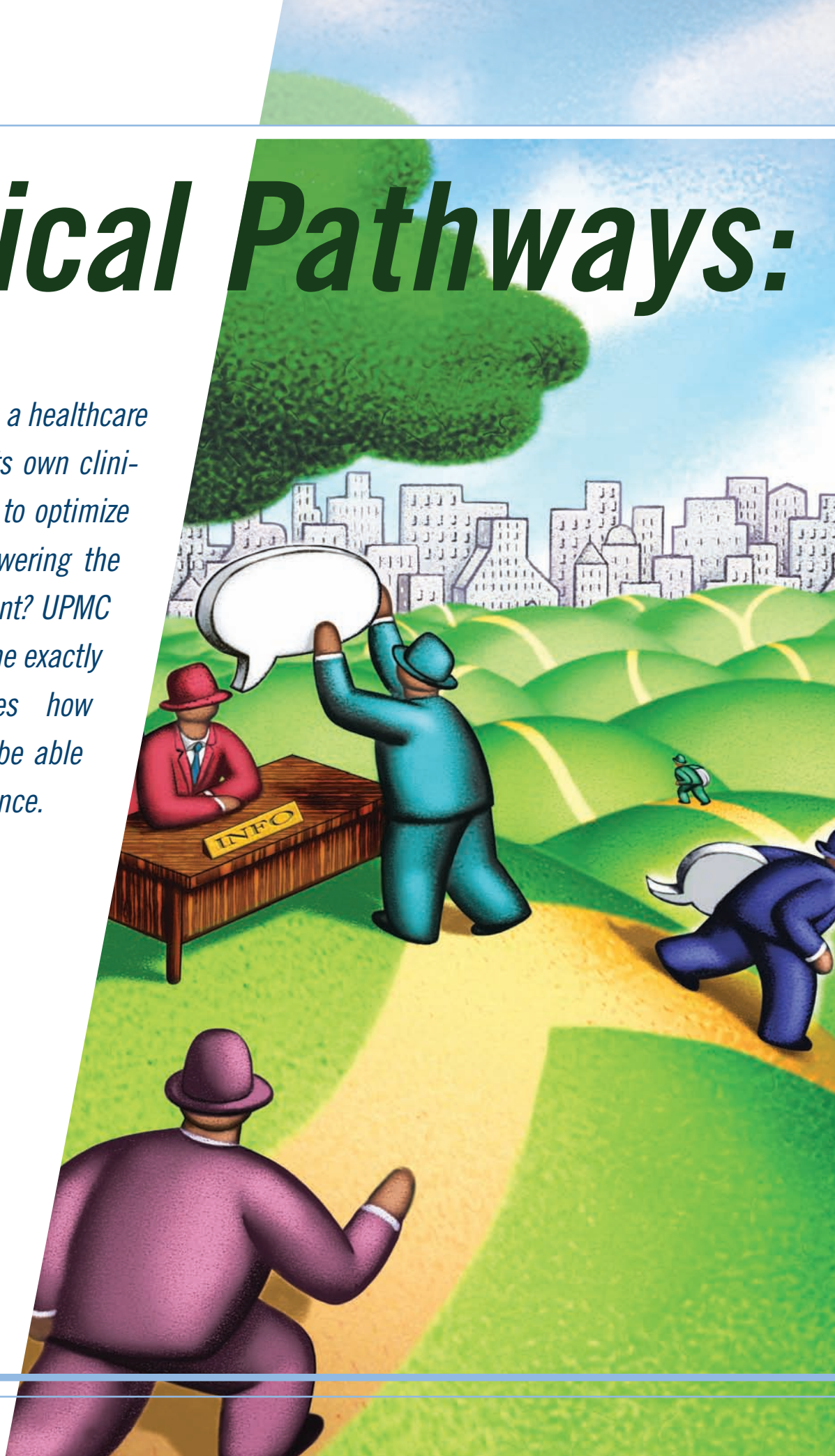


Clinical Pathways:

What happens when a healthcare institution creates its own clinical pathway process to optimize patient care while lowering the cost of cancer treatment? UPMC Cancer Centers has done exactly that and demonstrates how other institutions might be able to benefit from its experience.



Can the Art of Oncology Be Managed?

