Putting NCCN’s Guidelines Into Practice: It All Depends on Data

The National Comprehensive Cancer Network presented eight new practice guidelines last month at its annual meeting in Fort Lauderdale, Fla., and announced plans to create 10 more. By this time next year, the NCCN should have guidelines covering 91% of human tumors, said Rodger J. Winn, M.D., who is director of the community oncology program at the University of Texas M. D. Anderson Cancer Center, chair of the guidelines steering committee, and a driving force behind the network of 15 major cancer centers.

Despite this rapid progress, the new guidelines had to share a large portion of the meeting’s spotlight with NCCN’s other crucial concern: data. Implementing practice guidelines requires data — on how each patient in each NCCN institution is diagnosed, treated, and followed; on response, recurrence, and survival rates; and on demographics and functional status. It requires data that can be generated within each cancer center, pooled in a single NCCN outcome database, then analyzed and used for feedback.

Creating the infrastructure for all this is a massive project. “This is rocket science,” said Winn. “This is not easy.” Future NCCN meetings, he predicted, “will be totally related to clinical outcomes in oncology as we establish the structure.”

Even at this second meeting the importance of the outcome data was a recurring theme. The goal of the guidelines is to achieve a standardized approach to cancer treatment, according to an NCCN press release, and a standardized approach requires data.

Data promote standardized care in two ways, said Jane Weeks, M.D., of the Dana-Farber Cancer Institute in Boston, who is leading the NCCN database project. First, “using outcome data to monitor compliance with guidelines is a critical component to providing the feedback that’s actually going to change behavior,” she said. Second, data will make it possible to answer “the ultimate question: What management strategies produce the best outcomes?” Clinical trials will never be able to answer all the questions about patient management, Weeks said; outcome data can help fill in many gaps.

Meeting Needs

NCCN’s outcome database, which will reside at City of Hope National Medical Center in Duarte, Calif., is a keystone in the network’s effort to court third-party payers. While one NCCN goal is to improve the state of the art in cancer care, it also intends “to meet the need of employers and insurers to better predict costs while providing access to the best possible care,” according to its statement of principles.

Managed care organizations have expressed “definite interest,” in NCCN, said the network’s chief executive officer, William T. McGivney, Ph.D., who came to NCCN about 2 months ago from Aetna Health Plans, Pittsburgh, where he was vice president of clinical and coverage policy. One aspect of NCCN in which managed care groups and employers are particularly interested is the outcome database, McGivney said.

As an early step in creating that database, Weeks and her NCCN committee have launched a pilot project to gather data on the management of all breast cancer patients from five member institutions. The data will include all information needed to assess compliance with the guidelines as well as standard clinical measures such as response, recurrence, and survival rates.

NCCN will also gather information on employment and insurance status, days lost from work, and days in the hospital, Weeks said. “We recognize the audience for this information includes not only our institutions but also providers and employers and we are trying to collect what they would be interested in seeing,” she said.

Also in this pilot data set will be information on comorbidities. The five institutions will start entering data on all new patients in July, Weeks said.
Weeks also reported "very, very preliminary data" indicating that NCCN institutions were managing patients in accordance with the guidelines to a greater extent than cancer care providers nationally. This pilot data project is using data reported to the American College of Surgeons’ National Cancer Data Base by NCCN institutions from 1993 to 1995. It is comparing NCCN institutional outcomes to overall NCDB outcomes.

For example, breast-conserving surgery in stage I and II breast cancer was used more frequently by NCCN institutions, as was adjuvant chemotherapy, Weeks said. Both strategies are recommended in the guidelines. However, the use of breast-conserving surgery was only about 10 percentage points higher in NCCN institutions than in the NCDB as a whole. "We were a little upset it was not higher," she said.

Problems in Comparison

Weeks acknowledged that there are problems in comparing NCDB and NCCN data, such as demographic differences among patients. Those treated at NCCN institutions tend to be younger than those in the data as a whole, which might account at least partly for the greater use of breast-conserving surgery, she pointed out.

Nevertheless, Weeks said, the pilot project demonstrates the "huge potential" of outcome data. Using the data, NCCN institutions "can begin to get a handle on not just very early process measures, like did you order such-and-such a test, but did these patients receive the treatment stipulated by the guidelines?"

Meanwhile, back at the 15 individual cancer centers, creating the systems to track practice patterns and outcomes and feed them into the large NCCN database is another major undertaking. Weeks and her committee completed an audit of existing data sources and mechanisms of data collection within each institution, uncovering "many, many different information systems that are not necessarily compatible."

The good news from the audit was that many of the institutions are now on the verge of developing new information systems. "There is really a window of opportunity to bring some uniformity to the process right now," Weeks said. "There is urgency in this matter, more than anything else, because the decisions that we make now in terms of data collection we will live with for many years."

Not that total uniformity is necessary. "We are encouraging some diversity," said Weeks. Data collection strategies may range from "a data-manager-and-desktop-computer approach" to "a fully integrated information system with the data elements collected [for NCCN guidelines] becoming a part of the electronic medical record."

