

An interview with William T. McGivney, PhD, CEO of the National Comprehensive Cancer Network (NCCN)

The NCCN guidelines: how do they relate to community oncology practice?

By Ellen Okin Powers

Today's community oncologists not only face complex therapeutic decisions when managing their patients but also must deal with a myriad of issues when managing their practices, including looming changes in Medicare reimbursement for services. In 1995, the National Comprehensive Cancer Network (NCCN), an alliance of leading cancer centers, began to develop a comprehensive set of clinical practice guidelines in oncology. Almost 10 years later, the over 100 guidelines developed by the NCCN (which now comprises 19 centers throughout the United States) are recognized as the standard for clinical policy in oncology.

Community Oncology asked William T. McGivney, PhD, Chief Executive Officer of the NCCN, to explore how the NCCN guidelines relate to community oncology practice and to reflect on the potential impact of the new reimbursement policies. Dr. McGivney's background is particularly apropos for such a wide-ranging discussion. Prior to joining the NCCN in 1997, he held positions as Director of the Division of Health Care Technology at the American Medical Association (AMA) and Vice President for Clinical and Coverage Policy at Aetna Health Plans.

Community Oncology:

Community oncologists deal with many of the same issues that academic physicians face in their everyday professional lives. How can guidelines,

such as those developed by the NCCN, be applied by community oncologists in the most beneficial way possible?

Dr. McGivney: Before I answer your question, let me first emphasize that the NCCN guidelines really do represent the most appropriate and best care that can be made available to patients. The guidelines are based on rigorous scientific evidence and expert opinion, with scientific evidence taking precedence, obviously, when it's available. But our philosophy at the NCCN, which applies to both academic and community settings, is that a physician, whether in an academic or community setting, needs to make decisions as to what's best for each individual patient. And these guidelines seek to provide guidance about those decisions specifically. The mission of the NCCN and its member institutions is to improve the quality of cancer care and educate all interested parties. We decided a long time ago that we would make our guidelines available, not only to our academic centers but also to community oncologists and whoever else might be able to use them in decision-making.

With respect to community physicians, we try to make our guidelines as specific as possible. But I think there's opportunity for different groups to integrate the guidelines into their own analyses of what's appropriate for their patient populations. For example, at a particular branch point in the guidelines, four regimens may be specified as being appropriate first-line treatment. There's latitude for

groups to say that; for whatever reasons, we're going to use two of these four regimens, and "A" is number one and "B" is number two. So that's how I see community oncologists using the guidelines—tailoring them to meet the needs of their patients and the capabilities of their practice.

About 1½ years ago, we sent a survey about the NCCN guidelines to 2,500 doctors the week before Thanksgiving and got 254 responses. This 10% response rate is pretty high, particularly given the timing of the survey and the fact that people were given 10 business days to respond. Of the respondents, 93% agreed that the guidelines were useful in patient decision-making, and 45% strongly agreed that they were useful. To me, the results of this survey indicate that the guidelines are being used extensively in the community.

Also, on average, community physicians said they had looked up 17 NCCN guidelines within the course of 1 year. Now, I thought that was a lot. The average number of guidelines that the academic physicians referred to was 15, which was also surprising. In addition, the general physicians said they went back an average of 10 times during the year to look at a specific guideline.

More evidence of the widespread use of the guidelines is the number of "hits" recorded on the NCCN Web site (www.nccn.org). Currently, we tally 48,000 unique visitors to our Web site per month. In 2003, we had 23,000 monthly visitors, and in 2002, we had 11,000. So it's doubling almost every year. In 2002, the

guidelines were accessed (defined as going into a guideline once) 306,000 times. In 2003, this figure was up to slightly over 1 million. So that represents a tripling in terms of use of the guidelines.

It's been about 10 years since the inception of the NCCN. Can you briefly recap where you are today with respect to the guidelines, compared with the beginning?

We have about 112 guidelines and 44 guideline panels right now. Only the NCCN guidelines can claim to be truly comprehensive, as no other group has developed a complete set of oncology guidelines. There are what might be called technology assessments, which focus on very specific therapeutic classes of agents or look at adjuvant therapy in a certain cancer. But our guidelines cover the waterfront, if you will, in terms of the appropriate management of patients, including screening, prevention, follow-up, *et cetera*.

Perhaps more important is the way we've updated our guidelines. In the past, we maintained and updated them annually, at least. Now they're updated continually. If a study is stopped, or major research findings are published, or a drug receives FDA approval, within 2 to 3 weeks we'll get the appropriate panel on the phone to discuss that issue. And, after that, within 3 to 6 weeks, the recommendation on the new development will be reflected in the guidelines and posted online. I think a major reason the NCCN guidelines have been so successful is the timeliness of the recommendations.