By Michelle Nolin Flewell

Establishing clinical pathways has garnered significant buzz in the clinical and business realms of oncology. However, like any buzz or trend, clinical pathways do not come without controversy. Much has been written about clinical pathways and treatment guidelines as ways to standardize clinical care and reduce costs, but when it comes to oncology, any effort to restrict or limit care inevitably leads to a highly contentious debate.

Whether developed by a national medical society, a private insurer, Medicare, or a comprehensive cancer center, clinical pathways in oncology endeavor to offer the practicing oncologist guidance as well as a recommended treatment path according to tumor type.

In theory, clinical pathways make good sense—they deliver quality care while managing the utilization of resources, and in so doing, control costs. However, the motivational basis for developing clinical pathways in oncology, which may tip the balance toward reducing costs at the expense of patient care, is at the heart of the controversy.

Clinical pathways, sometimes called critical pathways, care plans, or other similar sounding terms, differ from treatment guidelines in that they define a path, or steps to take in disease management. Hopefully, these steps improve the quality of patient care while at the same time reduce utilization of resources. In contrast, treatment guidelines define what the appropriate care for a certain indication is and often they provide a list of appropriate agents for any given indication as well. Since their introduction in the 1990s, clinical pathways have been shown to improve clinical outcomes and reduce healthcare expenditures in a variety of practice settings.

In 1995, the National Comprehensive Cancer Network (NCCN) began a program to develop comprehensive diagnostic treatment and supportive care **cont. on pg 24 >>**

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guidelines designed to enhance clinical decision-making. At present, the NCCN Clinical Practice Guidelines in Oncology™ are developed and continuously updated by 44 expert panels, cover 97 percent of all cancer types and according to the NCCN, are the most widely used guidelines in the practice of oncology. The NCCN guidelines are formatted as an algorithm, and as such offer multiple appropriate options whereas an institutional clinical pathway such as the ones profiled in this article offer a single, definitive recommendation.

Genesis of Clinical Pathways in Oncology at a Major Center

Faced with the prospect of clinical pathways or treatment guidelines being imposed upon them by an external source, such as private insurers with perhaps different motivations, the UPMC Cancer Centers, under the direction of Peter G. Ellis, MD, Director, Medical Oncology Network, University of Pittsburgh Medical Center (UPMC) Cancer Centers, developed and successfully launched a clinical pathways program, called PATHWAYS, in a number of tumor types this year.

The highly ranked UPMC Cancer Centers work in tandem with the University of Pittsburgh Cancer Institute (UPCI), a National Cancer Institute designated Comprehensive Cancer Center, and treats 36,000 new patients each year. The Centers perform cutting-edge cancer research, and employ 2300 physicians, scientists, administrative staff, and other healthcare professionals.

Their clinical pathways program in oncology was developed and implemented in large part to offer quality, streamlined patient care while at the same time gaining efficiencies that would also reduce costs. Like other centers, the cost of oncology care has skyrocketed at

UPMC with pharmaceutical costs increasing from a minimum of 13 percent to a maximum of 32 percent yearly over the last 5 years. This significant increase is not lost on their insurers, who have likewise seen their pharmaceutical expenditures increase significantly year after year.

Similar cost increases have been noted around the US, and as a result, there have been attempts by private insurers and Medicare to reign in “runaway” pharmaceutical expenditures in oncology while continuing to offer quality care to their members. However, according to Dr. Ellis, prior attempts by insurance companies and government entitlement programs such as Medicare to control their drug spending have either crippled or threatened to cripple the delivery system.

Medicare, for example, has significantly limited the amount physicians can charge to administer chemotherapy and related agents that require an infusion. Dr. Ellis reports that according to UPMC’s calculations, Medicare routinely under-reimburses providers by as much as \$.50 for every dollar of what it actually costs to administer infusion drugs.

This pattern of inadequate reimbursement has led many healthcare providers to charge a higher amount for the drug itself to cover their costs for administration, a practice referred to as a mark-up or margin on drug.

“In reality,” Dr. Ellis said, “providers would prefer to have no such ‘margin on drug’ to cover administration and instead be reimbursed for the services they provide.”

