to establish new SEER registries in a number of states B thus expanding the geographic reach and depth of data available for tracking the quality of cancer care over time.

Central to this NCI research initiative is the need to expand the scope and improve the quality of population-based cancer surveillance, focusing especially on incidence cohorts of newly diagnosed patients. It is pivotal that we understand the treatments they receive, and do not receive, and the range of outcomes they experience.

In all these efforts, NCI expects to benefit significantly from the expertise it has acquired in supporting, and participating directly in, a number of quality-related projects over the past decade (see [Attachment](#)). These include SEER pattern of care studies, the Prostate Cancer Outcomes Study (which serves as a model for how to track patient outcomes over time), SEER-Medicare studies that link the registries' clinical data with HCFA claims data, and the Breast Cancer Surveillance Consortium, which examines the performance of screening mammography in eight community settings.

3. ***Assure Continued Improvements in the Quality of Cancer Care through a Restructured Clinical Trials System.***

Several important projects are underway:

- NCI is currently working through the Clinical Therapy Evaluation Program (CTEP) in DCTD and also the Outcomes Research Branch and the Office of Cancer Survivorship in DCCPS to expand the menu of patient-centered outcomes measures, such as quality of life and patient satisfaction, within clinical trials as an effective and efficient means of better understanding the determinants of quality cancer care. Cancer advocate organizations will continue to be active participants in identifying those endpoints and trials of importance.
  
- To assure that clinical trials continue to be conducted by well trained researchers, NCI is phasing-in several new funding mechanisms for mentoring fellows and faculty in clinical research, with a focus on the special needs of minority trainees.
  
- Together with the oncology community, NCI has reviewed its major clinical trials program and is currently engaged in an extensive restructuring with a focus on (1) ensuring that the best scientific ideas are evaluated in the clinic; (2) increasing access and participation for patients and physicians; and (3) streamlining all aspects of the clinical trials system to remove barriers to participation.

To assure that the best ideas proceed expeditiously from the laboratory into clinical trials, the process is being opened-up to allow interested investigators, irrespective of affiliation, to submit proposals for phase 3 trials. In addition, inclusive national forums are being planned to invite basic and clinical scientists from academia and industry, patient advocates, and others to "Astate-of-the-science" meetings that will more broadly identify new research opportunities as well as the gaps in knowledge that must be addressed. At least one of these meetings will focus on outcomes measurement and monitoring in trials.

Efforts to increase participation of physicians have begun with two pilot projects to assess the feasibility of a national network of physicians who will have access to an open menu of studies. The goal of the first pilot is to increase the participation of physicians from the cooperative groups. The goal of the second (termed the Expanded Participation Project) is to recruit physicians unaffiliated with the clinical trials program. The success of this project hinges on the participation of a variety of health plans; and formal relationships are in place with Kaiser Permanente, rural oncologists, and a number of physician practice management groups. Negotiations are also in progress with a consortium of VA hospitals.

To increase patient understanding of, and participation in clinical trials, NCI has embraced a comprehensive strategy, which includes: (1) an effort, in cooperation with NIH's Office for Protection from Research Risks (OPRR), to simplify the informed consent documents used in clinical trials; (2) a new clinical trials web site (<http://cancertrials.nci.nih.gov>) specifically targeted to the public, providing general information about studies and clinical trials results; (3) two clinical trials awareness pilots (one rural and one urban) that combine the resources of the pharmaceutical industry, advocacy groups, health departments and other local cancer resources to educate the public about the value of clinical trials; and (4) the continued development of agreements with public and private health plans, such as those sponsored by the Department of Defense, the Department of Veterans Affairs and United HealthCare, to assure coverage for clinical trials.

Particular attention is being given in the clinical trials restructuring to reaching minorities and the medically underserved. The NCI's Cancer Information Service has expanded its outreach program and is aggressively seeking community partnerships with nonprofit, private, and other government agencies at the national, regional and local level. Currently, two-thirds of CIS partners focus on reaching minority audiences, and more than three-quarters are striving to reach medically underserved audiences.

Streamlining of the clinical trials system requires removing barriers to participation as well as simplifying the process. Working closely with OPRR, NCI is beginning a pilot project to explore the feasibility of a central institutional review board (IRB) that would, ideally, improve the quality of review and reduce the burden of local IRBs for multi-center studies. To simplify the actual conduct of trials by physician investigators, NCI is constructing a fully modern national informatics infrastructure that will allow ease of participation and reporting by researchers no matter where they practice.

These efforts to restructure the NCI clinical trial system are supportive of NCPB Recommendation 6, which urges that federal and private research sponsors invest in clinical trials to address important questions in cancer care management.

4. *Improve the Quality of Cancer Care by Improving the Quality of Communications.*

NCI believes that effective communication is an important component of high-quality cancer care. Indeed, the Institute's 2001 Bypass Budget identifies communications as an area where an extraordinary opportunity exists to improve the quality of care, from primary prevention to treatment to survivorship.

In this regard, NCI plans to examine people's knowledge and perceptions about issues related to quality and to develop evidence-based strategies for encouraging health professionals, patients, families, and payers to use quality-of-care information in reaching informed decisions about cancer care. Problems in establishing effective communications among the underserved will receive special attention. In FY 2000, NCI will do the following:

- Conduct the planning necessary to implement, in FY 2001, a national cancer communications survey, which will have a Quality of Cancer Care module.
  