To some extent, managed care companies and insurers have started to use the NCCN guidelines to set coverage policy—a trend that will only increase in the future. Therefore, the guidelines need to be completely up to date because if there were an absence of a recommendation, the

insurance company might take that as evidence that the NCCN doesn't think this agent should be used for that indication. Also, our guidelines include a large number of recommendations regarding off-label use.

I feel very strongly that guidelines on appropriate cancer care should emanate from the oncology community and not from the payers. In the late 1980s, major medical associations abrogated their responsibility to step up to the plate and say, "Yes, this is appropriate care; no, this isn't appropriate in these circumstances." So, the payers decided to step into the breach. They recruited me from the American Medical Association (AMA). The rest is history. We had the battle of the 1990s. So, at the NCCN we feel that one of our responsibilities is for our experts to represent all constituencies, including insurers, to what appropriate care is and what options should be available to beneficiaries as patients.

Beyond your own survey, are you aware of any other studies on compliance with the guidelines that might have been published?

An article by Bernard Bloom and colleagues from the University of Pennsylvania appeared in the *British Journal of Cancer*. They looked at whether Philadelphia-area community practice patterns in treating women with breast cancer were in concordance with meta-analysis results or the NCCN breast cancer guidelines. They reported that fewer than half the women were receiving treatment regimens that were recommended in either the meta-analyses or the NCCN guidelines.¹

This study had a number of shortcomings. First, some believe that there were potential problems with the way the study interpreted the NCCN recommendations, and therefore doctors' practices could not be accurately measured against those recommenda-

tions. In addition, the first NCCN guideline was presented at the initial conference in 1996 and probably didn't reach the oncology community until the end of '96. The study focused on patients who were diagnosed from 1995 to 1999. So, at least 40% of the time, the NCCN guidelines were not in the public domain.

Another study from the University of Florida was published in 2001 in the *Journal of Surgical Research*. That study assessed the effect of implementation of the NCCN breast cancer guidelines on the efficiency of practice. The study found that use of



the breast cancer guidelines improved the efficiency of breast cancer care delivery. Although this was a small study, the results reached statistical significance.²

How would you characterize compliance with the guidelines in the community setting, as opposed to academic centers? And where would the funding come from if you were to conduct programs to assess this?

I don't know how well the guidelines are adhered to in the community setting. Within the next 2 to 3

months, the first major paper that looks at concordance specifically in NCCN institutions will be published. Long term, we're interested in involving the community in reporting to the NCCN outcomes databases and improving practice based on feedback.

Actually, about 1½ years ago, we began to involve community centers in the NCCN breast cancer database. In addition to 12 of our big institutions, 3 community cancer centers—one of which is very large—and 4 group practices are submitting data to this database. We collect about 270 data elements on each patient, and these data elements cut across subspecialties. In the community, you have different sites for medical oncologists, surgeons, and radiation oncologists, which increase the difficulty of collecting data. I think we've learned from this experience. Longer term, we're going to have to work closely with community oncologists to define the data dictionary of elements that we collect to ensure that, one, the data collected are valuable to practitioners in the community and, two, they make sense in general.

Continuing down that path, the next logical question is, why not just focus on quality indicators? We've been analyzing the data to look at the issue of quality indicators and to determine whether or not the specific recommendations in the breast cancer guidelines can act as surrogates for demonstrating quality of care across centers. Other groups outside the NCCN are also working on the development of quality indicators for cancer. Although these other groups may have clinical oncology input, unlike the NCCN, these organizations do not arise from within the oncology community. A lesson I learned when I was at the AMA is that, in order for guidelines to have cogency and credibility with practicing physicians, it's best that the recommendations emanate from the specialty or subspecialty group whose practice patterns you seek to influence.

So, we're about to launch into the development of quality indicators based on our guidelines because they're in such widespread use. And, ultimately, we'd like to see our database become the standard tool for quality measurement in the United States. Our first step in the development of quality indicators took place July 1 in Washington, DC, where we hosted a meeting of major employers and managed care companies, including national associations. At that meeting, we solicited input from these groups regarding the type of quality indicators these end-users want and how they envision public reporting of performance data in cancer care.