The mark-up on drugs customarily charged to help providers recoup their administration costs is in fact a small fraction of the total costs. He reports that many of the strategies that Medicare and large insurers have used to



Peter G. Ellis, MD, Director, Medical Oncology Network, UPMC

deal with the rise in pharmaceutical costs have involved placing financial pressure on the healthcare provider, which is the oncologist. While this saves a fraction of the total costs, it doesn't control the overall problem of high drug costs, he said. Further, Dr. Ellis explained, physicians will continue to prescribe the drug they think is best for any individual patient, regardless of whether a margin or mark-up is charged; therefore, reducing the mark-up will not fully address the issue of soaring drug costs.

Moreover, Dr. Ellis and his colleagues were concerned that unless physicians and care providers stepped in and determined the right drug for the right patient in the right circumstance, efforts by those outside of the care delivery system to do so could inadvertently diminish physicians' ability to deliver care.

"In an effort to be part of the solution and not part of the problem, our team at UPMC developed a clinical pathways program called PATHWAYS to guarantee the best and most appropriate care for patients, and our hope is that care delivered according to the pathways is also cost effective both for us and the payer," said Dr. Ellis.

A Systematic Approach to Setting Up Clinical Pathways

The team at UPMC followed a systematic process to develop clinical pathways in their program. They used evidence-based medicine as the central guiding principle and operated under the universal assumption that the application of evidence-based care will lead to improved quality for the patient and less cost to the provider and payer. In addition, they assumed that the best care resulted from the following tactics: offering only proven and effective treatments for the patient, limiting off-label drug use except in circumstances where clinical evidence clearly warranted it, and providing "stop rules" for therapy that is not effective.

They also operated under the assumption that through a pathway, they were developing uniformity in care, which would lead to significant gains in efficiency. As Dr. Ellis explained, this uniformity leads to less chemotherapy error and better management of toxicities. If all patients receive the same care at an institution, such as for stage IV lung cancer, then the nurses are more familiar with the regimen,

including dosing and scheduling, thereby making it easier for them to recognize errors in orders. They would also be able to predict when toxicity, such as neutropenia, was going to occur.

Uniformity also allows the care team to more accurately advise patients and caregivers on what to expect during treatment, which can have the added benefit of better toxicity management and reduced hospitalizations. This approach to uniformity benefits insurers, who know precisely which regimen a patient is going to receive, making it easier to predict the cost of care.

While treatment guidelines will list for providers all the proven therapeutic regimens for a given indication, clinical pathways establish one regimen for a given tumor type at a particular stage. If a patient presents to UPMC with stage IV lung cancer, he or she will receive a set treatment according to the clinical pathway set in place for that disease stage, no matter which provider within the UPMC system is managing that individual's care. Dr. Ellis and his team have found that this uniformity across multiple providers and clinics within the network produces efficiency in the system and allows the healthcare team to deliver streamlined, optimal care.

To develop a clinical pathway for each of the various tumor types, a disease-specific committee is formed, typically with a leading researcher and a community oncologist with special interest in that particular tumor type. Both academician and clinician serve as co-chairs. Volunteers are then invited throughout their network of medical oncologists to join the committee.

Using evidence-based medicine principles, the committee then determines the best treatment in terms of efficacy; if several agents or regimens appear to be relatively equal in terms of efficacy according to available published Phase II and III data, the committee then evaluates toxicity, selecting those regimens/agents with the most favorable toxicity profile. Finally, if several regimens/agents are the same in terms of efficacy and toxicity, the committee asks for an economic analysis and selects the preferred regimen according to which demonstrates **cont. on pg 26 >>>**

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to be the most cost-effective. UPMC currently has six clinical pathways up and running, and of those six, the committees only requested an economic analysis twice.

UPMC's pathways also include common exceptions and build in pathways for certain known toxicities or common contraindications, should they develop.

Once a pathway is developed, it is sent to all the physicians in the UPMC network for review and a committee meeting is held where questions or challenges can be posed. Based on the input from the meetings' attendees, the clinical pathway is then finalized and implemented throughout the entire network.

Currently UPMC has clinical pathways in place for lung, colorectal, breast, prostate, and head and neck cancers; their clinical pathway for lymphomas will be launched soon, and they are working on esophageal and pancreatic cancers. In the future they also plan to tackle less common malignancies as well.