- Develop and issue an RFA to create Cancer Communications Centers of Excellence and encourage prospective applicants to focus, in part, on quality of care issues.
  
- Develop plans for new communication products focused on helping consumers, cancer patients, survivors, and families to make informed decisions.

In a related effort, NCI is redesigning its comprehensive cancer information database, which currently includes summaries covering the full range of quality cancer care. These fully referenced statements are written in non-technical language for the public as well as in a technical version for health professionals and are developed based on levels of evidence. When the redesign is completed, this web-based cancer information system will feature powerful search capabilities that link to reliable sources of cancer information worldwide and will provide professionals and the public with information at varying levels of detail and sophistication.

Over the longer term, NCI intends to accelerate reductions in the U.S. cancer burden through more effective use of cancer communications. This means working to integrate cancer communication expectations into the continuum of care, as an identifiable component of quality care; using innovative approaches to disseminate best practices to the provider and payer communities; and developing

the in-house infrastructure to speed up fundamental advances in cancer communications capacity, including the ability to link more effectively with researchers, clinicians, patients, advocacy groups, and the public at large.

In this regard, NCI hopes to contribute to the Departmental work group formed to Facilitate Consumers' and Patients' Use of Information on Quality; to the QuIC work group on Patient and Consumer Information; and to other AHCPR initiatives to improve the quality of communications in patient care.

In summary, the National Cancer Institute understands the importance of ensuring that the tremendous advances in basic and clinical sciences -- which have created unprecedented opportunities for preventing, detecting, and treating cancer -- get translated into a higher quality of cancer care for all Americans. To expand the knowledge base for achieving this goal, NCI proposes now to work with its federal partners and an array of private sector organizations and groups to carry out this four-part research initiative. The subsequent challenges of translating what is learned about improving the quality of cancer care into community practice will require the sustained and coordinated efforts of providers, payers, and quality-monitoring organizations in both the public and private sectors. In all of this, NCI hopes to contribute through a research initiative which, while focusing on cancer, serves to deepen our general understanding of how to define and improve the quality of health care.

## **Attachment**

### **NCI ACTIVITIES IN THE AREA OF QUALITY OF CARE RESEARCH**

- 1987--89: SEER-CCOP patterns of care studies: early stage breast cancer and stage B2 and C colorectal cancer.
- 1987--present: Cancer Control Supplement is added to National Health Interview Survey (NCHS), providing new data on use of prevention and treatment services and cancer-related health behaviors; repeated in 1992 and appearing again in 2000, along with special California HIS Supplement.
- 1990--present: SEER patterns of care studies. Additional SEER data collection on detailed treatment patterns and factors associated with treatment. Eighteen types of cancer have been studied, including breast, colorectal, ovarian, and prostate cancer.
- 1991--present: The SEER-Medicare project links data for persons reported to registries participating in the SEER program to Medicare records. The link was updated in 1995 and 1999. SEER-Medicare has supported patterns of care studies in breast, colorectal, prostate, head and neck, and lung cancer. SEER-Medicare studies include

assessment of access to treatment by race and the influence of managed care vs fee-for-service delivery settings.

- 1994--present: NCI establishes the Breast Cancer Surveillance Consortium to evaluate population-based screening mammography in the United States. By the year 2000 it is estimated that the Consortium's database will contain information on nearly 3.2 million screening mammographic examinations and over 24,000 breast cancer cases.
- 1995--present: NCI establishes the Prostate Cancer Outcome Study to examine treatment patterns and quality of life in a SEER-based cohort of 3,800 patients.
- 1996--present: Office of Cancer Survivorship established to support research and education on how to extend the length and quality of life of individuals with cancer.
- 1997--present: NCI conducts a re-evaluation of its clinical trials program and embarks on a restructuring that will result in a national clinical trials system prepared for and responsive to the unprecedented discoveries that will lead to major improvements in cancer care.
- 1997--present: NCI expands its supportive care portfolio to better include research that addresses quality of care in the areas of pain control, symptom management at the end of life, and the management of symptoms secondary to treatment.
- 1998--present: Along with the Institute of Aging, the NCI invites applications from the adult NCI cooperative groups to conduct clinical studies that promote the development of a knowledge base to produce new treatment strategies for older patients (age 65+).
- 1998--present: To assure that surgical procedures are carefully evaluated and, when effective, quickly moved into practice, the NCI begins funding a surgical cooperative group through the American College of Surgeons.
- 1988--present: NCI develops and makes available a breast cancer risk assessment tool for women that can be ordered in disc format through its clinical trials web site. A web based tool is currently in development.
- 1999: NCI establishes Outcomes Research Section to focus and coordinate research efforts in the area of cancer related outcome measures and research methods.
- 1999: NCI establishes the Cancer Research Network to support research on patterns of cancer prevention and control in an HMO health care delivery environment.
- 1999: NCI begins formulation of concept for expanded activities in the area of patterns of care/quality of care research.

1999:

New clinical trials web site provides information for the public about how to evaluate the quality of health information on the WEB.