Also at this meeting we discussed the subject of pay for performance. I think pay for performance will be fairly difficult to achieve in oncology, but payers and employers are talking about it. And, obviously, we'll discuss these same issues with patient groups and get their input. Then we'll get our business people and scientific experts together to specifically address the process, the identification, and how the NCCN might design a way to report performance data publicly. Given the NCCN's track record in formulating guidelines, this will not be a long-term, esoteric debate. Rather, we expect to quickly develop an approach that can serve as a template, which, like the guidelines, people can use if they're interested. Our overall goal is to create a good, scientifically based product that, ultimately, will help improve patient care.

It takes funding to develop quality indicators. Do you see this as a major roadblock?

Funding is an issue because the collection of high-quality data is expensive. One interesting development is the appointment of Mark Clanton, MD, as the new deputy director for cancer care delivery issues for the National Cancer Institute (NCI). Dr.

Clanton used to be Chief Medical Officer of Blue Cross/Blue Shield of Texas. So, I don't know if this signals that the NCI is going to take an increased interest in funding proposals that seek to define or measure what appropriate care is and to then feed the results back to participating institutions. This is the entire continuous quality improvement process for cancer care. However, it obviously points to an interest in the whole area of cancer care delivery and the systems under which such care is delivered.

Clearly, the NCCN leadership has thought a lot about the quality-of-care issue. In the meantime, do you have any thoughts on how practitioners out in the field could view the current guidelines with regard to outcomes?

Community oncologists, as a group, can identify high-quality indicators based on the guidelines that they feel might be appropriate to evaluate their own practices and that are reasonable for them to collect. Over the long term, everybody has to be involved in benchmarking performance. And the best way to do that is to benchmark with your peers and colleagues in an educational format. However, in the not-too-distant future, I think that there will be the imposition and participation of third parties in the benchmarking process.

With respect to models, do you think the third-party payers will wait to see what Medicare does and follow suit?

I think there's a great deal of interest on the part of private payers in watching what Medicare does, in two arenas: first, coverage, because that relates especially to use beyond FDA-approved labeling; and second, level of reimbursement, particularly the final definition of average selling price (ASP). An article by Dr. Sean Tunis, Chief Medical Officer, Director of

the Office of Clinical Standards and Quality of the Centers for Medicare & Medicaid Services (CMS), that appeared in *The New York Times* in January suggested that CMS was going to get a little tougher about evaluating uses beyond FDA-approved labeling vis-à-vis national coverage policy, or even local or intermediary coverage policy. A lot of concern was expressed about this, and Medicare took that concern as an opportunity to rethink its position. But this issue is still unresolved.

Also, the pipeline is replete with relatively expensive biological agents that will be approved for one indication but will almost certainly be applicable to a variety of indications, not only in the cancer for which they were approved but also other cancers, especially solid tumors. Obviously, these new biological agents are certainly advances. They provide opportunities for benefit and hope for patients, and they also have more favorable side-effect profiles. But I think that payers are just beginning to realize the cost implications of this influx of biotech agents into cancer care and are looking for ways to exert some control. One way they are doing this is to move toward a consumer-driven healthcare system. Basically, this entails providing consumers with good information on treatment options, providers, alternative settings for delivery of care, *et cetera*, and giving them more of a say in choices about their care. Now, obviously, there will be economic incentives attached to these choices, from a managed care insurer's perspective. Certainly, there's a positive side to consumer-driven healthcare; however, one can also view it more cynically. In the 1990s, managed care companies were the bad guys who said "no." Now, they're turning the tables and saying, "Let's let the patients say 'no.'"

This system, with its co-pays, co-insurance, and deductibles, makes patients share more in the cost of their

care. One concern is that patients may stop making decisions based on what's medically best for them, according to the scientific data. A point may be reached where economic considerations make a particular therapy unaffordable for a patient. Although co-pays are not insignificant for drugs used in other diseases, such as asthma, they pale in comparison with potential co-pays for major biologicals in cancer care. Certainly, some managed care companies are aware of this problem with co-pays, and most have limits on out-of-pocket expenses, but still, it's a different ball game in cancer care, in terms of how you're influencing the decisions patients and their families make.

Wouldn't this whole concept of people opting for care based on how much they have to pay potentially create a class system in healthcare, where those who can afford it will get better care and those who cannot afford it will get poorer care?

Yes. The opportunity for economic discrimination definitely exists. When faced with high co-pays, patients may decide that they don't want to risk throwing away the small nest egg they've built for their family, notwithstanding the fact that they want to live, see their children graduate from college, or reach some other milestone. So I agree that you're going to reach a point where people who can't afford certain treatments are at an economic disadvantage.