Response to the Clinical Pathways at UPMC

In the 10 months since they have launched their first pathway, UPMC has achieved 80 percent compliance.

"The reason our compliance with the pathways has been so high is because our physicians understand that the guidelines have been developed in an academic way in the best interests of their patients. They also recognize that there are several different ways to treat any tumor type, but they are willing to accept the common wisdom of the recommended treatment in the pathway. They also realize the financial reality that if they do not do something to develop a clinical pathway, someone external will do that for us," said Dr. Ellis.



University of Pittsburgh Medical Center (UPMC) Cancer Center

So far, the two major insurers that UPMC accepts agree that the PATHWAYS program is a solution that gives patients the most appropriate care and controls costs. As such, these insurers have become willing participants in the program. Chief Medical Officers from two of the largest insurers sit on an oversight committee; while they are not involved in developing the actual pathways, they have accepted that the treatments developed are good for their companies as well as for the patients they insure.

Bob Wanovich, Vice President of Pharmacy Affairs, from Highmark, one of the major insurers accepted at UPMC said that clinical pathways provide value to physicians, patients, and insurers by reducing the variation in care of common diagnoses. "For physicians, following the pathways is akin to receiving a consult from the best and brightest in oncology care. For patients, the use of the pathways provides assurance that they are receiving the best possible care. Because the pathways are so well-documented and specific, they should also help to reduce or eliminate medical errors. Highmark sees great value in programs that promote the most effective treatments while reducing the use of less effective or unproven therapies."

Wanovich reports that Highmark is pleased to work in collaboration with UPMC on the program. "This program exemplifies our belief that it is vital for us to work directly with the provider community to support our mission of providing access to affordable, quality healthcare enabling individuals to live longer, healthier lives," he said.

The clinical pathways program has also streamlined the drugs that UPMC purchases. This has allowed them to have less variability in their drug buy, more frequent inventory turns, and has put them in a more favorable position

to negotiate better volume discounts. Dr. Ellis makes the case that clinical pathways result in conformity and uniformity, which brings cost savings. “It allows us to do more with less staff, the pharmacy is mixing the same chemotherapy infusions over time, and the benefits cascade from that efficiency,” he said.

Next Steps

Measuring clinical results beyond physician compliance is the next step. UPMC is currently working with one of their major insurance companies to compare their cost data with similar practices who do not have clinical pathways in place. In 1 to 2 years, Dr. Ellis and his team plan to examine additional surrogate outcomes, such as emergency department visits, costs associated with managing toxicity, and hospitalizations. They also plan to conduct patient satisfaction surveys and survival, which take longer to evaluate.



University of Pittsburgh Medical Center (UPMC) Cancer Center

In addition, Wanovich reports that Highmark is currently working with UPMC to conduct an extensive evaluation of the first clinical pathway developed in the program.

“Thus far, we are delighted with how this program has been received and what it’s been able to do. While there are always individual physicians who may disagree with the pathway, there has been less dissent than we anticipated. The PATHWAYS program has been a

team approach and insurers have been very supportive,” said Dr. Ellis.

Programs such as the one at UPMC gain economy by improving efficiency. By managing drug spending through their own incentives, centers are in a better position to foster good relationships with their payers and are able to maintain reimbursements at levels high enough to allow them to continue to provide their patients with excellent care. **MNF**

P4P Programs: Another Cost-Savings Measure

Pay for performance (P4P) programs are another type of evidence-based treatment program aimed at reducing costs while delivering quality patient care. A recently reported survey conducted by Oncology Therapeutics Network (OTN) and presented at the Onmark 2006 National Payor/Provider Forum asked community-based oncologists about their willingness to embrace and comply with regimen-based standards in oncology. The majority of those surveyed (66%) believed P4P initiatives are useful in oncology, and 94 percent believe such programs will improve outcomes for patients with cancer.

In addition, 70 percent of respondents believe regimen-standardizing programs in oncology “will help control treatment costs, improve patient outcomes, increase practice efficiencies and lead to the availability of better outcomes data.” Oncologists surveyed also believe that technology, such as electronic medical record (EMR) and claims scrubbing technology, is the way of the future in oncology.