Memorial Sloan-Kettering Cancer Center in New York is one NCCN member that is implementing the guidelines rapidly with the help of a full management information system, one that required new hardware, new software, and a training program, according to George J. Bosl, M.D. Bosl told the meeting that since July 1996,

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NCCN Guidelines: What They Are

The National Comprehensive Cancer Network guidelines are detailed, branching algorithms designating diagnostic, prognostic, and treatment steps for each type and stage of a particular cancer. The recommendations are based on consensus among NCCN members. The network will have 26 guidelines in at least draft form by its third annual meeting in 1998. Guideline panels and years of initial presentation are:

1996: Breast, prostate, ovarian, colon, rectal, non-small-cell lung, small-cell lung, and pediatric cancers.
1997: Melanoma, sarcomas, lymphomas, and bladder, central nervous system, head and neck, and pancreatic cancer, and use of anti-emetics.
1998: Hodgkin's disease, endometrial and cervical cancer, esophageal and stomach cancer, testicular and renal cancer, myeloma, chronic myelogenous leukemia, and neutropenic sepsis. In addition, NCCN will add guidelines for breast, prostate, and colon cancer screening, including the use of genetic testing.

When deciding what guidelines it needs, NCCN considers those of other organizations. For example, NCCN decided not to create a guideline for the use of growth factors because the American Society of Clinical Oncology already has developed one, said Rodger Winn, M.D., chair of the guidelines steering committee.
75% of new patients have been entered in the system.

Other NCCN institutes are at various stages of implementing the guidelines. An implementation committee will meet in June and may establish a timetable, Winn said.

Three NCCN members have conducted pilot “compliance audits” to learn how well the guidelines reflect actual practice. All turned up some cases of non-compliance, often in the areas of diagnostic testing, where the guidelines call only for tests deemed to have an impact on treatment decisions. Stephen B. Edge, M.D., who conducted one of the audits at Roswell Park Cancer Institute’s breast cancer clinic in Buffalo, N.Y., said that the audit validated the NCCN methodology. It demonstrated that the guidelines did work as a benchmark for assessing quality of care, he said.

Edge’s clinic does not have the benefit of a full management information system but has developed a database to track patient care. Edge said that a full-time data manager spends about a fourth of her time maintaining the database in the clinic, which sees about 160 to 170 breast cancer patients a year.

Despite the resources required, Edge is a firm proponent of collecting and using data on patient management. “I think it’s useful and I think it will get to the point where third-party payers are going to demand it of us,” he said.

George D. Demetri, M.D., of Boston’s Dana-Farber Cancer Institute and a member of NCCN’s board of directors, agreed. “Much of the variation in practice is due to a lack of data,” he said. “Once you have a system, you wonder how you did without it.”

— Caroline McNeil

NCCN: Who Is a Member?

The National Comprehensive Cancer Network began with 13 members and now has 15, most in the East and on the West Coast. Other centers may join, said William McGivney, Ph.D., NCCN’s chief executive officer, noting that “there are gaps in the map.” Members are:

Arthur G. James Cancer Hospital and Research Institute at Ohio State University, Columbus
City of Hope National Medical Center, Duarte, Calif.
Dana-Farber Cancer Institute, Boston
Fox Chase Cancer Center, Philadelphia
Fred Hutchinson Cancer Research Center, Seattle
Johns Hopkins Oncology Center, Baltimore, Md.
University of Texas M.D. Anderson Cancer Center, Houston
Memorial Sloan-Kettering Cancer Center, New York, N.Y.
Northwestern University/Lurie Cancer Center, Chicago
Roswell Park Cancer Institute, Buffalo, N.Y.
St. Jude Children’s Research Hospital, Memphis, Tenn.
Stanford University Medical Center, Stanford, Calif.
University of Alabama at Birmingham Comprehensive Cancer Center
University of Michigan Comprehensive Cancer Center, Ann Arbor
University of Nebraska Medical Center, Omaha

Alfred Knudson: Two Hits Times 25 Years

Just over 25 years have passed since Alfred Knudson, M.D., Ph.D., then a scientist at the University of Texas M. D. Anderson Cancer Center in Houston, proposed his famous “two-hit” hypothesis of tumor suppression.

Although groups in the 1960s had theorized that genes must exist that suppress tumor development, Knudson was among the first scientists to propose a stepwise hypothesis of how these tumor-suppressing genes might be selectively turned off in certain familial cancer syndromes.

Knudson formed his famous hypothesis by comparing numerous case studies of inherited and noninherited forms of the rare eye tumor, retinoblastoma. Knudson proposed that children who inherit RB must be born with one hit, or mutation, already in the germline and later acquire a second, tumor-activating hit.

For children with noninherited forms of RB, Knudson speculated that the first hit comes not in the germline, but in an already differentiated retinal cell. He then proposed that this once-hit cell accumulates a second hit later in childhood that triggers the tumor, explaining why noninherited cases of RB tend to arise later than inherited forms of the cancer.

Later, Knudson focused his hypothesis on the RB gene itself. He theorized that each hit must arise in one of the two copies of RB, suggesting that both copies of the gene must be inactivated for a tumor to form in the retina.

In the gain-of-function 1970s, however, Knudson’s loss-of-function hy-