Some have pointed to Oregon in the 1990s, when the state had, say, a set Medicaid budget. A series of healthcare "town meetings" were held to solicit public input on how to spend those healthcare dollars. Based on these meetings, the state developed and prioritized a list of therapies that Medicaid would cover and, conversely, those would not cover. I have a lot of concerns with that approach.

Although sick patients provided input into the decisions, a major portion of the comments came from healthy people. Clearly, the way you feel about such decisions is a lot different when you're healthy than when you're sick. When I was at Aetna making decisions about coverage for controversial cases, the pressures to pay for investigational technologies or therapies such as bone marrow transplants were enormous.

From the perspective of both academic and community cancer centers, we're reentering a time when the pressures on decision-making are going to be tremendous. Pending changes in the Medicare reimbursement system—especially the orientation toward "appropriate payment" for physician and office services—will lead to a rapid diminution in what Medicare is paying for those services starting in 2005. Coupled with the infusion of new biological agents, I think the financial pressures on everybody are going to be extraordinary.

Along those lines, what impact will ASP + 6% and the Medicare Prescription Drug, Improvement and Modernization Act (MMA) have on NCCN cancer centers and community oncologists?

All academic cancer centers have similar concerns, as do community practitioners, in that any reduction of reimbursement will be difficult for them to absorb. The community medical oncologist whose livelihood may be at stake clearly has more to lose, but everyone involved in cancer care is concerned about these issues. The importance of these concerns was clearly evident in the debate that arose during the development of the MMA. Also, there have been delays in the release of some of the proposals and the start of demonstration projects. And then there's the whole issue of oral chemotherapeutic agents.

How will these changes in Medicare reimbursement directly affect the usage of or compliance with the guidelines?

The guidelines will become more important in a number of different arenas. As I said before, we're noticing an increasing use of the guidelines by payers in making coverage decisions and, to a more limited extent, in setting reimbursement levels. National insurers are also using the NCCN guidelines in quality assurance programs, where they provide points for use of the guidelines.

Another reason the guidelines will become more important relates to the whole issue of biomarkers. In 3 to 5 years our guidelines will be 3 to 5 times as complicated as they are now because we have all of these biological agents, some of which are associated with appropriate use for certain markers. In the future, guidelines' branch points will no longer simply be surgery, go down this path; no surgery, go down this path. Instead, they'll be, surgery with this biomarker, go down this path, and all of the markers will have different paths. From an end-user perspective, whether you're a patient, physician, or payer, the complexity of cancer care will cause more people to look to guidelines, such as those developed by the NCCN.

With the reimbursement changes that lie ahead, one has to consider that decision-makers at these institutions also manage budgets for treatments. And even though an algorithm recommends a

particular treatment option, budgetary constraints may come into play. You hate to mix business and quality-of-care decisions, but can that potentially happen?

A lot of people talk about rationing of healthcare in this country. To be sure, we have a tremendous problem of uninsured and, to a certain extent, underinsured people. But individuals with health insurance, especially major employer-based health plans, have available to them almost every therapeutic option. Employers are still talking about denying payment for lifestyle drugs, such as sildenafil (Viagra). That's their concept of starting to limit access to care. So, I don't think we've reached the point of healthcare rationing yet.

Do seniors envision that the NCCN will initiate more programs with community-based centers in the future?

First, let me emphasize that the NCCN has created a large number of effective informational products to convey to academic physicians, but mainly to community doctors, what's in the guidelines. In addition to our Web site, where the most up-to-date versions of the guidelines are accessible, we also give out the guidelines on a CD-ROM at major meetings, such as the annual meeting of the American Society of Clinical Oncology. About 30,000 of those CD-ROM disks are distributed every year. In addition, we hold regional symposia tailored to the participation of community practitioners.

The Journal of the National Comprehensive Cancer Network is another vehicle for communicating the guidelines, and it also serves as a forum for discussing controversies stemming from the guideline recommendations. One of the original objectives of the journal, now in its second year of publication, was to focus on community physicians and address issues related to application of the guidelines that might be more pertinent to them.

Over the long term, we're very interested in having community oncologists participate in the NCCN outcomes database. That only makes sense. Guidelines are produced here; we feed back data from our own outcomes database to those guideline panels. If the community physicians are using our guidelines extensively, this is one way to measure not only concordance but also longer-term outcomes and benchmark against national data. So, I think there are opportunities for community oncologists to participate, but it's an expensive undertaking. Right now, we're considering whether we should continue going it alone or collaborate with other groups that might have existing databases. So, I think that will be the next big area of engagement.

References

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